Mapping the review of ethics in research: The work of National Health Service (NHS) Research Ethics Committees in England

Julie Winifred Morton

Submitted in Partial Fulfilment of the Requirements of the Degree of Doctor of Philosophy

University of Salford

School of Nursing, Midwifery, Social Work and Social Sciences

December 2016

Table of Contents

List of tables and figures

Acknowledgements

Thanks are due to Salford University who funded the PhD and allowed me time to undertake the research and the writing of the thesis. Thank you also to the National Research Ethics Service with whom I negotiated access and who assisted in the design of the study. The co-ordinators of Research Ethics Committees are invaluable and they liaised with Chairs of committees, sent out information sheets and made all the practical arrangements so that I could conduct the observations. I appreciate the time and patience of all the reviewers and researchers, who let me observe them, disturb their coffee breaks and then allowed me to interview them.

I have been fortunate in all my supervisors. Firstly, Dr Stephen Hicks who was my supervisor at the beginning of this research. Special thanks to Professor Martin Johnson who immediately 'got' the research and has been involved for the substantial part of the project. He has been supportive, insightful, generous academically and kind. Finally, Dr Anya Ahmed who has combined humour and warmth with academic incisiveness.

Thank you to my friend Claire Faichnie who proof read and formatted this thesis. To Fia and Annette who always believed I would finish – grazie mille! Thank you Dr. Julie Lawrence who was a fantastic support as we navigated the last stages together.

Thanks to Jane Norton who has encouraged me and given me emotional as well as practical support. She has kept children's appointments, done laundry, maintained a garden and a home as well as doing her own job, while I was travelling to committee meetings and then writing. Thanks also to Kim Morton, third parent to our children, who has eased our lives in so many ways. Finally, to Clemmie and Bea Morton, who were quite small children when I embarked on this PhD and are now teenagers. - thank you for ensuring that our lives have never been dull.

This thesis is dedicated to my mother Violet and my brother Andrew who I wish so much could be here to see me complete this PhD. Also to my father Bill, who daily proves to me that a life of worth does not depend on academic achievement.

Glossary of commonly used terms in the thesis

The Mental Capacity Act (MCA) 2005	The Act applies to intrusive research within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products.
	This may include research in healthcare, social care, criminal justice and other settings. It is not limited to research undertaken within NHS organisations or other public bodies.
	Sections 30-33 of the Act provide lawful authority for intrusive research to be carried out involving people without capacity provided that the research has been approved by an appropriate body.
	The appropriate body is an NHSREC.
NHSREC	National Health Service Research Ethics Committees
	These are RECs which stand outside of local NHS Trust RECs and outside of University or Local Authority RECs.
	NHSRECs in England and Wales and the Social Care REC are appointed by the Secretary of State for Health and Welsh Ministers.
	Studies with capacity issues must be heard at one of these RECs. It is advised if possible for researchers to apply to a 'flagged' REC.
'Flagged' RECs	There are 24 'flagged' committees for capacity in England and Wales. REC members can undergo additional training for a range of 'flags', for example, in qualitative research. I attended RECs 'flagged' for capacity studies, which meant that members had undergone additional training in the MCA and its requirements.
	All RECs attended have been allocated a letter to anonymise.
Membership of RECs **Chairs and committee members- also referred to in**	NHS Research Ethics Committees consist of up to 18 members, 1/3rd of whom are lay (broadly, this means their main professional

the thesis as reviewer or panel member for stylistic purposes. Used interchangeably in the thesis except where a lead reviewer for a study is specified. **Role of Lead Reviewers: generally, two are allocated and expected to closely read the researcher application and lead debate at the REC.**	interest is not in a research area, nor are they a registered healthcare professional). They safeguard the rights, safety, dignity and well-being of research participants, independently of research sponsors. http://www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/#sthash.pHMSB691.dpuf **Anonymity:** Individual members of RECs and researchers have details, for example, gender changed or are referred to as s/he.
'Researchers' or Principal Investigators	Refers to researchers who make applications and attended the REC. Generally, the term 'researcher' is used in the thesis. **Anonymity:** See above.
Health Research Authority (HRA) and the National Research Ethics Service (NRES)	I negotiated access for the study with the National Research Ethics Service who administer the RECs. Whilst the study was being conducted, their National Research Ethics Committee (at the outset of the study, NRES were responsible for the administration and support of RECs). Their functions have now become part of the Health Research Authority and they are now called the Research Ethics Service (RES). This is a core function of the HRA and is committed to enabling and supporting ethical research.
Co-ordinators	Co-ordinators' work is crucial to the running of the RECs as they ensure communication between members, circulate applications and have in-depth knowledge of the requirements.
Personal or nominated consultees	To comply with S32 of the MCA 2005, reasonable steps must be taken to identify a "personal consultee". If no appropriate person can be identified who is willing to act as a personal consultee, the researcher may consult a "nominated consultee", i.e. a person independent of the project appointed in accordance with the Department of Health's Guidance. The consultee does not give consent on behalf of the person but can give advice. This requirement is the source of difficulties, which are discussed in the thesis.

Applications	These refer to the researcher applications under review by the RECs. **Anonymity**: In each case, the research study details have been modified and minimal details provided, though sufficient to make sense of commentary.
The Mental Capacity Act 2005 and the capacity checklist –	Specific guidance about what reviewers are required to consider. A checklist summarises the conditions under which research may take place with people who lack capacity to consent. Any research since October 2008, which involves people who lack capacity, must comply with sections 30-33 of the Act. These sections are summarized in the checklist. This is analysed in the second part of the thesis.
Research participants **Research subjects** **Human subjects**	**The term 'research participants' is used in the thesis and refers to people who took part in this research.** When the terms 'human subjects' or 'research subjects' are used, these reflect the terminology used in particular literature and/or historically specific documents.

Abbreviations

NHSREC	National Health Service Research Ethics Committee
REC	Research Ethics Committee
IRB	Institutional Review Board (ethics review committee in the United States)
NRES	National Research Ethics Service
NICE	National Institute of Clinical Excellence
HRA	Health Research Authority
NVivo	Qualitative data analysis software
A&E	Accident and Emergency department

Abstract

Background: The effects of ethical regulation in the form of review and bureaucratic procedures on research are perceived as challenging for researchers. The centrality of the achievement of *informed* consent in ethical regulation and review has also been problematised from a range of perspectives which view it as unachievable in some methodologies, as necessary but problematic, or as an overly bureaucratic requirement which makes it informed but not genuine. However, in the existing critiques of regulation, there is limited attention paid to ethics review which is where decisions are made about the ethics of research. Much is claimed about the barriers and limitations the review of ethics presents to researchers, however, there is little evidence which starts from the standpoint of committee members and explores how the work of National Health Service Research Ethics Committees (NHSRECs) is accomplished in the everyday contexts in which decisions are made. This study aimed to reveal new knowledge about how NHSECs work to reach decisions about applications with a particular emphasis on consent and capacity. The RECs included in the study were 'flagged' for capacity which meant that members had undergone additional training in the requirements for research with people who lack capacity in the Mental Capacity Act 2005.

Methods: The study used ethnographic approaches and institutional methodology to 'map' the work of RECs. Theoretically, institutional ethnography starts with the standpoint of those involved in the seemingly mundane and everyday work of institutions. The research sought to deepen understanding and provide insights into how committee members view their work and their perspectives on research and researchers. Interpreting the everyday is foundational to institutional ethnography and the endeavour also seeks to describe how work is shaped and organised by wider social discourses. The methods employed were observation, interview and an analysis of a significant text. Altogether, there were nine observations of RECs with a total of seventeen research applications heard. Twelve interviews were conducted with reviewers and eight with researchers who had attended the REC at the time of my observations. Data was managed using NVivo software, organised into themes and then analysed with the aim of producing a detailed ethnographic description of the work undertaken.

Findings: The study produced an ethnographic 'mapping' of the work of NHSRECs. Findings and subsequent analysis revealed (i) how the setting, order and membership of committees shaped their work and supported the institutional and social imperatives for ethics review to be transparent, fair and objective; (ii) that 'judgement' and 'decisions' could be distinguished in deliberations. Much of reviewers' discussion of applications is subjective and discerning. Relationships with each other and with researchers were significant. Committee members considered abstracted principles of ethical regulation and the framework of bureaucratic procedure, but used subjective means to translate these into meaningful and practical concepts and requirements; (iii) that 'texts' in the form of requirements were important in decision-making. Committee members made reference to procedures in order to legitimise their judgements. Finally, a text used in NHSRECs, the 'Mental Capacity Checklist' is the focus of analysis and this demonstrates how committees make their judgements 'fit' with requirements, looking for evidence of the required categories in the application and in the dialogue with researchers

Conclusions and implications: NHSREC reviewers are committed to their work, to research and researchers in general regardless of the nature of research. However, procedural ethics delineates and draws boundaries around the field of review. In addition, wider social structures and discourses of trust and transparency influence and shape formal review. These may constrain and limit REC members as much as researchers. RECs may benefit from a reflexive analysis of their work which would enable them to consider the local and wider influences on their judgements and decision-making. There is potential for this to be included in training programmes which already exist for REC members. Researchers may benefit from gaining insights from 'within' the ethics committee   increasing their knowledge of review from the perspective of those making decisions. This may assist in them feeling better equipped to overcome the challenges of ethics review.

Approvals and scientific review: Organisational approval for the study was given by the National Research Ethics Service (NRES) whose functions became part of the Health Research Authority during the course of this study. Scientific review of this study was undertaken by my Lead Supervisor at the start of the PhD and reviewed internally by the Executive Committee of the School of Nursing, Midwifery and Social Work at the University of Salford. The University of Salford's Research Ethics Committee gave ethical approval.

Part One: Discovering the work of Research Ethics Committees:the context of inquiry

Chapter 1: Introduction

1.1 Research Ethics Committees

The ethical regulation of research has extended and increased significantly over the last decade with the result that virtually all research in the United Kingdom, North America, Europe and in the Western world is subject to review by a recognised Research Ethics Committee (Wiles, 2013). Research Ethics Committees (RECs) are therefore perceived as authoritative bodies by researchers. It is possible however to see their authority as exercised in relationships and 'ethics committees as one among several actors that exert power and that act in a relational interplay with researchers and participants' (Juritzen et al, 2011). RECs review the ethics of research and make decisions on behalf of institutions, Universities, National Health Service Trusts and Local Authorities – wherever research is active. The RECs which are the subject of this thesis are National Health Service (NHS) RECs in England. NHSRECs are a fundamental part of the formal, legal, institutionalised review of the ethics of research and are invested with authority as they are appointed by the Secretary of State. For some particular kinds of research, for example, research with people deemed to lack capacity, it is these appointed RECs which review and make decisions on the ethics of research. While all RECs are instrumental bodies in the regulation of research, the study focusses on NHSRECs. The critique of ethical regulation in general and ethics review in particular is acknowledged, but importantly the study seeks to discover ethics committees and their work, from the perspective of those involved.

The extension of the regulation of research, along with the associated systems of review and establishment of Research Ethics Committees, has been subject to critique and this has come from biomedical and social science research communities. Social scientists in the United Kingdom have been critical of 'ethics creep' (Dingwall, 2008; Hammersley, 2009) with concerns that the transfer of review from biomedical research to virtually all research involving human subjects will have consequences for the nature of research being undertaken. Historically originating in medicine, ethical approval processes for research in general seem to be dominated by a particular perspective on research. Murphy and Dingwall (2007) voiced the concern of qualitative researchers and ethnographers that developments in ethical regulation over the last decade have been characterized by attempts to bring ethical

approval in the social sciences to meet the same type of scrutiny set for biomedical research. This concern with the expansion of ethical regulation seems to have some claim to validity given that the Health Research Authority's (the 'HRA') brief now includes responsibility for overseeing research in health and social care. This oversight extends to biomedical, health and social sciences research in both qualitative and quantitative paradigms.

The aim of this ethnographic study is not to map out the total landscape of ethical regulation but to explicate (explain, by paying close analytic detail to) a significant part of the whole - the place where ethics review happens – in the NHSREC meetings. In part, the purpose of doing this is to bring into view the everyday work of reviewers and address what could be viewed as a deficit in most critiques of RECs and NHSRECs. These do not give attention to the work undertaken by reviewers in the settings where it takes place and from their perspective. Sheehan (2013) for example, has responded to criticisms of the functioning of RECs as over-generalised and therefore inaccurate. He argues that critique requires evidence and this is not always apparent in the arguments for changes in the current system of ethics review. Furthermore, he argues that attention would first need to be paid to whether the current system can evolve and develop in response to any existing problems. I wanted to find out about the work of RECs from the people undertaking the work and discover this by getting close to that work, where it 'happened'. Moreover, I concur with Sheehan that much of the existing critique (discussed in the literature review) is over-generalised and does not take into account the standpoint of committee members nor the particular and specific experiences of researchers who attend RECs

RECs are where the ethical regulation of research 'happens' yet despite this, little is known of how they work and reach decisions. The aim of this thesis is to provide an ethnography of ethics review, specifically, describing the everyday work of ethics committees. The focus is on those committees flagged to consider 'capacity studies', however, in order to explain the work fully, it is necessary to refer to the wider context of ethics review. The development and extension of ethical regulation has resulted in the formation of research ethics committees in Universities and other research organisations including the NHS. It is important to note that NHSRECS review the ethics of research but they do not directly influence procedural

arrangements and the regulation of research ethics overall though they work within these. In fact, what is made apparent in the second part of the thesis is how reviewers as well as researchers are required to make sense of ethical regulation and its procedures in order to make them 'work' in practice. The study and this thesis seek to explain how the RECs function from the perspective of those carrying out the work of review, exploring committee member roles and the ordering of meetings to reveal how work is co-ordinated across sites. It interprets their debates and deliberations as 'ethics work' describing how judgements are made about research. It explores the significance of 'texts' and how they are used in the review of ethics, explicating how they are integral to decision-making. NHSRECs formally 'give an opinion' in ethics review, however, in reaching that opinion, I argue that the committee members exercise *'judgement'*. By 'judgement' in this thesis, I mean the reasoning, discernment and qualitative weighing up of complex factors in the balance to arrive at a decision (referred to as an 'opinion' by the HRA). Unless otherwise specified, this is what is meant by judgement in this thesis.   I also describe the situated nature of this discernment by providing context and description for members' deliberations. I use '*decision-making'* in this thesis in order to contrast those considerations which inform and lead to an outcome – a decision. The analysis illustrates the role of these two conditions – judgement and decision-making, arguing that both are required in the practice of balanced review. Furthermore, the analysis draws on a range of ideas and theoretical perspectives. Different perspectives are used as a prism through which the seemingly mundane work of committees is interpreted and brought into view. By 'mundane', I mean the situated understandings that committee members had about their work and which they shared in interviews and my interpretations of their work which was 'everyday' or 'taken-for-granted'.

Consent is an important part of research and review of ethics. As will be seen in the literature review (see particularly 3.6.3 and 3.6.4) consent has been referred to as an 'ethical panacea', being placed above other considerations and acting as an insurance against paternalistic practices in research (Corrigan, 2003). This study was focused on 'flagged' NHSRECs where applications that involved research participants who lacked capacity were considered. However, all research involves consent (or assent) by someone whether people lack capacity or not. (The exceptions to this would be covert research). Therefore, the range of this study extends to and is contextualised in those generic processes which constitute the

everyday work of NHSRECs. They are only one part of institutionalized review of the ethics of research but a highly significant component of the regulatory system.

Israel and Hay (2006) comment on the paradox in researchers' conceptualisation of ethics. Researchers generally want to do good and ethical research with sound intentions yet they frequently view RECs (who review their research) as hampering their progress in this endeavour.

They note however:

> '*The vast majority of committee members do not seek to obstruct research. For little reward, they invest considerable time to provide ethical oversight, and, in many cases, are able to offer constructive and practical suggestions to improve the quality of research proposals.*'
> *(Israel and Hay, 2006: 137)*

Though discussing research ethics committees in general, these authors make an important point. Ethical conduct in research can be facilitated and improved by helpful and supportive review. The process may have educative value for researchers (Iphofen, 2009). Existing critique has often omitted to consider the work of RECs from the 'inside'. The research I have conducted produces insights into the workings of committees and evidence of how they work which may in turn contribute to their future development.

1.2 Aims of the study

The reflexive approach taken in the study illuminates how research questions evolved and altered as my research journey progressed. A thesis is inevitably a retrospective commentary however; I am open about shifts in my positioning as researcher where these arose as the research developed.

I can however detail the broad intended aims and objectives of the study and these provide a clear and consistent leitmotif throughout the whole presentation of context for the study in Part One and the interpretation of findings in Part Two.

Overall Aims:
1.   To provide an interpretive ethnographic description and 'mapping' of the everyday work of RECs by use of institutional ethnography. 2.   To illuminate processes in ethics review. 3.   To promote a reflexive approach in the further development of NHSRECs.
Objectives:
Primary Objectives: 1.   To investigate *how* RECs reach opinions in their review of research applications. 2.   To explore *how* research applications (including capacity and consent) are operationalized (use of requirements in practice) in meetings; and, 3.   To investigate *how* research applications (including capacity and consent) are conceptualized (thought about and discussed) in meetings, by members and by researchers. 4.   To describe ethics review in NHSRECs from the perspective of those who live it, experience it and talk about it. 5.   To analyse ethics review in order to provide a 'mapping' of processes in the REC. **Secondary Objectives:** 6.   To explore *whether* there are differences in the review of qualitative and quantitative research. 7.   To investigate the experiences of researchers of attending for review and their conceptions of consent.

1.3 Current context of review and its significance

My research coincided with an important time for research ethics in the United Kingdom with the establishment by the government of the Health Research Authority (HRA). The HRA was established in December 2011 to 'promote and protect the interests of patients in health research and to streamline the regulation of research' (HRA, 2011). The HRA has now incorporated the National Research Ethics Service

(NRES) and its functions and will oversee the regulation of all health and health related research in the United Kingdom. Initial changes indicated further streamlining of processes and a harmonized approach with a United Kingdom wide edition of Governance Arrangements for Research Ethics Committees published in 2011 (DoH,2011). Nevertheless, alongside changes, RECs continued and continue to function as the committee where decisions about the *suitability* of research are made. Researchers are encouraged to attend. The outcome decisions available to each REC are categorised as opinions and are: 'favourable'', 'conditional', 'provisional', 'unfavourable' or 'no opinion'. However, in the observations I conducted these were referred to as 'decisions' rather than 'opinions'.

RECs are charged with reviewing applications for research. The HRA summarizes their work as follows:

> *'They safeguard the rights, safety, dignity and well-being of research participants, independently of research sponsors.*
> *They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical.'*
> (HRA, 2016)

It is worth noting here that the HRA places the protection (safeguarding) of participants at the forefront of the description of the work of RECs. It could be argued that they also do rather more than 'give an opinion' on ethics. Until research gains ethical approval, it cannot proceed. RECs have authority to give an opinion on the ethics of research and though this may not equate to a decision on whether research takes place or not, it would be undesirable for research to commence without ethical approval from an appropriate committee. Given this significant function, closer attention to understanding their work is justified. According to the HRA website, each year, RECs review around 6,000 research applications across the UK. On average, they give an opinion in less than 40 days, within the maximum allowance of 60 days. Members have to be committed to reading lengthy applications and attending committees usually monthly. Their work is undertaken on a voluntary basis and requires considerable commitment, in addition to attendance at training outside of scheduled meetings. It is important to note that this study does not seek to evaluate committees or the activity of REC members but seeks to illuminate the ways in which they go about their work.

Safeguarding becomes a particular concern where people lack capacity, and this study specifically focusses on the NHSRECs which have a special 'flag' for reviewing capacity applications. This section has described the current context of ethical regulation and this has been subject to change during the course of the study. For example, my negotiations on access were formally undertaken with the National Research Ethics Service (NRES). An updated (as far as possible) description of current systems is included in 3.4.1 below.

1.4 Formal codes and statements underpinning research ethics

The frameworks and principles which underpin research ethics have been influenced by the historical development of formal codes and statements. There are early historical examples of research where scant attention was paid to ethics. Researchers were viewed as professionals with integrity and a vocation. In the case of nursing for example, this meant that putting patients' interests before their own could be assumed (Long and Johnson, 2007). The development of current research ethics has its origins in medical research. The Nuremberg Code (1947) developed following the Nuremberg trials after the Second World War where abuses of research subjects arising from Nazi experimentation were evident. The Code set out ten key principles to underpin medical and experimental research (Wiles, 2013) and is generally viewed as the first statement of consent requirements. This conventional version of events leading to formal review was in fact more complicated. Regulation in medicine did exist prior to the Second World War in Germany (Prussia) (Israel and Hay, 2006). Nevertheless, Israel and Hay explain that four statements have been influential in the development of research ethics and these are the Nuremberg Code (1947), the Declaration of Helsinki (1964), the Belmont Report (1979) and the Council for International Organisations of Medical Sciences (1983). Though these statements relate to biomedical research they are also relevant to the social sciences and

> *'…provide key foundations for much current thinking and practice in social science research….'*
>
> *(Israel and Hay, 2006:11)*

The background to each of these statements, their key features and their historical significance is provided below and adapted from Israel and Hay's commentary. This is included because it provides context and background on the development of the

ethics of research practice. I have particularly emphasised those areas which relate to consent and to ethics review.

Table 1: Key statements and codes influencing regulation and review

Statement	Context and influences	Significance and key features
The Nuremberg Code 1947	Prior to the Second World War, consent based on trust of physicians. Some moves towards more formal contractual arrangements from medicine and other professions but rather limited. Public's abhorrence of medical experimentation in the war. Concern also that public faith in science undermined by Nazi experimental research. Fear in western democracies of loss of trust and confidence in doctors and researchers.	Ten key principles emerged. Most notably, the Code emphasized voluntary and informed consent of people competent to make decisions. Research subjects could cancel experiments and researchers had to stop research if likely to cause harm or death.
The Declaration of Helsinki 1964	Drew upon and amended provisions of Nuremberg. Origins were in the World Medical Association (WMA) Medical Ethics Committee. Emphasis on medical research. Revised using more contemporary medical and scientific language.	Shifted the emphasis for ethical conduct on to researchers. Responsibility for stopping the research if it was likely to cause harm was placed with researcher. Introduced means of gaining consent from 'incompetent' research subjects via proxy. Autonomy still central but there was a fuller role for researcher. Responsibility for the human subject rests with the researcher even though consent given. Research risks to be justifiable. Emphasis on respect for the individual. Review of research: The Declaration stated that research procedures were to be guided and commented on by specially appointed independent committees.
The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects for Research (1979)	The Declaration and the Nuremberg Code became models for some professions and their approaches to ethical research. Found to have less relevance to non-biomedical settings and difficult to adapt. Increasing evidence was emerging in the 1960s and 1970s in the United States and the United Kingdom of misconduct with doctors and medical researchers betraying the trust of the	Recognised the complexity of ethical situations and the difficulties in interpreting rules. Offered a broader principles approach as a basis for rules to be devised, criticized and interpreted. Three key principles of respect for persons, beneficence, and justice were outlined.

	public. Beecher (1966) identified twenty-two studies where research subjects had been involved in research with their knowledge or without their knowledge of potential harms. A series of scandals including the Tuskegee study which denied black men in Alabama treatment for syphilis between 1932 and 1972. In the social sciences, Laud Humphrey's 'Tearoom Trade' (1970) had revealed sexual behaviours in public places through means of covert research.	
The Ethical Principles and Guidelines for the Protection of Human Subjects for Research, 2002	Referred to as CIOMS as it was drafted by the Council for the International Organisation of Medical Sciences. It attempts to internationalise research ethics. Applies the principles of the Declaration of Helsinki and extends these to developing countries. The concern with research conducted in developing countries taking into account the socio-economic conditions of the country, cultural and religious conditions and local bureaucracy and law.	The principles echo those in the Belmont Report but extend the discussion of justice. There is an attempt to establish universal principles which can be applied globally and be relevant to diverse populations. Emphasis also on autonomy and the protection of the vulnerable or dependent. Also significant is the centrality of ethical and scientific review in research. Requirements for ethics committees including competence of members and composition are described. 'National or local ethical review committees should be so composed as to be able to provide complete and adequate review of the research proposals submitted to them. It is generally presumed that their membership should include physicians, scientists and other professionals such as nurses, lawyers, ethicists and clergy, as well as lay persons qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected.' (Commentary on Guideline 2, CIOMS 2002)

These codes and statements are relevant to social researchers in that they outline the parameters for research involving human subjects and how they should be

treated (Ransome, 2013). Following these templates for ethical medical research, professional organisations and institutions where research takes place developed codes of ethical practice. Alongside these, codes of ethics for professional practice have also flourished.

1.5 The Development of Research Ethics Committees

Noting the lack of attention from medical historians to the broader historical origins of RECs, Hedgecoe (2009) has provided a helpful analysis of how RECs developed in the United Kingdom between 1967 and 1972. He describes the complicated development of RECs and the tension between the desire to maintain professional (medical) autonomy in research and the drivers for bureaucratic and independent oversight of research. The notion of formal and independent review of research by an independent committee which was highlighted in the Declaration of Helsinki and COIMS became imperative. Research Ethics Committees in the National Health Service in England were formally established in 1991, following the publication of the Royal College of Physicians report known as 'The Red Book'. This outlined the responsibilities of Local Research Ethics Committees (LRECs) and led to the creation of a comprehensive system of research ethics committees for the NHS in Britain. Alongside critics of the system, particularly in the social sciences, other commentators have identified the potential educative value of engaging with review systems (Wiles, Clark and Prosser, 2011; Guillemin and Gillam, 2004; Israel and Hay, 2006) despite acknowledging some of the (historic) limitations in relation to particular methodologies. There is also an important distinction made in this literature between compliance and actual ethical conduct in the practice of research. For example, both Israel and Hay (2006) and Guillemin and Gillam (2004) distinguish between compliance with regulation and practical research ethics. Israel and Hay refer to 'ethical conduct' and 'regulatory compliance' whilst Guillemin and Gillam refer to 'procedural ethics' and ethics in practice'. This implies a concern that ethics review may not assure ethical research practice. Nonetheless, these commentators view ethics as integral to the whole research process from design to completion and see the review procedures as potentially helpful in assisting researchers to reflect on the ethical elements in a project, whilst also acknowledging that in qualitative research, not all dilemmas can be anticipated at the outset.

1.5.1 Ethics Committees and qualitative research

In 2004, consideration was being given to the establishment of RECs for social research and though differences in research were acknowledged, the Association of Research Ethics Committees (AREC) at the time took the view that the original report contained principles that were relevant in guiding the performance and process of ethics review of all research involving human subjects. There had been concern that research in social care in particular was being undertaken without a consistent approach to reviewing ethics. There was awareness that social care researchers were concerned about a lack of understanding of methodologies. AREC's position was:

> *'…. that the ethical questions raised in dealing with research in any human context are common to those raised in clinical research whether that be qualitative, epidemiological or quantitative in nature. What will be required, whichever system of review is established, is recognition that researchers and academics themselves will require some awareness of the need to place the ethical consideration of their project as a central core of the research.*

> (Dawson, 2005:34)

Dawson also acknowledged that:

> *'social research has very different traditions that reflect views of the world and views about ethics that are unfamiliar/less familiar to those who sit currently on RECs.'*

Therefore, training would be needed for REC members but Dawson comments that researchers in social care may need to consider some changes to 'their beliefs'. In fact, training was established and continues for members alongside other extensive training opportunities. In addition, a number of RECs have become 'flagged' for qualitative research. This means that researchers may apply to any committee for their research to be reviewed but those which have been 'flagged' have 'demonstrated a level of experience and expertise in this area' (HRA, 2012).

It is important to note that regardless of discipline or research paradigms, both positivist and constructivist traditions have to have regard for ethics. Researchers have to justify their research with regard to potential benefits and consider the probability of harm to participants. In addition, researcher competence requires research to be carried out using the best available knowledge in the field including research design and methodology. For all research with human subjects, there

needs to be both regard for participants' ability to give consent and consideration of the opportunities for giving consent (Ransome, 2013).

1.6 Background to the study

This study arose from a concern about the barriers to undertaking research with people deemed to lack capacity. As will be seen in the literature review, these concerns have been expressed by researchers from positivist and interpretive traditions and from both medical and social science researchers. Alongside this, there is a strong perception that review of research can be a barrier to research due to the volume and range of procedural requirements imposed. The starting point for this study was the direct experience of attending a NHS appointed REC which was 'flagged' meaning that they had specific training in capacity requirements. This experience was pivotal in that it led to a complete reconceptualization of the study focus.

My original PhD proposal (which had been approved by the University of Salford's Ethics Committee pending NHS approval) was to build on previous research I had undertaken with Crisis Resolution Teams in adult mental health services. I had wanted to extend this research and undertake an ethnographic study in order to investigate how practitioners intervened to assist people who presented in crisis to a local Accident & Emergency (A&E) department. The application was given an unfavourable opinion by the REC which gave a long list of issues to be addressed on resubmission. The two major concerns related to consent. Firstly, how I could ensure informed consent from people in A&E who were not part of the study, and the second concern was how I could secure informed consent from patients who the REC assumed would lack capacity and would be 'not with it' (their terminology). In other words, an element of their concern was with perhaps, at that time, unfamiliar methodology (ethnography) and the other was their concern that protective measures were put in place for people who were in crisis who they assumed would be 'florid' (again, the terminology which was used).

I could have gone away and resubmitted the application to the REC ensuring that requirements had been met but perhaps changing the design somewhat. I was pointed to an article, 'An Exercise in Fatuity: The emasculation of HSR' by Robert

Dingwall (2006) which is somewhat polemical in tone, but which questioned the extension of institutionalised research governance in biomedical research to health services research and medical sociology. (Dingwall's argument was that health research and sociology are usually concerned with the social consequences of ill health and not experimental in the same ways as medical research). Given my interest in ethics more broadly and my background as a mental health social worker, I set out to explore at how NHSRECs review ethics in research applications with a particular focus on consent and capacity. For this reason, 'flagged' NHSRECs with additional expertise in consent and capacity issues were selected.

1.7 Reflexivity: locating myself in the research and accounting for bias

All research has the potential for bias. Guillemin and Gillam (2004) describe how all stages of the research process are governed by our values and reciprocally research shapes and influences our vales (p74). In other words, our values influence the research questions we pose but engaging with research in turn influences our values. One way we can overcome bias is not to claim impartiality at the outset since it is ethically dubious to present research as value neutral (Ransome,2013:109).

 In acknowledging the origin of this study there is a risk. An alternative approach would have been to omit the background detail in 1.6 from the thesis. The inclusion could potentially lead to charges of negative bias towards ethics review processes. However, reference to this early experience in the thesis seemed to me to be honest and open, characteristics which I went on to respect in the participants in the study. (I should also declare that I had a previous positive and facilitative experience with a NHSREC and gained ethical approval for a study in a crisis team in mental health). Nevertheless, following what I experienced as a negative experience at a NHSREC as described above, I wrote an auto-ethnographic account of my experiences at the REC using this as a way of producing meaning and knowledge from my direct involvement in a committee. This undoubtedly contributed to my reflexive decisions in changing course with the research

This early account also affected my initial questions and demonstrated the first of a series of shifts in my own epistemological and value position in the research. I detail these below.

1.7.1 Shifts in value position

- Recognition of the limited value of an overly critical approach in the literature to ethical regulation. I recognised that critique was often making two claims simultaneously. Firstly, that ethical regulation and institutionalised review was flawed as a result of its inevitable bureaucracy and in its expertise in methodologies and secondly that research being proposed by these authors was 'ethical'. This contradiction led me to want to find out what 'actually happens' in ethics review, making inquiry a process of discovery and of orientating people in their own worlds. This theorised process of discovery from the standpoint of people engaged in the work of ethics review, helps institutional ethnographers to 'see "how it works," so important elements can be mapped.' (Campbell and Gregor, 2008)[1]. In other words, knowledge of ethics review is sought and gained by starting from the place it happens.

- My professional background as an Approved Social Worker (ASW) in mental health, (now Approved Mental Health Professional or AMHP), has given me an interest in people and mental health and the limited ways in which we assist people whose mental health breaks down. I am therefore interested in research into ways of intervening to help and to increase our understanding of people's challenging experiences. My initial interest was in the ways in which capacity and consent ere operationalised and conceptualised in ethics review and how 'vulnerability' was considered. However, this second shift came about because of the limited number of studies I heard discussed which were directly linked to mental health. This meant that I saw how consent was important for all research with human participants **in research** and that often discussions about capacity and consent were relevant even where the Mental Capacity Act 2005 conditions for research would not have been necessarily viewed as relevant.[2] This led to a wider consideration of consent and who is vulnerable in research.

---

[1] Institutional ethnography as method is discussed fully in 4.8 and 4.9.
[2] An example of this in the findings is a study where parents were being observed as part of research on attachment with babies born with 'abnormalities' – what were they consenting to? Was this potentially making them vulnerable? Was their attachment being judged? Did they have 'capacity' to make sound decisions in this context?

- The third and final shift was the realisation that it was impossible to separate out elements in REC discussions about consent and capacity and that the whole context of the work was important. This led to the need to describe and analyse the actual processes and the everyday work of committees to provide a detailed 'mapping' of how they worked. Through this, new insights and theorising about the work of ethics review could be brought into view.

1.8 Ethical Regulation and adults lacking capacity – the legal and regulatory position

A range of legislation is relevant to ethics review including (amongst other legislation) The Children Act 1989, The Data Protection Act 1998 and The Human Tissue Act, 2004 as well as the Mental Capacity Act 2005. Changes in legislation have placed the responsibility for ethical conduct on researchers who need to 'always act in a manner deemed acceptable by society and the wider scientific community'. (Gelling, 2010 p 116). This is of great importance when participants lack capacity. Section 30 of the Mental Capacity Act (MCA) 2005 makes it lawful to carry out research with adults who lack capacity as long as the conditions detailed are adhered to. These conditions aim to provide protection of people who lack capacity when they may be the subjects of 'intrusive research'. Intrusive research has a wide definition and can include access to personal data which might be viewed as breaching that person's privacy. No one group of people is singled out for particular consideration. Examples of who might lack capacity are adults who have dementia, use mental health support or have physical conditions, for example stroke, which may impair capacity. Having a particular medical condition in itself does not mean that a person lacks capacity. The Act is concerned with protecting people to ensure that if they cannot consent to research then their interests, such as privacy, are being protected.

Approval under Section 30 of the MCA to undertake research with participants who lack capacity to consent, requires approval by an 'appropriate body'. In England and Wales, an appropriate body is a committee established to advise on particular matters including the ethics of intrusive research with people who lack capacity and is recognized for that purpose. NHSRECs in England and Wales along with the Social Care REC are recognized for this purpose by the Secretary of State for Health and Welsh Ministers. Some social care research is exempted from review by the

REC but for 'intrusive' research with adults who lack capacity, intrusive being defined as 'those requiring consent in law, including use of identifiable tissue samples or personal information', then, 'application for ethical review should be made to a Research Ethics Committee within the UK Health Departments' Research Ethics Service.'

1.9 Summary of the literature – contextualising the debate

Searches were conducted in the usual ways but my intention was not to conduct a meta-analysis of what was identified, but rather to interpret the literature. In their account of meta-ethnography, Noblit and Hare (1988) argue that review and synthesis of research should not be driven by technical meta-analysis but instead ought to reflect the paradigm within which ethnographic research is located. This means that the desire to construct 'adequate interpretive meanings' in a broad interpretive paradigm extends to the review of existing research and literature. This runs counter to the traditional review which aims to provide a kind of balanced approach, evidencing that the thesis simultaneously can demonstrate a level of 'generalizability' and 'originality'. Methodologies and approaches to review and synthesis usually suggest tools or strategies for evaluating the quality of papers and determining how many articles to include. Critical appraisal of papers is followed by analysis and grouping into themes which have emerged for a discussion of the literature. (See for example, Aveyard, 2014).

My approach differs slightly in that I conducted searches using research terms which inevitably in the field of research ethics brought up literature which spanned qualitative and quantitative paradigms. The comparisons and juxtaposition of these has produced a review which is original in that new meanings have been developed which could not have emerged in a more traditional or systematic approach. An example of this is the synthesis in the review of critiques of ethical regulation which look at the overlap in the complaints about bureaucracy from biomedicine and sociologists. I also reviewed literature which problematizes informed consent from sociological perspectives and from moral philosophers. My interpretation of the literature reviewed resulted in some key findings. The perception of increased regulatory requirements was viewed as problematic by researchers from a range of different disciplines and professional backgrounds. Engagement with the difficulties

in the perceived primacy of consent requirements in regulation was similarly critiqued by sociologists and in bioethics.

1.9.1 The gap in existing research and originality of this study

There was limited literature on how researchers view their experience of the interface with RECs and how they practically seek consent especially where people are viewed as not able to make rational and autonomous choices for themselves. There is some limited literature and research available on RECs but these have mostly focused on 'outcome' decisions rather than 'what happens' at committees. Correspondingly there has been little investigation on how researchers think about consent and capacity in the process of ethics review, for example in the preparation of written formal applications or attendance at RECs. Limited attention has been paid to what influences committee members in their decision –making in the context of the committee. What their views are about vulnerability and protection and how that relates to consent requirements is hardly described in current literature. What happens at RECs is important and yet we know little about RECs from the standpoint of those involved – both the reviewers and the researchers who attend.

There is a lack of studies exploring the activity of RECs from an observational starting point. Two notable exceptions are Adam Hedgecoe in the United Kingdom and Laura Stark in the United States. Hedgecoe (2008) undertook an observational study across a number of RECs and compared their attitudes to qualitative research. He has highlighted that assumptions about REC activity cannot be made based only on decision outcome. This suggested that richer or more in depth analysis of REC activity may shed light on what takes place in the committee meeting which leads to the decisions taken. Stark (2012) undertook an observational study of Institutional Review Boards (IRBs) in the United States. Her research revealed the 'Behind Closed Doors' world of these Boards to assist understanding of how they did their work. She described Boards' discussions about applications, how they reached consensus and the differences between what was said at the meetings and what was produced in subsequent official accounts. Her study is the closest to mine that I have found, though Stark does not have a focus on capacity and her analysis takes

a different form. Her observations of the Boards play a part in her overall project which is a description of the origins of ethics in research in the United States. Though IRBs differ to NHSRECs in the United Kingdom (for example, it is not usual for researchers to attend meeting, this study is highlighted because it uses parallel methods to the research I have undertaken (observation of meetings) and is a detailed description of some of the deliberations which take place at those meetings. My descriptions of deliberations have different emphases. Further references to Stark's work are made in the thesis (particularly, 3.11 on trusting researchers and 6.4 on categories of membership) and where relevant, have illuminated my own findings.

The uniqueness of the present study that its focus is on the (internal) practices of the RECs to enable a description of how the work of ethical regulation is achieved. The study is also distinctive in that it is orientated to the conceptualization and operationalization of capacity and consent. Its context and field are RECs flagged to review capacity studies. Observations are extended through interviews with significant players – the committee members and the researchers. The aim of the study was to develop an analysis of what 'capacity' means in the context of the regulation of research and how this is linked to concepts of consent and vulnerability. This has been partly achieved. However, what emerged as more significant questions, related to how ethical regulation was achieved in the everyday. The study researches the internal practices, the work, of the RECs.

Although I set out with particular concerns about research with those people deemed to lack capacity, it was not possible to look at how consent worked without contextualising in the organisational setting of the REC, and exploring everyday ways in which ethical regulation is achieved. In addition to this, despite research on the outcome decisions of RECs, there was little research available on what happened in the meetings and the content of discussions about consent or other ethical issues. In short, how judgements and decisions were negotiated. Furthermore, despite substantial critique of the bureaucracy involved in review, attention had not been given to how procedural requirements work in practice. However, what was startlingly obvious from the outset of my fieldwork was the small number of applications which involved people with mental health problems. It was therefore important that my objectives were broad and that; (i) though I would

maintain a focus on research applications for people who lacked capacity, that 'incapacity' may relate to a range of conditions and (ii) that the scope of the study would extend to how the work of RECs was accomplished.

As I stated above, despite my initial interest in capacity and consent relating to those with mental health difficulties, it emerged early on that these would only form a small proportion of the applications heard. Whether the lack of studies involving those people with a psychiatric diagnosis is a result of the perceived consent barriers is beyond the scope of this study. Most RECs invited me to stay for the duration of the meeting. This enabled observation of discussions about studies which were not specifically highlighted by NRES as capacity studies, nonetheless these did include discussions about consent. The table below gives a brief description of the specific 'capacity' applications which I heard being discussed. Identifying features have been taken out and only outline details provided. In all a total of 17 applications were heard.

Table 2: Range of applications

Studies
• Pharmaceutical - emergency medicine
• Dementia - communication
• Implants in eyes – people may lack capacity
• Use of device - unconscious
• Use of device - unconscious (2)
• Taking tissue samples – (to include patients lacking capacity due to anaesthesia or ICU)
• Service – user perspectives on a service approach - substance misuse
• Dementia – communication method
• Medical intervention in intensive care
• Mother and Baby Unit (psychiatric)
• Links between substance-misuse and eating disorder
• Anonymized psychiatric register for researchers
• Dementia - occupational health
• Quality of parent/baby interaction where baby has 'abnormalities'
• Radiography and other assessments of musculoskeletal conditions in rare disorder (learning disability)
• Learning disability health outcomes database (affects people with Down's Syndrome)
• Study of co-morbidity including mental state in patients with heart conditions

Whether studies are highlighted as having capacity issues or not, consent to research is a central concern of all inquiry with human 'subjects' and is scrutinised in ethical regulation. The fact that I accessed those committees 'flagged' for capacity, meant that I could focus on those studies which were perhaps more problematic or raised more challenging questions in relation to consent.

In this introductory chapter, I have provided an overview of how the research evolved. Its origins were in the concern with how capacity and consent were understood in ethical regulation and the perceived over-bureaucratisation in regulatory processes. What was evident was that there had been limited focus on the work of RECs and I sought to undertake an ethnographic project which would look at how the work was done, where the work of decision-making happened. This can be distilled into the single question:

How does ethics review 'work' in the real-life setting of a REC?

Finally, in this chapter, I summarise below the structure of the thesis in the hope that this might guide the reader through the development of my thinking and the interpretation of findings.

1.10 Structure of the thesis

The thesis is in two parts.

Part one sets out the context of the inquiry into Research Ethics Committees. Following this introductory chapter, the remainder of the first part of the thesis describes the epistemological context of the inquiry, locates the study in current literature and gives an account of the methodological choices made. It concludes with a description of data and the approach to analysis.

Chapter 2: Seeking knowledge

This chapter briefly outlines my epistemological approach to the inquiry. It locates the inquiry in a qualitative and interpretive paradigm. It explores the perceptions of power which I draw upon and explains how reflexivity has been important to the pursuit of knowledge about RECs and ethical regulation.

Chapter 3: Literature Review

In this chapter, I outline my approach to the review which was influenced by Noblit and Hare's (1988) meta-ethnography in literature and research review. I then

describe the literature under key headings. This approach is intended to reflect the paradigm within which ethnographic research is located. This means that the desire to construct meaning in a broadly interpretive paradigm in the field of study extends to the review of existing research and literature.

The literature review deals broadly with two overarching questions. The first relates to the question of the legalistic and bureaucratic nature of RECs in the United Kingdom and whether this has placed burden and constraints on research. Academic critiques described are derived from the perspectives of qualitative and quantitative research paradigms primarily in health and social care fields. Studies which have undertaken direct research on ethical regulation in the context of committees or institutional boards are identified. The second question relates to consent, exploring the meaning and achievability of consent in ethical regulation and the gap between ethical research practice and the regulation of ethics. This draws on sociological and philosophical literature on biomedical ethics and shows through existing literature how regulation is connected to social discourses about accountability, vulnerability and protection.

Chapter 4: Methodology and methods

This chapter aims to show the development of the methodological approach to the study. Rather than a traditional account of broad methodological paradigm, methods and limitations of methods, it provides instead a background to and history of the research. I describe the process of negotiating design with NRES and some of the exigencies which impacted on design. I describe and analyse ethics for the project and some of the inherent challenges in what was a complex study.

The chapter explains decision-making in relation to theoretical choices I include a discussion of how I delineated the 'field', drawing some parameters around the object of inquiry. I discuss what constitutes ethnography, before going on to describe institutional ethnography and in particular the approach of Dorothy E Smith (Smith 1990; 1999; 2001; 2006). The methods used to obtain data (observation and interviews) are introduced

Chapter 5: Data description and analysis

This chapter takes a more orthodox approach and contains a description of data and my approach to data analysis. It describes in detail the records collected in the field which were a product of the methods of observation and interview. It explains the coding which then leads to some key concepts. I distinguish features of ethnography, critical ethnography and interpretive ethnography. Though some contemporary ethnographers would take issue with the descriptions and definitions here, I found this process a useful way of explaining the distinctiveness of this study and a way of investigating my own claims-making in relation to the findings. (This chapter also has an Appendix (6) which shows the process of coding in detail).

Part two of this thesis is concerned with the findings and analysis leading to an ethnographic mapping of ethical regulation. The second part of the thesis provides a rich description of the everyday world of the REC and how its work is ordered. It interprets the engagement with research as 'ethics work' of RECs and shows how judgements are made and then explicates how 'texts' are used in decision-making emphasising those texts with the legal mandate of the Mental Capacity Act 2005 (Department of Health, 2005). The interpretation of findings distinguishes judgement and decision-making.

Chapter 6: Introducing the REC

This chapter provides context for the findings and interpretative chapters which follow. It describes the liminal position I occupied both in the field and in the intellectual task which takes place between the amassing of data and the decision-making about what was significant in that data. The chapter is rich in description. It 'sets the scene' and contextualises the meetings as well as providing background to how the later interpretation and analysis emerged. It describes the REC and some of the typical ways in which they worked detailing the physical features and location of meetings, the atmosphere and dynamics in the RECs, the roles of members particularly the categories of expert and lay, the allocation of applications, participation and sequencing of meetings.

The chapter is therefore a 'threshold' chapter, setting the scene and describing the atmosphere of the REC. It demonstrates how the ceremonials of the REC and the ritualized and routinized ways of 'doing' the work were reproduced across sites. This

co-ordinated the work that RECs did, which, I argue assists the idea of objectivity in decision-making. The following themes emerged. These were the use of abstract ethical principles and how these were translated into the concrete to achieve the practice of regulation and how RECs used 'texts', the particular ways these were used in ethical regulation and the understanding of consent in regulation.

Chapter 7: Judgement-making in the REC

This chapter is about the subjective ways in which applications are discussed and judgements made about them. Detailed description of how judgements were arrived at and the range of practical means employed in order to achieve the work of ethical regulation. I set out to deepen insights into the everyday work of REC and reveal some of the concrete and practical ways in which ethical regulation works. I draw on a range of ideas and concepts in the analysis. I reflect on the distance between 'abstract and remote' requirements and the concrete ways in which they are made sense of. By concrete, I mean the 'here and now' available means with which committee members make sense of research applications. I consider the range of concrete and practical means the committee members employed in order to bring meaning to their decision-making. Abstract ethical requirements were brought into being by use of, for example, individual morality, emotions and were influenced by a strong sense of duty and/or by the consideration of consequences for participants and the prospect of positive outcomes for patients or citizens more widely. The sense of duty also included a feeling that 'good science' needed to be upheld and this section discusses how committee members debated and made decisions on good and worthwhile research. Finally, this chapter utilises Banks' developing concept of 'ethics work' (2013:599) in the professions to illuminate the ethics work carried out by committee members. It illustrates the processes and range of strategies used by committee members when making judgements in the REC by using examples from observations and interviews. Judgement-making is distinguished from decision-making.

The description offered in this chapter is partial. It is impossible to do 'ethics work', the work of ethical regulation, in this highly regulated domain without reference to the texts. The following chapter provides a close analysis of how texts are used in the REC.

Chapter 8: Doing ethical regulation and the use of texts – decision-making in the REC

This chapter is primarily concerned with the requirements for the inclusion of research participants deemed to lack capacity. I use Dorothy Smith's ideas on incorporating texts into institutional ethnography (2006) as a starting point for this section. I argue that much of the deliberation and discussion in the REC is an expression of the ethical requirements. The process of the REC (discussion of the application, interview with researcher, more discussion and deliberation leading to the decision) is the means by which ethical requirements are expressed or upheld. It is the doing of this work which achieves ethical regulation. The REC spends a great deal of time looking for evidence in the applications they receive of the concepts required by the regulatory text. I argue that *judgements* are made in myriad ways described in the preceding chapter but final *decisions* are made by reference to the requirements. I describe this work undertaken by the REC members as 'recognition work'. I look at some of the researchers' perceptions of the experience of ethical regulation and the requirements, particularly relating to the 'consultee' requirement for research participants who lack capacity.

Chapter 9: Mapping ethical regulation

I summarise my 'mapping' of the processes of the REC as the key findings in the thesis. I discuss the importance of processes and the distinction between judgement and decision-making. This mapping reveals the distance between the abstract and fixed procedures of ethical regulation and the doing of ethical regulation which is more practical and mutable.

Chapter 10: Conclusions

Finally, I provide my conclusions to the thesis. I summarize the arguments made, and then address any methodological weaknesses of the research. I make connections between the everyday doing of ethics review and the wider concepts of trust and accountability in public institutions. I suggest that RECs could benefit from a reflexive analysis of their work (for example, how they 'do' regulation) and the underlying ethical and moral frameworks which they draw upon including an examination of their use of texts to justify decisions.

Chapter 2: Seeking Knowledge

2.1 Introduction

This brief chapter provides the epistemological context for the study. It explains the choice of methodology which enabled me to access the everyday world of ethical regulation. It also aims to define what reflexivity meant in the research and in the approach to writing the thesis. I do not intend to use the concept of reflexivity solely as a conceptual tool which is necessary in order for researchers to be credible. I therefore use Bourdieu's (1992, 2000) definitions to show how reflexivity need not be egocentric introspection but actually lead to insights which are 'useful'. I am also interested in Guillemin and Gillam's (2004) ideas of ethical reflexivity which link reflexive thinking processes to the processes of seeking knowledge and the production of knowledge. This constitutes an important element of being open and ethical in the ongoing practice of research.

2.2 Perceptions of power and knowledge

The study is distinctly sociological in that its broad focus is on examining the assumptions which underpin self-evident and 'obvious' beliefs (Bauman and May, 2001). It takes a phenomenological approach in that it interprets the everyday. The consistent focus is on work of the committees – where ethical regulation is happening. It seeks to understand from the perspective of key players how they interpret and make sense of their work. These everyday practices were observed and recounted to me in interviews so these were the two major sources of data and my way in to the everyday world. I seek to show how everyday practices are linked to power in as much as RECs are making sense of studies in order to make judgements about what is ethical in research. My concern is at the micro-level with a focus on process. Lastly, although I am looking at how judgements are negotiated and what leads to decisions, I am not particularly interested in an evaluation of these judgements.

An opposite approach would have been to undertake this inquiry at a macro-level with a large- scale survey of outcomes. However, I wanted to pay close analytical attention to the work of, or doing of, ethical research. My intention was not to evaluate or judge the quality or consistency of decision-making. Subjectively, I had a

negative personal experience of a NHSREC but I had previously had a positive experience. Though researchers were extremely keen to tell me of difficult experiences, others were more reflective about the relevance of RECs. I therefore resisted adopting a perspective of good and bad committees, as well as the dichotomised conceptualisation of powerful committees and powerless researchers. My view of power has been influenced by reformulations of power relations. Rather than viewing power as fixed and invested in particular individuals or institutions, I find it more helpful to consider how power is experienced and exercised. To summarise then, I have avoided an orthodox perspective of power as operating in hierarchical or dichotomous ways but instead adopted a view of power as being exercised rather than possessed. The approach taken in this study has been to explore how power is expressed at micro levels. The methods employed have enabled attention to the everyday and taken for granted activities of organisations which can potentially deepen understanding of *how* power operates. This has avoided reproducing typical dichotomies such as researcher/researched and researcher/reviewer as I feel that would have provided a limited analysis of review. Ultimately, I am not imposing a perspective which views power as located in particular individuals or particular categories as this would not inform us about *how* review is achieved. As well as this, structures which shape and influence ethics review and research may be located outside of local activity and practice.

My engagement with postmodern ideas arose from thinking through the use of such ideas in challenging social work practice(s). What I mean by postmodernism can probably be best explained by contrasting it with modernism. Modernism is characterised by the operation of grand narratives which have a universal application and universal sets of principles. Bauman (1992) argued that 'solid' modernity was characterised by categorisation, bureaucracy, rules and regulations in order to create certainty in a world which could be experienced as chaotic. Modernism can therefore be associated with a particular and restricting perspective on knowledge and the exercise of power. However, Foucault (1980) described an alternative perspective on knowledge and power. He did not view power as straightforwardly hierarchical and commented that in a Western view of power, it was exercised as:

> *'juridical and negative rather than as technical and positive.'* (1980:121)

The relevance of this for inquiry and research is that power and its relationship with knowledge can be viewed in an alternative way. 'Meta-power' (p122) can only take hold where it is rooted in multiple and indefinite power relations. Rather than power being possessed and fixed in particular people or institutions, it is found in social interactions which may include resistance as well as compliance. Subsequently, it is philosophically naïve to see power as solely hierarchical, power is found and produced in social interactions, while power and knowledge are mutually constituted and inseparable (Heizmann and Olsson, 2015). In this study, the analysis seeks to show how power and knowledge are exercised in the REC by reviewers and researchers. RECs have legitimising powers but these powers give reviewers the capacity to act in a range of ways which might be helpful or unhelpful to researchers.

For social work practice (my professional background) postmodernism leads to insights about privileged power and knowledge for example, the ways in which attention is paid to 'expert knowledge' which can exclude (or devalue) other forms of knowledge such as that belonging to service-users or patients. This perspective on power and knowledge is highly relevant for this study as a considerable amount of time in the REC is spent on making judgements about the creation of new knowledge through research. It is also a relevant perspective which resonates with institutional ethnography in that the aim is to learn and discover from 'what happens' rather than attending only to institutional forms of knowledge and formal outcomes. As will be seen, RECs spend a lot of time determining what constitutes 'good' or worthwhile science. The model of the Randomised Control Trial (RCT) as the gold standard for research, for example, assumes that research is an objective, knowledge seeking activity with fixed goals and measurable outcomes pursuing the 'truth'. For some forms of research, this may be entirely appropriate but there are many prospective studies taken to RECs for which this kind of standard is unhelpful. A secondary objective of this study is to explore how RECs approach the review of different kinds of studies.

Postmodernism would resist definition as modernist, however, the following features (adapted from Gray and Webb, 2009) are the alternate ways of viewing knowledge which influence my research:

- All knowledge forms can potentially be opened up for critical questioning

- Knowledge forms may be embedded in social, political and individual ways of seeing the world
- A wide range of understandings can operate and can illuminate questioning
- Questioning can start from the everyday
- Deconstructing taken for granted and dominant theoretical frameworks has a central place in analysis
- Dominant discourses can be opened up to critical scrutiny

It is important to state what I mean by 'dominant discourses' in the field of ethical regulation. Drawing on Foucault, discourses are intersections of power, language and institutional practices which become taken for granted social practices at particular historical and cultural points in time. These discourses are so embedded that they dominate but are largely left unquestioned and intact. Epistemologically then, the embedded, taken for granted discourses in ethical regulation can be uncovered by an approach to research which seeks first to capture and describe the everyday, in order to access discourses which, inform ethics review. In ethical regulation, the dominant discourses I sought to interrogate in this thesis were those about trust in contemporary life where the disintegration of trust in institutions and organisations has corresponded with a decline in trust of professionals and researchers. The second 'troubling' of a taken-for-granted discourse is that of autonomy linked to consent. Here consent is viewed as obvious, easily understandable and achievable with capacity as a state which can be straightforwardly assessed.

These dominant ways of seeing are enacted through practices which are every day and therefore difficult to access and 'know'. It has been through becoming familiar with the worlds of ethical regulation through the ethnographic method that I have been able to access these practices. Rather than seeing the activity of the RECs as fixed, I view their activity as contradictory, complex and having multiple agendas. Rather than viewing their status as objective and rational, I view them as regimes which are open to critique. Boden et al (2009) examine the operation of power and its consequences in ethical bureaucracies in universities. They are critical of claims to objectivity.

> *'They (ethical bureaucracies) reduce and codify ethics into sets of highly scripted rules, procedures and behaviours. Whilst they invoke an aura of*

objectivity, reliability and justifiability, we argue that this is a chimera because such schemes invariably mask the hidden operation of subjective power.'
(Boden, Epstein and Latimer, 2009:734)

However, to reiterate, I am not seeking to evaluate or to expose the truth of what goes on 'behind closed doors' at RECs.[3] Rather, I seek to explicate (explain in detail) the work of RECs and seek in the thesis to explain how my findings led me to see three areas as key in mapping what happens at RECs:

- The rich description of how meetings function (including processes, roles of members) and how their work is replicated and co-ordinated in these ways across sites.
- The use of abstract (meaning extracted from context) ethical principles and how these were translated into the concrete (subjective, situated, practical, contextualised) in order to achieve the practice of review.
- The use of 'texts' and the particular ways these are used in ethical regulation with a focus on 'capacity' requirements.

I am mindful of the charge of relativism in postmodern inquiry, where postmodernist approaches ignore the structural operation of power. A potential consequence of which is that all claims have validity and all are relative. It then becomes difficult to take an ethical position or make judgements about the negative consequences of power. However, postmodern critique interrogates *all* knowledge claims no matter how embedded they are in political, social or individual processes. Potentially this is useful in a study in which the 'researched', the subject, is part of a powerful institution (the HRA), which is invested with authority by government to make decisions about whether research conforms to a particular standard of ethical approval. In terms of impact, I would argue that my analysis and interpretation, informed as it is by many perspectives, provides a rich description (Geertz, 1973) providing insights into how this work is accomplished. This may inform REC members of their practices and encourage them to consider some of the assumptions they work with and yet do not generally have time to interrogate.

---

[3] I have been asked more than once if I am going to 'whistle-blow', by which I think people have meant that I will be able to expose the RECs as operationally suspect through the research.

2.3 Methodological choices

The methods were informed by ethnography as a methodology. The reasons for this were that I wanted to inquire, discover and learn. Rather than being tied to a particular methodological dogma, I was keen to develop effective research practices that would assist me in the inquiry of how review is undertaken. I wanted to employ methods which enabled me to become familiar with the activities people undertake in the work of reviewing ethics and decided the best way to do this was to observe RECs and to interview committee members and researchers applying for review. My analysis and interpretation of the subsequent data seeks to identify and describe the complex processes involved. The aims were to construct an ethnography revealing how capacity and consent are operationalised and conceptualised in ethics review and to describe, explicate how key players accomplish the work they are charged to do. The methods employed draw on institutional ethnography. Dorothy Smith (2006) comments, that researchers of institutions can discover through ethnography, 'how we are ruled and participate in our ruling and are then able to make plain to people (including themselves) just how it works' (2006:11). RECs' work has significance beyond the committee. Their work is institutionally organised. The ways in which all players interact and talk and debate in the REC are the means by which the larger societal need for oversight of research is accomplished. Smith (1999) refers to the social relations that accomplish organization and control as 'ruling relations' where bureaucratic forms of coordination are 'the forms in which power is generated and held in contemporary societies' (p.79). In other words, the REC is the means by which the review of the ethics of research is seen as being achieved. Trust in the larger institution – the HRA – is accomplished through the decision-making body of the REC. The other reason that Smith's approach appealed was that knowledge and assumptions of the researcher are acknowledged. In fact, my experience of attending a REC which prompted the inquiry was central to it. I gained insights which led me to identify initial questions (problematics or 'puzzles' as Smith (1987) refers to them) as an 'insider' researcher in attendance at a REC and this can be openly acknowledged in institutional ethnography. The experience provided me with some preliminary insights into the working of RECs, how their members interacted and provided me with the early 'puzzles'.

The ethnography aims to offer dynamic constructions of meaning (Crotty, 1998) by which I mean that I did not undertake a comparative study examining a prescribed set of questions. What I have aimed for is an integrated conceptual interpretation of what I found in my inquiry. My analysis and interpretation openly cites various theoretical perspectives. I draw on writing from a range of disciplines including nursing and social work as well as using sociological concepts. This provides a level of transparency and openness in my account. In other words, I have not shaped the analysis in order to correspond to one overarching theoretical position and I feel that drawing on a range of positions has strengthened the thesis in that I have sought to construct a relevant and truthful account using perspectives which serve to illuminate the work of the RECs and the interviews I had with committee members and researchers. The data chapter (5) is a reflexive account of how I approached the data and what I was seeking in my analysis.

2.4 Reflexivity in the study and the thesis

At its simplest reflexivity refers to self-reflection, a level of self-awareness in what one is doing. Demonstrating reflexivity has become a methodological requirement in research and is referred to in most handbooks of qualitative research (examples are Silverman, 2005 who expresses some reservations about the 'reflexive turn' in social sciences research and Denzin and Lincoln, 2011). The thesis itself demonstrates a reflexive approach to research, however, it is important here to say something about my understanding. Perhaps the concern about reflexivity relates to the tendency for reflexivity to be claimed by researchers when it is far from clear what they mean by it. Bourdieu (1992) distinguishes 'epistemic reflexivity'. Reflexivity for me must mean more than simply 'intellectual introspection' (Bourdieu and Wacquant, 1992:40) or reflection. Bourdieu referred to 'epistemic reflexivity' as a process of identifying the ways in which one's interpretations are located within a particular discourse. In my background profession, social work, epistemic reflexivity in practice might lead a social worker to question the professional discourses which dominate (and limit) practice. In the study, it has been the awareness or attention to the situated nature of myself as researcher and being aware of the potential limits to the approach I adopt. However, in 2000, Bourdieu highlighted a hazard of reflexivity when he talked about sociologists being 'condemned to speak of historicity and relativity in a discourse that aspires to universality and objectivity' (Bourdieu, 2000:93). In other words, he

highlighted a problem for sociological research which tries simultaneously to be reflexive in the sense of self-aware and objective at the same time. He also warned against inquiry becoming abstracted from contexts, losing sight of the problems to be addressed or solved. Epistemic reflexivity requires us to consider dominant discourses which are usually left intact and yet lead to particular consequences in the ways in which we think about/act in the world. In ethical regulation, these discourses might be about vulnerability, safeguarding and protection, harm). Revealing these dominant ideas about trust, transparency and accountability in public life and how they influence ethical regulation informs the analysis.

The examination of how these discourses influence the everyday work of RECs is an important part of what this research has been about. Bourdieu draws our attention to the importance of not abstracting practices from their contexts (Bourdieu, 2000) if we are to understand them better. I have tried to maintain a focus on the 'doing', the work of ethics review. Institutional ethnography develops its analysis from the standpoint of people engaged in the 'local particularities of everyday experience' (Smith, 1999:73).[4] Using institutional ethnography as both theory and method has enabled me to (i) remain practically rooted in the everyday (observing and attending) and; (ii) theoretically aligned to the practices and work of committees, committee members and researchers. Geertz's (1973) concepts of experience-near and experience-distant are also helpful in this context. He explains how the researcher who confines her/himself to experience-near can become swamped with the immediacies of research whilst experience-distant may mean that the researcher becomes lost in abstraction. I argue later in the thesis that these concepts were particularly helpful to me in the context of my study design as I was protected from a position of experience-near by the practical necessity of having to observe more than one REC. Although I am sure Geertz did not mean the concepts to have this concrete relevance to design, they were nonetheless helpful. I was integrated into the REC setting but not one particular committee. This meant I was able to maintain a distance which was required in the intellectual activity of interpreting what I observed. I developed what I observed into themes and concepts assisting with

---

[4] Smith's work began with inquiry into women's experiences from their standpoint and particularities. The second part of this endeavour moved from understanding standpoint to developing an analysis of the intersection between local settings and the abstracted relations of ruling which are a complex of 'discourses, scientific, technical, and cultural' (Smith,1990:6). These discourses are frequently text-mediated.

analysis of the everyday practices of the RECs. I am not claiming my research or this thesis to be objective but I have tried to guard it against being self-indulgent. Finally, the next section considers ethical reflexivity.

2.5 Ethical reflexivity

In their account of reflexivity and 'ethically important moments' in research, Guillemin and Gillam describe how reflexivity runs throughout the research process. They suggest that reflexivity is connected to practice in the field and is in fact an integral part of researching ethically. Importantly, it is 'an active, ongoing process that saturates every stage of the research'.

> *'Our research interests and the research questions we pose, as well as the questions we discard, reveal something about who we are. Our choice of research design, the research methodology, and the theoretical framework that informs our research are governed by our values and reciprocally, help to shape these values.'*

(Guillemin and Gillam, 2004:274)

Furthermore, our research interests and questions reveal something of ourselves. Though reflexivity is not usually articulated as being connected to ethics, Guillemin and Gillam demonstrate how reflexivity has a focus on the production of knowledge but also on the process of knowledge. Reflexivity is of epistemological relevance but a critically reflective approach to the process of constructing and producing knowledge would additionally give attention to the ethical issues in research. This kind of reflexive ethics means that I would be open about the reasons I came to focus on RECs in the first place. These reasons have been outlined above in explaining the origins of the study. I have resisted demonstrating reflexivity in solely one section of the thesis and hope that the approach is evident throughout. Nonetheless, ethically speaking, an acknowledgement of the reasons for my interest in RECs is important. I had attended a NHSREC to seek approval for my own study which was to be an ethnographic study of crisis resolution teams in mental health services. The application was not approved and the experience was negative. Following this, I reconceptualised the study to turn an ethnographic gaze on ethical regulation itself. This experience influenced the choices I made about methods and yet ultimately the choice of method (institutional ethnography) led me to consider RECs from their own perspective, the ways in which committee members understood their work. In other words, the theoretical framework that informed my

research was governed by my values and as Guillemin and Gillam state, helped in turn to shape my values in pursuing the research. It is for this reason that this thesis reports on more than the study design, methods and findings. It also demonstrates a research journey which transformed a negative experience into a positive learning experience.

2.6 Conclusion

The thesis takes a reflexive approach throughout and though I have referred to the problem of reflexivity being a mechanism used in order to demonstrate credibility in research and researcher, I do nonetheless adopt this approach. This is in order for there to be a transparency in the thesis. Attention is paid to my developing knowledge, the development of research questions and choices in analysis about what was significant. I feel that this does lend credibility but also authenticity to the account. Finally, my account acknowledges the subjective in epistemology viewing knowledge as existing within a particular perspective. In other words, I am seeking knowledge from a subjective position and acknowledge that people generally act in the world based on their own subjective knowledge (Ravenek and Rudman, 2013). Reflexivity requires that there is acknowledgement and an account given of this, rather than attempting to demonstrate an unattainable position of neutrality. Epistemic reflexivity is the process of analysing and challenging meta-theoretical assumptions while methodological reflexivity is concerned with monitoring our own impact on the research (Ransome, 2013:139). This research and the thesis evidence both these forms of reflexivity. Methodologically, it acknowledges my position in relation to the research from its inception to writing up (The ''shifts' in my subjective position are described in detail in the introduction under 1.7 addressing the question of potential bias in the research). Theoretically, the analysis (including the mapping the work of committees) connects findings to wider social discourses challenging notions of transparency, trust and accountability this being an important and constituent part of institutional ethnography.

Chapter 3: Literature Review

3.1 Introduction

This chapter reviews literature which has informed the study as a whole. The study is concerned with the practical and commonplace ways in which ethics review is undertaken for studies which include adults who lack capacity. The literature on the formal review of ethics is more often critical than not of the processes involved and the decision-making authority of the Research Ethics Committee (REC). However, there is a difficulty in that researchers want to claim that their research would be ethical. Literature here is often trying to demonstrate a quite convoluted argument, maintaining a critical stance against bureaucratic review whilst simultaneously showing how their research can still claim to be ethical. Given that the study is contextualised in RECs which review 'capacity' studies, the review also explores literature form a range of perspectives on capacity and consent. Therefore, two key literature strands are relevant to this study. Literature concerned with ethical regulation and the role of the Research Ethics Committee (REC) specifically, and secondly, theoretical literature which considers the meaning of consent and capacity.

3.2 Methodology of review and the paradigm clash

> '*To our way of thinking, the synthesis of qualitative research should be as interpretive as any ethnographic account*'
> (Noblit and Hare,1988:11)

Contextualizing ethnography presents a challenge because an ethnographic approach emphasizes particularity and close interpretation of the situation being researched. The orthodox way of conducting a review of literature aims to provide context and show some connections in existing literature between what is already 'out there', what is missing and where the researcher's study fits. The endeavour is then to provide a kind of balanced approach which evidences that the thesis simultaneously has some level of 'generalizability' and 'originality'. Methodologies and approaches to review and synthesis usually suggest tools or strategies for evaluating the quality of papers and determining how many papers to include. Critical appraisal of papers is followed by analysis and grouping into themes which have emerged for a discussion of the literature. (See for example, Aveyard, 2014). Noblit and Hare take issue with this approach.

In their account of meta-ethnography, they argue that review and synthesis of research should not be driven by technical meta-analysis but instead ought to reflect the paradigm within which ethnographic research is located. This means that the desire to construct 'adequate interpretive meanings' in a broad interpretive paradigm extends to the review of existing research and literature.

This appealed to me for a number of reasons. I was seeking answers to particular questions but in seeking answers I was not looking to develop generalizable theories inn the positivist tradition but to describe and interpret what was happening in a particular social and cultural context, that of ethical regulation. There seemed to be a dissonance or even a clash of paradigms here if the values, methods and techniques that I was committed to utilizing in my approach to research, were suspended when reviewing literature and existing research. I conducted searches in the usual ways (see below) but my aim was to not to conduct a meta-analysis of what I found but to interpret. Noblit and Hare (1988) refer to meta-ethnography as an approach to synthesizing literature from qualitative research. The synthesis looks at literature as a whole and the interpretation brings out new meanings which could not have been gleaned from looking individually at those pieces of literature or research.

My approach does not only focus on qualitative research as Noblit and Hare intended. It differs in that I conducted searches using research terms which inevitably in the field of research ethics brought up literature which spanned qualitative and quantitative research paradigms. The comparisons and juxtaposition of these has produced a review which is original in that new meanings have been developed which could not have emerged in a more traditional or systematic approach. An example of this is the synthesis in critiques of ethical regulation say in the complaints about bureaucracy from biomedical domains and sociologists. I have also found literature which problematizes informed consent from the perspectives of sociology and moral philosophy.

The literature and research which I discuss in this review do not share a research methodology but they do relate directly to the broad areas/questions I wanted to address. This was surprising. Quantitative and qualitative researchers may not

always articulate their concerns in similar language but the critique of regulation and the contradictions inherent in seeking consent have parallels.

Lastly, I have explained how my approach has differed form a more traditional systematic approach. This includes the adoption of a 'neutral' stance. I hope that as researcher I am as present in this review as in the remainder of the research. The three areas which are investigated in this review are:

- RECs and ethical regulation in the United Kingdom
- The critics of regulation and limitations of some of the common critiques
- The meaning of consent and how this relates to capacity

The literature search strategy is in Appendix 3. What follows in this chapter is my interpretation of the meaning of this published literature and what it can reveal as well as demonstrating a paucity of literature on processes at ethics committees or analyses of how work happens and business achieved.

3.3 Scope of the topic searches

The initial aim was to capture literature in distinct areas. The first of these was current ethical regulation including official governance documents – research frameworks and guidance for Research Ethics Committees (RECs). I also needed to explore literature which had researched RECs directly and this was more difficult. There was very little on RECs themselves and their activities apart from that which focused on reviewing decisions made by committees. As noted, an exception was Hedgecoe (2008) who used ethnographic data from a study of UK RECs to explore the perception of quantitative bias by sociologists undertaking research. For ethical regulation, more generally, literature available grouped around themes of criticism of bureaucracy (from a range of research paradigms), accusations of quantitative bias (social science researchers), and formulaic regulation in the context of contemporary and prevailing risk aversion practices in society and institutions. There was limited literature on the particular issue of capacity and the ability to give informed consent which prompted me to question whether there is an assumption that this is self-evident. However, searches on consent yielded much more literature particularly on the meaning and origins of consent (linked to ideas of autonomy and the self) and the problem of consent in research requirements. Consent appears much more

frequently as an issue for biomedical treatment so searches were focused on consent in bioethics and on sociological inquiry into the meaning of consent.

3.4 Ethical regulation in the United Kingdom

3.4.1 Ethical Approval Systems

At the outset of this research and for most of the time during which it was undertaken, NRES part of the NHS National Patient Safety Agency). NRES (now part of the HRA) functions to co-ordinate the operation of the NHSRECs. Although relating to medical research, the Research Governance Framework (RGF), (Department of Health, 2005) stated that the same principles of review apply across health and social care. When the HRA became a Non-Departmental Public Body in January 2015, it took formal responsibility for research in adult social care. The previous Social Care REC which had been hosted by the Social Care Institute for Excellence (SCIE) was transferred to the HRA in April 2015. The differences in scale, volume, funding and the range of academic disciplines particular to social care had already been acknowledged prior to this transfer. The HRA are seeking to expand the number of committees who can review social care research. It has been argued that developments in ethical regulation over the last decade are in effect attempts to bring ethical approval in the social sciences to meet the same type of scrutiny set for biomedical research by these RECs (Dingwall, 2006). However, as I have argued in 1.51 above, differences in research paradigms are acknowledged.

Even before the most recent changes, social care or social science research which takes place at NHS sites has to be considered by an NRES appointed NHSREC. In addition, any (health or social care related) studies which may involve the participation of adults who lack capacity had to be considered by an NRES appointed REC. Flagged RECs may have particular expertise in specialized aspects of review including capacity. Twenty-four 'flagged' RECs for adults who lack capacity have been established. These REC committee members have undergone additional training on Section 30 of the Mental Capacity Act 2005 which relates to the conditions under which research can take place in circumstances where people are deemed unable to give consent to being involved in research.

It is important to state that bureaucratic procedures are subject to change and have changed during the course of this study. This seems to reflect willingness on the part of the HRA to take feedback and adapt procedures. An example of this is a relaxing of ethics review where studies can demonstrate that they constitute an audit of a service rather than research into a service.

3.4.2 Ethics review and adults lacking capacity

1.4 above describes the position in law regarding participants in research who lack capacity. The MCA (2005) is concerned with protecting people who lack capacity to ensure that if they cannot consent to research then their interests are being protected. As described above in 1.8, the approval under Section 30 of the MCA 2005 to undertake 'intrusive research' requires approval by an 'appropriate body'. For England and Wales, an appropriate body is a committee established to advise on matters which include the ethics of intrusive research in relation to people who lack capacity to consent to it and is recognized for that purpose. NHSRECs in England and Wales and the Social Care REC are recognized by the Secretary of State for Health and Welsh Ministers. These RECs have regard for the legal and regulatory conditions in place to protect consent for all potential research participants.

The twenty-four flagged RECs have been established where committee members have undergone specialized training and may consider a range of studies from research applicants including clinical trials using investigational medical products (CTIMPs) and non-CTIMPS. Even where research does not relate to the NHS or medicine at all and is in a social care setting, for example a care home, if the research involves adults lacking capacity it must be reviewed by an NHS or other 'approved' REC. A University REC or site-specific Trust approval would not be sufficient for such studies. An example would be a study wanting to research interventions which may help with the well-being of people with dementia living in a local authority or private residential or nursing home.

3.4.3 'Lacking capacity': criteria to be met

In addition to the standard ethical considerations for research, in studies involving 'lacking capacity', the summary of criteria which have to be satisfied in order for

approval of a study are provided by the HRA to RECs and will be considered in more detail later in the thesis. However, in brief the RECs are asked to consider a list of criteria with reference to Sections 30-33 of the MCA (2005). The first of these two criteria are that the REC has to be satisfied that the research is connected with an impairing condition affecting participants who are unable to consent or with the treatment of the condition and that, the research could not be carried out as effectively if it was confined to participants able to give consent. These two seemingly straightforward conditions are in fact frequently the source of detailed discussion in the REC.

3.5 Critiques of review systems

3.5.1 Contextualising the critique of ethics review

'*Two distinct kinds of criticism can be identified in the many lines that have been written on the shortcomings of RECs. First, there are criticisms of the research governance system and the way it is constructed and functions in practice. These criticisms range from over-bureaucratisation and inconsistency to actual failures to prevent harm to vulnerable research subjects. Second, broader theoretical questions are raised about the need for RECs at all. These sceptical claims go to the heart of the ethical issue here, raising questions about the right of society to decide what research should and should not be permitted'.*

(Sheehan, 2013:485)

This section of the review illustrates some of the concerns with processes of review (and ethical regulation more broadly). The aim is to show the extent of criticism from quantitative and qualitative paradigms. However, this is not to suggest that these critiques do not have shortcomings in themselves. Sheehan's comment on the scepticism in both the critiques and the questioning of the need for RECs is important. He argues that criticisms of the research governance systems do not take into account the possibility of development and change in systems. The question of whether there is a need at all for any form of review (or only in certain cases) presumes that research is a private matter and not of public or state interest. This is contentious as there may be potentially problematic consequences for the 'researched' if researchers were to determine the ethics of their own research and decisions about research would be taken out of the public domain of formal regulation.

This section of the review therefore highlights some of the shortcomings found in the literature but with a note of caution in that though it is legitimate to critique, it is equally legitimate to consider how review systems can take on board criticisms and adapt accordingly. Further, there is evidence that the reviewing the ethics of research evolves in response to changed perceptions of for example, risk and benefit and training for REC members (and membership) develops according to changing research communities. An example of this is the extensive training open to members of committees and researchers provided by the HRA. In addition, the HRA are aiming to make materials accessible to the public so that any interested party can access them.

3.5.2 Levels of bureaucracy

Critiques of ethics review in research have elaborated on the bureaucratic nature of regulation, concerns about the dominance of medical/ scientific models and that current systems are inappropriate for research in the social sciences. Difficulties with current NHS research processes and the REC system of decision-making have been noted in the literature. The REC meetings which are integral to the review process present difficulties which may be particular to health and social research. The first is in the decision-making authority which they possess; secondly, the lack of expertise in research paradigms other than those which are quantitative with a biomedical focus and the related issue of whether there is an ability in the membership of the committees to distinguish how features of qualitative research approaches may present qualitatively different ethical dilemmas.

Criticisms of the current regulatory system have come from a range of interested parties and include those involved in both quantitative and qualitative research. Social science researchers feel that ever-increasing regulation is stifling social and health research. Dingwall (2006) argues that research governance with its roots in understandable fears of biomedical experimentation in the 2nd World War has no counterpart in health research. Ethical regulation is often therefore ill equipped to deal with research projects located outside of the biomedical domain. The arguments here are driven by a conviction that the type of intrusive and experimental research required in some medical research is not replicated in social science research and Hammersley (2010) has described the extension of this level of scrutiny into the

social sciences as the 'creep' of regulation into for example new approval frameworks. An example of this was the framework published by the European Social Research Council (ESRC) in 2005. In an extension of review and governance, the Economic and Social Research Council (ESRC) revised its ethics policy for research with the Framework for Research Ethics (FRE) and outlined what it considered would be the exemptions from full review. These were summarized as research relying on data already in the public domain and projects that are not considered 'research' (for examples see ESRC 2010). Hammersley (2010) in a paper critical of the revised policy commented that his interpretation of the new framework meant that few research projects would escape ethical scrutiny by committee and expressed concerns also about the extension of the scope of regulation to all aspects and stages of research which, along with other difficulties of restricted access to people and place, constitute a threat to the future existence of good quality social research in many fields.

The overly bureaucratic nature of ethical regulation is a common criticism found in literature. Social work researchers undertaking studies in the social care sector are currently dependent on decisions taken by Directors of Social Services. Here, variation in the required amount of bureaucracy and levels of support given to external researchers has been noted (Mclaughlin and Shardlow, 2009). McLaughlin and Shardlow further highlight how confusing regulation can be when University researchers may potentially need ethical approval from a range of committees who may request contradictory changes to the submitted study. However, these concerns are not held exclusively by health and social science researchers. Increasing amounts of paperwork for submission and delays in the processes are highlighted in medical research also. Stewart et al (2008) used case studies to illustrate the delays involved for clinical researchers in gaining approval for research through existing structures and comment that currently it is the bureaucracy involved which is a threat to research being carried out rather than a lack of researchers or research capability. A further difficulty which has been highlighted in the medical domain is the necessity for participants in research to 'opt-in' to research studies. Researchers are required to demonstrate how this will be evidenced in their application for ethical approval. In interventional medical studies, NRES guidance supports an opt-in of research participants which is linked to the concern for there to be no coercion of participants.

For non-interventional studies, which would include many health orientated and all social research, guidance from NRES still supports the requirement to opt-in (NRES, 2007). However, NRES acknowledges that medical researchers would prefer an 'opt-out' approach for studies viewed as presenting low risks to patients citing Junghans et al (2005) carried out a randomized trial of 'opt-in' versus 'opt-out' strategies in medical research and concluded that the approach adopted by ethics committees of an 'opt-in' approach impacted on response rates and resulted in biased samples.

There have been more recent changes to improve the speed of review and avoid delays. According to the HRA website,

> *'A REC is required to give an ethical opinion on an application within 60 calendar days of the receipt of a valid application.'*

> (HRA, 2016)

Furthermore, there have been notable examples of authors who have highlighted the value of formal review procedures. In particular, from qualitative perspectives, Wiles (2013) has commented that committees which review the ethics of research monitor and advise on the management of ethical issues at the anticipatory stage of research (p21). This can be an advantage to the researcher. I elaborate more fully on this point in the analysis of findings in Part Two of the thesis when the value of review for researchers is discussed.

3.5.3 Dominance of biomedical concerns, the quantitative 'bias'

A common concern in the literature from qualitative research orientations is that approaches to ethics in regulatory systems are dominated by biomedical ethics and that there is a lack of understanding of social science, in particular, qualitative research among RECs. Social science researchers feel that ever increasing regulation is stifling both social and health research (Dingwall, 2006; Hammersley, 2009; Hammersley, 2010). Concerns have also been raised about the straightforward transferability of ethical principles in review to qualitative research.

> *'Similarity of principles (in qualitative research) does not translate into similarities in their operationalisation in research practice'*
> Burr and Reynolds (2010:132)

Though ethical principles may be shared in medical and social scientific research, they argue, there are in practice different challenges in adhering to them. They cite anonymity as one such principle which may be more difficult to preserve when there is a smaller sample and closer engagement with the participants in some kinds of qualitative methods.

The adoption of the NHS ethical requirements by the Economic and Social Research Council (ESRC) in 2010 prompted a forensic critical examination by Stanley and Wise (2010) of RECs' composition and described the excessive bureaucracy involved as 'ethics creep'. Hammersley (2010) referred to the extension of this level of scrutiny into the social sciences as the 'strangling' of research. However, against a background of critique of bureaucracy and the particular concerns of qualitative researchers, there is also some research evidence which counters these perceptions and this is discussed below.

The prevailing regulatory frameworks which set out a prescribed way of seeking consent (by the provision of information or transaction) present challenges for qualitative research. Issues of consent and criticisms of the anticipatory review of ethics have been raised by Murphy and Dingwall (2007) in relation to qualitative research and ethnographic research in particular. They argue that ethnographic research does not carry comparable risks to biomedical research. They do not argue that qualitative research is risk free (emotional upset, embarrassment, hurt can be consequences) but that these kinds of 'harms' should be supported by a responsible researcher. Bureaucratic processes for gaining informed consent do not get around this problem and greater harm may be caused by publication (or how research is subsequently reported).

Contrary to the view that RECs do not 'get' qualitative research, Hedgecoe (2008) has challenged the prevailing perception amongst sociologists and other qualitative researchers that RECs are ideologically biased against qualitative research. He undertook an observational study of RECs which included informal discussion as well as interviews with members of committees. There was an acknowledgement among some of those interviewed that they did not always understand the aims of qualitative research. However, he suggested that the lack of expertise which some REC members expressed should not be interpreted as hostility to this type of work.

Hedgecoe links objections to RECs from social sciences as being connected to resistance to the regulatory ethical appraisal of their studies, and, in this he argues, they are not unlike biomedical scientists who also dispute the need for ethical oversight. What is significant, Hedgecoe concludes is that it is the institutional form of RECs which is potentially limiting. He proposes that engagement with and investigation of the institutional and social relations of RECs would be helpful rather than an unsupported critique of the activity of RECs. In fact, detailed examination of the processes of review and scrutiny of what happens within the REC meetings is scant.

There is evidence also that the Health Research Authority recognizes that concerns about review of qualitative research need to be addressed. The website details training available to members of committees, which includes qualitative research in review. It also briefly describes qualitative research:

'…… (it) does not try to quantify anything or use statistical methods. Rather, it seeks to understand other people's perspectives and motivations. Typically, qualitative research focuses on words and their meanings, and does not seek to count things. Consequently, qualitative researchers often use small sample sizes because they are not seeking to statistically generalise their findings'.

(HRA: NHS, 2016)

Importantly, though this does not provide evidence from individual committees it does show that the HRA acknowledges the differences in qualitative research and promotes awareness of its features amongst its community. Additionally, it notes other distinguishing features relating to study design and methods as being:

- Less specificity of sample size due to the approach of continuing fieldwork until no new insights are yielded.

- Estimations of number of interviews, which may need to be altered.

- The need for questionnaires to be unstructured so that issues can emerge from undertaking the research.

- Allowing topics to emerge from the research

Source: Health Research Authority. Retrieved from www.hra.nhs.uk/patients-and-the-public-2/types-of-study/what-is-a-qualitative-study/ August 2016.

3.6 The meaning of consent

In a philosophical sense, notions of consent are integral to autonomy and a core element of the social contract of the European enlightenment. In the twentieth century in both medicine and research, there has been a shift from a broad 'beneficence' approach based on the idea of doctors generally and paternalistically doing the best for their patients to an approach which emphasises patients' decision-making (Berg et al,2001). Berg et al further argue that following Nazi experimentation in the Second World War, individuals were required to exercise 'autonomous decisional authority in order to safeguard their welfare.' (p20). This was because, even if doctors and researchers could be relied on to make sound anticipatory judgements about risk-benefit ratios, individuals' autonomy would be protected if they were informed and could make their own decisions about participation. Critics of the requirement of consent may sometimes neglect to consider the alternative which might be a paternalistic approach where decisions are made on behalf of research participants.

3.6.1 Feminist critiques of consent

Bioethicists have been critical of the preoccupation with autonomy, particularly individualistic conceptions of autonomy, and note its apparent primacy in relation to other ethical principles, though critics generally would be supportive of advances against medical paternalism. A significant critique of consent is that it abstracts consent from the contexts in which it individuals make decisions. For example, feminist commentators have argued that consent is seen as individualistic and that the grounding of consent in autonomy creates a separation from the contexts and communities in which individuals exist (Sherwin, 1996). This argument critiques the private/public dichotomy in bioethics where encounters are generally seen as private between doctor and patient and yet which are shaped by public and political norms (Wolf, 1996).

Kittay (2007) considers autonomy and informed consent in medical contexts and proposes that autonomy is *relational* rather than *individual.* In her view, contemporary understandings of autonomy are perhaps more linked to notions of dignity and are viewed as part of our being a whole person It is '…. a self-reflective capacity that permits an individual to be self-determining, to make choices for which

one can take responsibility and choices with which one identifies, that is an expression of who one is and what one authentically desires' (Kittay, 2007:67). An alternative version of autonomy would view it as more *relational,* where the development of autonomy is dependent upon social interactions, which then provide us with the competencies needed for autonomy. The conditions in which consent is sought are medical and Kittay's point is that autonomy in either of these definitions seems to require sophisticated social and cognitive skills and yet it occupies centre stage in the field of biomedical ethics when people may feel most vulnerable due to illness. I would argue that this emphasis on the significance of conditions and contexts which prevail in situations of seeking informed consent, is relevant to research with **research** participants in general.

Kittay further comments on how in medical contexts, autonomy is operationalized as informed consent. This is of course highly relevant to the concerns of this study which explores the operationalization of consent (and in/ability to give consent) in research ethics. This study investigates decision-making about research applications in general including those aspects relating to consent.

3.6.2 Development and practice of informed consent

Our understanding of consent in both medicine and in research ethics is linked to certain requirements which must be present – consent must be freely given; no coercion should be involved in seeking consent and the consent should be 'informed.' The Nuremberg Code 1947 is viewed as the first statement of principles of consent in relation to medical treatment and as already noted, this followed abusive treatment by Nazi researchers during the Second World War. Informed consent is particularly discussed in the context of medical and biomedical ethics as well as in the research field. It is important to note therefore that as the first principles were developed as a reaction to inhumane *medical* experimentation (Dingwall, 2006) research ethics are often viewed as emerging from the medical realm. However, it is important not to conflate consent in treatment with consent in research and an understanding of the evolution of consent in research illuminates the differences in each of these realms. Berg and Appelbaum (2001) describe how the evolution of consent in research plots a different course from consent in medicine.

> *'Consent to treatment is largely a creature of case law, with some subsequent statutory modification. Consent to research has been shaped by professional*

> *codes, statutes and administrative regulations, with the courts playing a less important role.'*

(p 249)

Informed consent is often viewed central to research ethics (given prominence in review possibly above other ethical considerations) and has been described as functioning as an 'ethical panacea' counteracting the potential danger of paternalistic and autocratic practices' (Corrigan, 2003:769). More recently, Corrigan (2016) has summarised dominant ways of thinking about consent and the consequences of these. In the first conceptualisation, consent is an absolute principle which is abstracted from context and becomes 'empty ethics'. In the second conceptualisation, consent is an important principle which it might be ethical to breach in some contexts. The third conceptualisation is where consent is viewed as essentially unworkable. The consequences of this in practice might be that a paternalistic approach is adopted which leaves decisions about competence to consent to researchers. The amount of information given and level of sophistication of information provided would be at the discretion of the researcher. An alternative conceptualisation would be to:

> *'……. see informed consent as an ongoing process rather than a discrete act of choice that takes place in a given moment of time.'*
> (Corrigan, 2016:34)

For consent to be meaningful, it needs to be thought of as being of continued relevance through the research process rather than a one-off event. One of the unfortunate consequences of review procedures is that researchers are not challenged to necessarily think through the potential and ongoing consent issues, which might arise because their aim in review is to have the research positively reviewed.

3.6.3 The meaning of consent in research practice and the importance of context

What we as individuals mean by consent is actually hard to define. Its relationship to autonomy Manson and O'Neill (2007) suggest it is a propositional attitude – by which they mean that like 'desiring' or 'hoping' it is a state which can only be partially known. Consent is agreement to something when you can never fully understand the meaning of what you are consenting to because you have not yet experienced it.

The view of consent held in ethics is based on the idea of a rational being – an individual need to have made an autonomous decision (not coerced), and to be informed (given information). Current regulation requires informed consent but Manson and O'Neill (2007) argue that it is formulaic consent which is required meeting the needs of the institution rather than the participant. In a critique of the individual nature of consent, Corrigan (2003) (apparently concurring with a relational view of autonomy) - highlights the lack of the social aspects of consent. Some communities or societies understand decision making as a social activity rather than an individualistic one and view ethics which is abstract and speculative as 'empty' ethics. A further problem Corrigan outlines is that seeking and giving consent always takes place in contexts which are influenced by prevailing norms. These shape expectations and influence decisions about whether to take part in research such as drug trials or RCTs. In the context of medicine and treatment for example, patients generally believe that doctors are acting in their best interests and may consent to research but taking part in a drug trial often means that the best treatment option is unknown and this brings about a level of uncertainty for both doctor and patient. In other words, prior perceptions and beliefs influence patients' decisions and patients generally see research as part of 'curing'. The idea of consent as straightforward and individual does not take account of the situation. Individual decisions do not take place outside of contexts of power and influence.

This perspective constitutes an important problematizing of informed consent as is currently understood in research ethics. Greenhough (2007) stresses the importance of context and emphasizes that we may need to view ethical decisions made as 'partial (as opposed to impartial or objective) and situated (as opposed to objective and distanced)' (p1149). This is because in her research, patients making decisions were influenced by all kinds of factors beyond solely medical contexts. She proposed that participants were influenced by the political climate, obligations to relatives, future offspring and previous experience of medical science.

Understandings of consent are frequently understood, taught and practiced in research in more nuanced ways than procedural approaches might suggest. Even within a procedural framework, consent is viewed as more than a 'one-off' prospective matter. Ethical debate in the HRA (a process started by NRES) is an

ongoing activity which enables detailed discussion of particular issues relevant to the research ethics community. An example of this was a discussion of the issue about the time allowed for participants to consent which acknowledged that information (on the study) was the most important decision aid. They noted that trust was important in decision-making with many participants wanting to share decisions with a healthcare professional. The discussion acknowledged:

> *'This process (of consent) is much more than provision of an information sheet and a signature on a consent form and a recent review of evidence indicated (not surprisingly) that talking one–to–one was the most effective way to provide information that was understood. This could be scheduled in (possibly with the length of time this might be expected to take) and explained at the beginning of any printed information. Subjects need time to ask questions and reflect. There is no exact defined time for this, Time provided needs to be commensurate with the research, shorter or longer'.*
> (HRA, 2013)

This suggests that in the practice of review itself, the limits of a 'consent-taking' formulaic approach are recognised. For consent to be meaningful, context needs to be acknowledged. In fact, as can be seen, the discussion does not conclude by suggesting particular time limits to consent taking, acknowledging the uniqueness of each situation. This perhaps suggests that at HRA level that there may be a more nuanced understanding of consent.

3.6.4 Limitations and problems with consent in research practice
In a Foucault-inspired analysis of ethics committees, Juritzen et al (2011) focus on Foucauldian notions of power (firstly as dynamic and unstable and secondly as linked to knowledge) to examine ethical regulation and to support their contention that ethical regulation in itself has potentially 'harmful' consequences' (albeit indirectly) for research participants. They argue that informed consent is enforced as a basis for all research with humans. The assumption which lies behind the bureaucratization of the process of gaining informed consent is that of an asymmetrical power relationship between the researcher and subject. The central position given to informed consent and the concern to protect the weaker research participant is linked here to the overly bureaucratic nature of review and subsequent consequences. Juritzen et al argue (citing Boden et al, 2009) that this bureaucracy, these regimes of guiding and monitoring transform researchers themselves into compliant self-regulating actors.

> '*The regimes of control… institute technologies of the self that require researchers to become 'docile bodies' within the research process, self-regulating and self-disciplining their own actions against particular ideas of what is standard and good.*'

(Boden et al, 2009: 743)

The significance of this may be that the researcher who is seen as possessing power and knowledge and the linked notion of the vulnerable, unknowing research subject may in itself lead researchers to regulate their research, set parameters upon it, or even avoid areas of work which interface with 'vulnerable groups'.

A significant difficulty highlighted by Juritzen et al is that informed consent as a principle potentially excludes large groups of people including for example those viewed as mentally unstable or disabled (Juritzen et al, 2009). This exclusion of those deemed incompetent to consent may lead to their lives being concealed. Paradoxically, they argue, those who may be vulnerable are protected from research but also from the critical scrutiny which may in fact benefit them. Although as we have seen, there are specified conditions under which those unable to consent are able to participate in research, it is difficult to estimate how many researchers design their projects to avoid inclusion of this group of people and so avoid the capacity and consent issues completely.

3.6.5 The process of gaining consent

This last observation about who may be excluded from research in the current regulatory regimes is taken up by Miller and Boulton (2007) who comment that RECs have played a role in distorting recruitment by imposing restrictions on how participants may be approached. Changing notions of risk in society have influenced individuals' decisions about whether to sign up to take part in research. Their paper highlights how the abstracted notions of autonomy and self-determination in the individual are seen as integral for informed consent. In fact, informed consent cannot be separated out from society and the practical aspects of social relationships. Miller and Boulton are also concerned that the prescriptive routes and formalized nature of consent requirements will result in a smaller pool of potential research participants and a restricted group of willing participants will become the 'professionally researched'.

Surveying their own research over the last 35 years, Miller and Boulton show how the both the nature of research and the willingness to be involved in research has been influenced by prevailing discourses of power and perceptions of risk. Research encounters cannot be anticipated or contained within the required paperwork and informed consent is highlighted as a particular difficulty. Miller and Boulton (2007) describe these protocols, the presentation and signing of consent forms as mechanisms which act to 'contain' complex social worlds and research encounters which do not fit into tick box approaches. Looking retrospectively at research they have undertaken, they note the shifting meaning of informed consent over time. They argue that the ways in which the relationship between researcher and researched is understood has an influence on what informed consent means. Describing for example, how their own feminist research challenged the hierarchical roles (of researcher and researched) in favour of more collaborative approaches. The consequent expectations of trust, privacy and even friendships which arose challenged the traditional focus of consent procedures on risks and benefits of involvement in research. Their concern is with the incongruence between the fluid and complex worlds which are researched and influenced by society in which the research takes place. In contemporary (Western) society where relationships and social life are viewed as risky and uncertain, these risks are viewed as requiring regulation. They suggest that qualitative researchers need to develop ethical literacy and demonstrate ethical sensitivity in conducting research, whilst RECs need to show trust in researchers' abilities to make ongoing decisions as needed 'in the field'. Their paper concludes with the proposal that informed consent might be better seen as a process rather than one-off event. Hem et al (2007) also discuss the idea of process in gaining consent and suggest that in their research in a psychiatric ward with psychotic patients that they were continually challenged by patients to address the meaning of consent on a continuous basis. Even though researcher knowledge may be important, an ethical researcher needs to have an awareness of the context (in this case, psychiatric) in which they are working and be aware of the assumptions about individuals and diagnosis found within that context.

As noted above, nuanced understandings of consent and capacity seem to consider contexts. Undertaking research with people in a persistent vegetative state Gelling (2004) involved families closely in the research, engaging them to assist in looking

for signs of awareness in observations. Assenting to participation in the research was checked out with families as part of a process which involved them in ongoing decision-making and they were viewed as partners in the research. Gelling defended research with this group of patients who were unable to consent to research into their condition. He argued that even though considerable ethical and moral challenges are presented, this kind of research is worthwhile. All patients should be able to potentially benefit from clinical research and emergent new knowledge, furthermore, the exclusion of any patient group could be deemed as discriminatory. Gelling's discussion invokes the principle of justice in research in its consideration of the ethics of exclusion and inclusion in research as a right. This is interesting because it is a claim that this right ought to remain even when a person is incapacitated or vulnerable.

Although Miller and Boulton focus on qualitative research and the challenge of consent in complex social worlds, O'Neill's work on consent makes some parallel observations in the field of bioethics. O'Neill also frames her discussions of consent in a wider context of prevailing contemporary views about accountability and trust in public institutions (O'Neill, 2004; Manson and O'Neill, 2007). Trust is seen to be guaranteed by the introduction of contractual relations, detailed accountability and specific and explicit consent. Therefore, consent is linked to increased bureaucratic checks, accountability and explicit consent, which requires information to be given to research participants, which O'Neill argues, is not always understood. 'Explicit consent' is described as a two-way process requiring the researcher to be open about the nature of research, purpose, effects and possible risks and those who are asked for consent must show that they understand. This approach, intended to achieve higher standards rely on 'formalistic, uniform and, strictly speaking, impossible procedures and standards for achieving ethically acceptable clinical practice and medical research.' (Manson and O'Neill, 2007:11).

Problems with achieving the requirements for consent have also been raised in relation to action research and participatory inquiry, methodologies which aim to bring about direct and innovative changes in practice. Gelling & Munn-Giddings (2011) discuss the challenge of how to decide 'to whom' participants are consenting in action research given that researchers may be difficult to distinguish as they are

potentially a colleague, a practitioner or friend. These authors also describe the difficulty of describing 'to what' participants are consenting. This is because the nature of the prospective research and even its methods may be unknowable at the outset. The requirement therefore of participants to be informed of the type of involvement expected of participants cannot be explicitly provided as the nature of action research can take a direction which is unanticipated. In contrast to some commentators critical of ethics review, Gelling and Munn-Giddings do propose some ways of navigating the process of approval with RECs outlining for example how researchers might explain the roles of all those involved in the research and provide clarity in the description of methods, whilst suggesting also that RECs need to demonstrate greater flexibility in reviewing these evolving projects (p106).

3.6.6 Consent and ethical approval

Some studies have been concerned solely with consent and the processes of ethical approval. Dixon-Woods and Angell (2009) looked at decision letters to research applicants sent out by RECs when studies involved adults who lacked capacity. This study was concerned with outcomes. The researchers accessed decision letters and undertook an analysis of the contents of these. The study's findings were that there were inconsistencies in the interpretation of the MCA (2005) requirements between different RECs. However, as stated above, the study did not explore the internal operation or discussions of RECs, only the consequent decisions made following consideration for approval. This may suggest that different interpretations of the MCA (2005) may have been justified as the contextualised deliberations leading to an opinion on an application were not included. Again, there is a lack of attention paid to the detail of RECs' work in the situations and contexts in which it occurs.

A further study undertaken directly with researchers revealed that it may be the attitude of the researcher which prevails upon how much of an obstacle seeking consent is perceived to be. Crowe et al (2006) identified 'pessimistic' and 'optimistic' accounts of social science researchers about ethical regulation, in particular the requirements of consent. Accounts were gathered through focus groups and telephone interviews with researchers whose studies involved 'vulnerable' subjects. Whilst 'optimistic' accounts seemed to value having to consider thoughtfully the

process of gaining consent with vulnerable subjects, the 'pessimistic' researcher accounts identified informed consent requirements and procedures as creating a potential barrier in the relationships which could be made and the potential rapport forged between researcher and subjects (Crowe et al, 2006). This suggests it is the attitude of the researcher rather than the process of ethical regulation itself which influences the perception of review as a 'barrier'.

3.6.7 Consent, capacity and vulnerability

Given that the basis of autonomous and informed consent is the idea of a rational human being, a problem arises if the person is viewed as lacking the mental capacity to consent and therefore in a vulnerable group. Oeye et al (2007) questioning the notion of vulnerability and research with psychiatric patients define a tension here in that medical ethics doctrine places itself in 'dim epistemological landscape' caught between the right of a person to voluntarily participate in research on the one hand and the human right to protection (from harm) on the other. Ethics in research is anchored in the epistemological traditions of liberal-humanist and paternalistic traditions which create paradoxes for researchers and researched.

There are studies which have critiqued the concepts of 'non-maleficence' and vulnerability in the context of research. Johnson (2004) argues that non-maleficence can never be an absolute principle, as we cannot set out to research being certain that we will not cause harm. This argument that the consequences of research applies in health contexts such as those which Johnson is describing but it is often referred to in the context of qualitative research. Some research papers have shown though that straightforward approaches to seeking consent are inevitably bound up with an ongoing assessment of protection of vulnerability and that the difficulties are presented by the expectation that seeking informed consent is a bureaucratic and straightforward exercise.

In an ERSC funded project, Wiles et al (2007) interviewed researchers about seeking and gaining informed consent from a range of 'vulnerable' research subjects. They described a range of difficulties about the practical, on the ground dilemmas faced including how much information to give, what to reveal and how often to reveal it. The difficulty in undertaking ethnographic research with informed

consent is highlighted as by its nature, research participants are signing up to research at the start of the study when the focus and intended outcomes might not be fully realized. The authors concluded with the suggestion that regulations should be flexible, offering guidance to assist researchers with the reflexive negotiating which is needed when seeking informed consent both with vulnerable groups and wider.

3.6.8 Questioning vulnerability in consent

Although this study focuses on those groups deemed vulnerable and unable to give informed consent, it is important to note that the process of seeking informed consent is a challenge for researchers generally. The assumption that certain groups of people will present an inevitable problem in consent has been contested. The meaning of 'vulnerability' in studies involving people who are viewed as being unable to consent, such as psychiatric in- patients, has been considered in medical contexts. Okai et al (2007) in a review of an assessment tool developed to assess capacity, concluded that patients on general medical wards were just as likely to have problems understanding treatment options as were patients on a psychiatric ward and that these two groups of patients should not be treated as intrinsically different when considering consent to treatment. In addition, whist there is concern within current regulatory systems about those people who lack capacity, '*massive empirical evidence indicates that patients and research subjects with high cognitive competence do not assimilate a significant proportion of the information disclosed to them.*' (O'Neill, 2004:275).

In a research context, lack of capacity to consent may be anticipated in participants rather than assessed *at the point of* participation. It may also be the case that protections put in place to protect the vulnerable may have the opposite effect. One of the respondents in the Wiles et al (2007) study discussed above talks about how at times 'vulnerable' prospective participants were over-ruled by carers or spouses when they had indicated that they would like to be involved. Another respondent talks about the assumption of inability to think through participation in research when studies involve children with disabilities. Clearly, consent is not straightforward, capacity to enable informed consent can be an issue   for many people not those just those in the predictable categories of perceived incapacity (the vulnerable, the old,

the mentally ill and so on). We also need to ask questions about what we are protecting vulnerable people from in research more broadly.

3.6.9 *Informed* consent in ethics review and 'trust'

Some philosophical critiques of regulation of consent have been framed within and influenced by our understanding of 'trust' as a public discourse which demands transparency and accountability. Philosophical perspectives on bioethics and medical treatment can provide helpful ways to think about the meaning of consent practicalities on the ground. In relation to general medical treatment and in the context of bioethics, informed consent seems to rely just on the notion of 'informing', giving people information and being transparent about risks and benefits. However, these 'transparency transactions' (Manson and O'Neill, 2007) satisfy bureaucratic requirements but may not inform patients in a meaningful way. Manson and O'Neill also comment that this sort of disclosure limits secrecy but does not address fundamental issues of good communication or 'successful communicative transactions' which they argue are needed for consent to be realized. In an earlier paper, O'Neill (2003) suggests that informed consent has become more prominent because it is seen as a protection of institutions or professions from litigation, accusation or compensation claims. In this paper, she attempts to delineate what constitutes genuine consent and suggests that this is not found in the ritual of consent procedures.

> *'Our aim in seeking others' consent should not be to deceive or coerce those on the other end of a transaction or relationship: these are underlying reasons for taking informed consent seriously…….Complex forms that request consent to numerous highly specific propositions may be reassuring for administrators (they protect against litigation) and may have their place in recruiting research subjects; yet they will backfire if patients or practitioners come to see requesting and giving consent as a matter of ticking boxes. Our aim should, I suggest, be to achieve genuine consent, and this may not always be best done by seeking specific consent to a great many propositions.'*

(O'Neill, 2003:6)

O'Neil's view is that 'perfect specificity' is doomed to fail and that patients instead should be given relevant information with more detailed information being available

and she suggests that the issue of coercion and freely consent can be achieved by ensuring that participants know that they can withdraw. These two principles of access to *extendable information* and *rescindable consent* are proposed as ways of ensuring that participants in research have the power of veto over what happens. O'Neill is not suggesting these are unproblematic for researchers or participants but I think she is attempting to identify the core objectives of informed consent and translating these into meaningful and achievable principles.

3.7 The consequences of not attempting ethics review

Given the extent of the critique of bureaucratisation in relation to ethical regulation and review, it is appropriate to conclude this section with brief discussion of the consequences of no ethical regulation. Though there is undoubtedly an important argument about whose needs are being protected by procedural ethics review which O'Neill (2003; 2004; and Manson and O'Neill, 2007) outlines in her extensive commentaries on consent, she does not suggest that we abandon consent but suggests ways to make it more meaningful This leads to a consideration of the prospect of abandoning review of ethics more generally. The consequences of no review might be that participants in research are not afforded adequate protections. Gallagher (2011) in a commentary on the review of research ethics in a global context, contrasts overly procedural processes with insufficient scrutiny of research where consequences may be the exploitation of vulnerable or marginalised groups. Both of these approaches to review in research exist currently in international contexts, that is, 'scrutiny' and 'insufficient scrutiny' that could fail to adequately protect people who participate in research. Gallagher's argument here also prompts us to think through the possible consequences of 'insufficient scrutiny'. More reliable safeguarding of research participants, Gallagher suggests, may be found in continual self-scrutiny in the research community, where researchers ask questions 'of ourselves and each other regarding the motivation for, and ethical conduct of, our research and scholarship.' (p752).

Dyck and Allen (2013) argued that in order to prevent unnecessary expansion of ethics review then it ought not to be mandatory for all research. Specifically, they proposed that only funded research and research involving vulnerable people should be subject to review. In response, Israel (2013) highlighted that although he had

sympathy with the concern with expansion of review, there was a potential problem in determining who was vulnerable in research and determining categories of people who might be deemed vulnerable risked a discriminatory approach.

> *'…making decisions about vulnerability on the basis of group characteristics draws on categorical stereotypes which might be inappropriate and might also lead researchers and regulators to pay less attention to the processes and contexts which might result in the exploitation of research participants.'*

(Israel: 525)

Though this review has highlighted concerns with the assumption of vulnerability and incapacity, Israel's perspective is important in that the prospect of lowering thresholds for review might also be problematic and potentially discriminatory because it would depend upon *a priori* judgements being made about which categories of people would be vulnerable.

3.8 Summary of key findings in the review

Regulation: This review illustrates the concern with the legalistic and bureaucratic approach to ethical regulation generally as potentially problematic. It raises questions about whose interests are being served by ethical regulation. Regulation of consent requirements in the field of both biomedical and qualitative research is also discussed. The views of qualitative and quantitative academics are not as polarized as might be assumed in relation to the burden of review generally and specifically of informed consent. Literature that is more recent has highlighted some possible advantages in the formalised review of ethics. Wiles (2013) for example acknowledges that requirements can constrain research but argues that an understanding of frameworks, legislation and regulation can provide a basis for researchers to think through and argue the case for their ethical decisions.

Consent and capacity: Consent is viewed as central to good ethical conduct and consent has to be 'informed'. This presents a particular difficulty when people are deemed unable to consent and are 'lacking capacity' due to a range of conditions or situations. This study acknowledges some of the difficulties outlined in the existing literature. The philosophical or theoretical meanings of informed consent have been explored in this review. Some of the difficulties and dissatisfaction for researchers in both qualitative and quantitative research paradigms in existing literature have been

described. The problems of seeking informed consent in practice and the changing nature of consent influenced by changing contexts is another theme which emerges. The challenge to the notion of objective and impartial seeking of and gaining of consent to research is evident in sociological literature but also in the attempts to reframe what consent means in bioethics. Problematizing the notion of objective and impartial seeking of and gaining of consent to research is evident in sociological literature but also in the attempts to reframe what consent means in bioethics. This perspective constitutes an important problematizing of informed consent as is currently understood in research ethics. However, we know little about how capacity and consent are operationalised in review and how judgements are made about this kind of research, specifically, how committee members understand and make sense of consent in the context of RECs.

Protection and consent: Foucauldian perspectives have been used to analyse power in relation to both RECs and the notion of 'vulnerable' research participants in ethical regulation. Juritzen et al (2011) contend that ethical regulation in itself has potentially 'harmful' consequences' (albeit indirectly) for research participants. The assumption which lies behind the bureaucratization of the process of gaining informed consent is that of an asymmetrical power relationship between the researcher and subject. The central position given to informed consent and the concern to protect the weaker research participant is linked here to the overly bureaucratic nature of review and subsequent consequences. A significant difficulty highlighted by Juritzen et al is that informed consent as a principle potentially excludes large groups of people including for example those who are viewed as mentally unstable or disabled (Juritzen et al, 2011). This exclusion of those deemed incompetent to consent may lead to their lives being concealed and render this group of people even more vulnerable and marginalised.

The analysis of power extends with Boden et al (2009) to the practice of RECs who argue that regulatory regimes transform researchers themselves into compliant self-regulating actors. The significance of this may be that the researcher who is seen as possessing power and knowledge and the linked notion of the vulnerable, unknowing research subject may in itself lead researchers to regulate their research, set parameters upon it, or even avoid areas of work which interface with 'vulnerable groups'. Though this an important concern, research has paid less attention to power

and how it operates in the REC and this means that the assumption of powerful RECs and powerless researchers may be an adequate or accurate description of what happens in ethical regulation.

3.9 Conclusion: The gap in the literature and originality in this study

There is limited literature on practical ways of seeking consent especially where people are viewed as not able to make rational and autonomous choices for themselves. There is some limited literature and research available on RECs but these have focused on 'outcome' decisions rather than 'what happens' at committees. There is little on how researchers think about consent and capacity in the review processes they go through, for example in the preparation of written formal applications and attendance at RECs. We know very little of what influences committee members in their decision-making in the context of the committee. What their views are about vulnerability and protection and how that relates to consent requirement is hardly described in current literature. RECs are authoritative and their decisions can potentially delay research if ethical requirements are not met. It seems important therefore to investigate what happens at committee meetings.

There is a lack of studies which have explored the activity of RECs from an observational starting point. Hedgecoe (2008) has highlighted (when writing about RECs' attitudes to qualitative research, see above) that assumptions about REC activity cannot be made based only on decision outcome. This perhaps suggests that richer or more in depth analysis of REC activity may shed light on what takes place in the committee meeting which lead to the decisions made. The study will do this by researching the everyday practices of the RECs to enable a description of how reviews are undertaken in the context of flagged committees. How are matters of consent to research conceptualised and operationalized? What is the extent to which procedural ethics dominates and by what other means do committee members review and arrive at opinions? It is the intention of this study to develop an analysis of how judgements are made about research in the context of applications involving research participants who lack capacity. This is contextualised in general inquiry into how committees do their work.

3.10 Coda: Ethical approaches - locating the study

Following this review and during the interpretation of my findings I read more widely about the range of approaches which can be identified in research ethics. These are relevant for researchers but also relevant to this study in relation to the work of reviewers who are engaged in deliberating about whether research is ethical and are charged with giving opinions about whether to approve research as ethical or not. Wiles (2013) explains how the most common approaches (consequentialist, deontological, ethics of care and virtue ethics) influence and offer ways of thinking about research dilemmas. It is important therefore to outline these broad frameworks or theories because they influence and shape the ways in which researchers may reflect on their research practices and they are relevant to how reviewers may consider and reflect on research applications. I also state which approaches emerged as more (or less) relevant in my subsequent analysis.

3.10.1 Deontological approaches

The term derives from the Greek 'deon' meaning duty. Central to Immanuel Kant's (1724-1804) thinking on moral theory was that morals ought to be based on obligations to others. Obligations flow from core expectations that we should treat each other with humanity, dignity and worth (Hay and Israel. 2006). This notion (often referred to as the 'categorical imperative') places duties and obligations to do the right thing above the potential consequences of that moral action. Kantian philosophy attempts to make this abstract notion more concrete by exhorting that we only act in ways which one would wish others to act or recommend others to act (Israel and Hay, 2006: 15). Consequently, research would be driven by universal principles such as honesty, justice and respect (Edwards and Mauthner, 2002). The potential difficulty with the approach is that it places doing the right action above a consideration of human consequences.

3.10.2 Consequentialist theory

This type of theoretical framework describes how people's decision- making should be congruent with maximising 'good' and with regard for the consequences of their actions. People should seek to act in accordance with the consequences of their behaviour and in ways which maximize well-being (Kent, 2000). The right or wrong of an action is judged by its consequences rather than intent. In this theoretical framework. research would be justified by its outcomes such as the generation of

new or increased knowledge about a treatment for a condition for example. The difficulty here is that privileging outcomes could involve arguably dubious 'means' such as covert research. There was evidence in the findings of reviewers engaging with and thinking through the consequences of research for all of those involved but it did not exclusively describe the deliberations of committee members.

The differences between the two normative approaches described can be summarised thus: '*Consequentialism exhorts us to promote the good; the latter (deontology) to exemplify it.*' (My brackets) (Israel and Hay, 2016:16).

3.10.3 Virtue ethics
Rather than a focus on rules and duties or the consequences of actions, virtue ethics is based on the qualities of the person.

> '*Whereas consequentialist and non-consequentialist approaches to ethics might be regarded as act-centred, virtue ethics is an agent-centred approach.*'
> *(Israel and Hay, 2006: 17)*

This emphasises an underpinning dependence on the notion of the right-acting individual who will act appropriately and in accordance with rules due to character or virtuous traits. The qualities of the researcher would be paramount, highlighting the characteristics and qualities of a researcher (Wiles, 2013). Importantly, a virtue ethics approach problematizes the idea of abstract and universal principles and stresses situational or contextual ethics. For researchers, intuitions, feelings and reflective skills are emphasised along with the sensitivities involved in dialogue and negotiation with parties involved in the research (Edwards and Mauthner, 2002).

Virtue ethics emphasises the possession or development of qualities or character traits such as honesty, loyalty and integrity. In the context of RECs, committee members would be guided by personal judgement and responsibility for those judgements. The personal would be privileged over the de-personalised principle-based approach.

> '*…. personal responsibility for decisions rather than justifying actions on the basis of a de-personalised but rational rule or principle for making judgements.*'
> *(MacFarlane, 2008:34)*

I had no reason to doubt the good and virtuous motivations of reviewers. However, I was unable to reach conclusions about the individual virtues of reviewers and I therefore focus on what I observed and discovered. Nevertheless, it was evident that reviewers acted with care for what they did, thought themselves into situations where empathy was required and demonstrated through their actions the importance in their work of relationships and engagement, both with each other and with researchers.

3.10.4 Ethics of care

For care ethics, a decision is judged ethical if it is made based on care, compassion and a desire to act in ways which benefit an individual or group involved in research. Care ethics contrasts with both consequentialist and principlist approaches which employ rules and principles to make decisions.

An ethics of care approach would mean that researchers would consider the issues in relation to a particular case rather than applying rules (Wiles, 2013). Responsibilities in an ethics of care derive from relationships between people rather than solely from principles. Deliberation therefore would be empathy-based rather than duty or principle based (Collins, 2015).

In the analysis of findings and in Section 7.8 below I refer to Gilligan's ethics of care which stresses relationship and engagement rather than principles and rules. I show how reviewers are inevitably influenced by overarching principles and are immersed in procedure and yet within the confines of REC meetings manage to engage meaningfully with the researchers and employ empathy in thinking through each application.

3.10.5 The place of principles in ethics review

Formal review of ethics draws upon ethical, principles. Principlist approaches in particular those summarised by Beauchamp and Childress (2013) in the classic text 'Principles of Biomedical Ethics'[5], have informed the regulation of research where principles of beneficence, justice, non-maleficence and autonomy are fundamental to procedures governing review. Researcher applications for review are written with these principles in mind and as will be seen they are considered during decision-

---

[5] First published in 1979 and now in its 7th edition.

making in review by reviewers. For Beauchamp and Childress, the four principles represent 'clusters'. Taken together these pivotal principles provide an analytic framework of general norms derived from the common morality. The 'common morality' as understood by Beauchamp and Childress is challenging to define and has been subject to development and change by the authors. Nevertheless, in the most recent edition of their text, the four principles appear theoretically to be derived from the common morality approach. The 'common morality' refers to the idea that there is a shared understanding of how to conduct oneself well, which is universal, that is, common to all rational people. In the 2009 edition of their text, Beauchamp and Childress describe how this is based on the hypothesis that 'all persons *committed to morality* adhere to the standards we are calling the common morality.' (p4) The four principles, drawing on these norms, are universal. Debating the primacy of moral philosophical theories of virtue, obligation or rights has no place in this conceptualisation of principles. An emphasis on any one of these positions limits the scope intended by the principles approach, delineated by Beauchamp and Childress as a framework for thinking through ethical practice in a range of situations. Principlism therefore is 'a theory about how principles link to and guide practice.' 2013:25).

Hammersley (2015) has critiqued the nature and role of principles in ethical regulation arguing that the principles informing frameworks are turned into specific judgements about research in RECs and become 'prescriptions' and 'proscriptions' required of researchers (p444). Beauchamp and Childress acknowledge however that:

> *"Principles require judgement, which in turn depends on character, moral discernment… Often what counts most in the moral life is not consistent adherence to principles and rules but reliable character, moral good sense, and emotional responsiveness.'*
> (Beauchamp and Childress, 1994:462)

In the most recent 7th edition (2013), this has been slightly revised and expanded:

> *'What often matters most in the moral life is not adherence to moral rules, but having a reliable character, a good moral sense, and an appropriate emotional responsiveness. Even specified principles do not convey what occurs when …………physicians and nurses exhibit compassion, patience and responsiveness in their encounters with patients and families.'*
> (p30)

Moral rules and judgements are supported by principles rather than being derived from them.

'Principles, being more abstract than rules, leave considerable room for judgement about individual cases and policies'.
(Beauchamp, 2010:154)

The interpretation of findings in this thesis is concerned with how such judgements are made in the context of research ethics. Hammersley's claim that RECs translate principles into an exercise of control over researchers requires further investigation. The gap in the research is that this has not been 'tested out', in other words, we have little knowledge of how individuals and RECs make judgements and whether these are purely principle-bound.

It is not that I disagree with Hammersley's view that ethical research practice and judgements are derived in a 'quasi-logical way, from rules or principles' (p446) but this review evidences the paucity of discussion about and inquiry into how reviewers are involved in the review process. We need to look at what happens where these rules and principles are enacted and where judgements about research take place to discover how they work in practice. In other words, from a place where the work is done and from the standpoint of actors, in this case, members of ethics committees. The next chapter on methodology describes how this was to be achieved.

3.11 The place of 'trust'

Finally, in this review, the issue of trust has emerged as relevant in two ways. Firstly, as O'Neill describes, much of the development of ethical procedures are tied to societal need to feel they can depend upon trustworthy organisations. The second important issue is that 'trust' may be operating within RECs in important ways. Stark (2012:2013) has highlighted in her study of IRBs, that committee members evaluate the trustworthiness of researchers in seemingly benign and mundane ways. In the case of IRBs, researchers are judged solely on the written application as they only attend 10 per cent of boards. Nevertheless, this is interesting because members of boards still need to develop a sense of whether they can trust the researcher and do this through the application. Board members referred to this in Stark's study as 'housekeeping'. This referred to the ways in which they checked the paperwork for indications of trustworthiness. The personal contact in NHSRECs would seem to have an advantage over this as issues or areas of concern can be clarified directly and I discuss the role of trust in this process in my findings. However, this notion of

'housekeeping' resonated with the ways in which I found reviewers using 'texts' and the use of texts (applications and requirements) forms part of my analysis. I suggest that there is a need for a closer analysis of mundane practices in the REC, both in the activities of the RECs and the particular ways in which they use applications and other 'texts'.

Chapter Four: Methodology

4.1 Introduction

This chapter aims to show how ethnography is the most appropriate methodology to answer questions about how ethics committees go about their work. It also explains how features of institutional ethnography are relevant to analyse texts, in the form of bureaucratic requirements of formal review. Rather than a traditional account of the methodological paradigm, methods and limitations of methods, it provides instead a background to and history of the research. It describes decision-making in relation to theoretical choices. It goes on to describe some of the practical barriers I encountered in access and how I responded to them and how these impacted upon the methods. Silverman (2010) has called this a natural history approach to methodology by which he means an account of the decisions made, the reasons and description of some of the challenges encountered and how these were negotiated. However, it might also be described as analytic autoethnography (Anderson, 2006), by which I mean that throughout the analysis I seek to be present as I develop understandings of the social phenomena I describe.

4.2 Conceptualising methods

> *'Methodology in its narrowest sense is the collection of methods or rules by which a particular piece of research is undertaken. However, it is generally used in a broader sense to mean the whole system of principles, theories and values that underpin a particular approach to research'*
> (Somekh & Lewin, 2011:346/7)

When starting out to think about methods, my supervisor at the time advised me to read research which had been undertaken rather than purely methodology. I think his idea was that this would lead me to think about the kind of approaches which interested me. I had begun to read about ethnography particularly autoethnography when writing about my experiences at a REC. In this second phase of reading, the influences which led me to decide on ethnography were Atkinson (1995) and Coulter (1973). The significance of Atkinson and Coulter was their epistemological position which questioned certainty and objectivity. In Coulter's case, this was about the ascription of insanity and with Atkinson the objectivity of diagnosis and intervention in haematology cases in a clinic. Both had a focus on everyday interactions as a site where knowledge and 'truths' are created, produced and reproduced. As I proceeded

with the study, I realized that what was also important was the acknowledgement of ethical regulation as *institutionalized* with RECs representing the 'institution' and so I came to look specifically at methods in Smith's work (1987, 2001, and 2006).

What unifies this range of distinct authors is an epistemological troubling of dominating discourses of truth, transparency and objectivity in medicine and health and other aspects of social life. In particular, the ideas that decision-making is objective and straightforwardly achievable. I started here with the work of Coulter and Atkinson in relation to diagnosis and the accomplishment of decision-making in work settings. The second fundamental approach was derived from the work of Dorothy Smith particularly the idea that we can only understand institutions by examining them rather than believing what is said about them and linked to this, that part of the analysis of what happens in ethical regulation has to include a consideration of how texts work. Lastly, 'institutional' means not just the institution of local RECs or even the Health Research Authority but research governance more widely and how that is brought into being through the REC system. What this means is that what happens at micro levels can be explicated and then connected to relations of ruling – how what is done is co-ordinated by and connected to some ruling concepts and categories such as 'protection', 'trust', 'vulnerability' of individuals and/or public institutions.

4.3 The theoretical context

The methodology and methods I selected needed to assist me in the broad task of the study which was to draw attention to an institutionalised aspect of social life, more specifically, ethics review as performed in the REC. Review takes place in wider contexts of ethical regulation and governance and involves engagement with fundamental questions about the underlying assumptions and 'facts' about ethics in research. As noted above, I wanted to look at the construction and processes which define how we think about research ethics as well as capacity and consent. The purpose was to both describe and explicate an important functional component of ethical regulation (the NHSREC) and the way in which I accessed relevant data was through the meetings (observations) and key players (interviews).

Clarke and Star (2007) note that sociological theory has multiple 'theory-methods' packages where particular methods are aligned to specific theories. 'The combination of qualitative methods and constructivist theories…. Initiates a critical inquiry into the origins and assumptions of health knowledge and beliefs' (Clarke and Star, 2007:125). They are referring here to health research but the idea of a theory /methods framework as a way of approaching inquiry into 'origins' and 'assumptions' broadly describes what I want to show in this chapter which represents the thinking and development of my ideas about methodological theory and methods. Broadly, by the use of a constructivist paradigm and ethnographic methods, I sought to examine the assumptions and constructions of capacity and consent in research ethics and as this is so tied up in the requirements and procedure of regulation (in the REC) that this inevitably involved an exploration of some of the work/everyday practice of the REC in order to unearth these assumptions. In this case, not the assumptions of health knowledge and beliefs but the knowledge and beliefs about ethics and research.

I start by outlining influential ethnographies which determined the theoretical perspective and from which the methods arose. I consider qualitative research and its use when investigating organizations then go on to explain how ethnographic methods in particular those derived from institutional ethnography (specifically, Dorothy Smith) provided a framework of principles for my approach.

4.4 Influences

4.4.1 Atkinson and ritual

Atkinson's (1995) study of haematologists at work in a clinic, described how through the repetition and enactment of certain rituals, particular knowledge is produced and maintained. This study demonstrated how interactions between practitioners, in this case, consultants and junior doctors, (rather than between doctors and patients) were important in defining knowledge in this particular area of medicine. This seemed to me to be directly relevant to my own experience at the REC. I wanted to explore in more depth, how every day working practice might produce understandings of capacity and consent (and connected concepts of vulnerability and harm) in ethics review. Knowledge and understandings of these are realized, come into being through the processes, rituals and talk within the committee

meeting. I wanted to find out how these ways of understanding are framed and bound by the remit of the committee. An important aspect of this would be how and to what extent the regulatory process governs (or operates as a disciplinary force) in the REC.

Atkinson described how weekly reviews were marked by a ceremonial of occasion; the clinic provided a spectacle with set conventions in place. These conventions turned on a clinical division of labour which reinforced the legitimacy of medical knowledge. The conventions themselves imposed rhetorical formats on the description and reconstruction (in the weekly review) of medical events. This again was highly relevant to the ceremonial of the REC and assisted with a description of the REC, what happened, who spoke and the ritual of the meeting which helped to constrain and lend legitimacy and authority to the meetings' decisions.

4.4.2 Coulter's diagnosis (decision-making) as practical and *ad hoc*

For Atkinson, disease categories and diagnoses are subject to processes of definition and negotiation rooted in social processes. Labels are not determined by naturally occurring categories and phenomena. Similarly, with decisions about treatment the option selected is often dependent upon the available repertoire of options. These may be determined by a whole range of factors. He cites Bloor (1976) who observed that in ENT clinics when clinicians were making decisions for example, on children's tonsillectomies, treatment decisions were not based on considering all the options but on a repertoire of recipes which resolved clinical work into one self-evident course of action. These ideas assisted in my analysis of what happened at the RECs and helped to make sense of some of the practical ways in which decisions were mad and to what extent were decisions made which could be fitted into an available repertoire of options. Coulter's 1973 work is described by the author as a sociological and philosophical approach to insanity and uses accounts of people who have been diagnosed with mental illness to show how these accounts are interpreted in particular ways by psychiatrists to affirm diagnosis. He demonstrates how the diagnosis and ascription of insanity is tied to practical exigencies and insists that ascription of insanity is a moral and cultural activity above everything else. Coulter is interested in how standard psychiatric interviews are situated in the practical need for determining disorder with reference to the

appropriateness of an existing treatment or appropriate ward. Secondly, in considering psychiatry's role in making judgements about behaviour which is viewed as socially or culturally problematic, Coulter provides examples of how lay judgements about bizarre behaviours are made first, usually by families, this is followed by dominant psychiatric practices and methods which focus on differentiating behaviour looking for evidence of signs and symptoms which can then be fitted into diagnosis. Psychiatric interviews, Coulter claims are ad hoc and practical encounters. Claims of objectivity are unfounded.

These writers share an orientation to the 'here and now' to the everyday doing of work. They reveal how those involved need to demonstrate objectivity in the application of their knowledge and skill when in fact what frequently determines clinical decisions and outcomes are contingent upon what the professional is faced with. Decisions are socially produced and often have a moral dimension. They also seem to me to emphasise the importance of organisational cultures and social interactions in decision-making. The ideas were important in that I wanted to examine how objectivity was suggested by/produced by current procedures in the regulation of research ethics. Further, I wanted to explore the extent to which practical considerations and ad hoc events influence review. I wanted to discover how committee members arrived pragmatically at decisions regarding approval of research within the restricted (in time, in form of meeting) context of a REC. Making a judgement in the REC is linked to practical reasoning and the *ad hoc*. As I will explain later in the thesis, decisions are based in review on all sorts of factors which then have to be justified in a practical and efficient way. Methods had to capture the day to day work of the REC as a site in which decisions are made about whether research is ethical or not and I needed the opportunity to observe how decisions were made in the practical undertaking of review.

4.5 'Doing' ethics review - qualitative research of organisations

Organisations and institutions adopt all kinds of ways of achieving their work which are largely unacknowledged. In their reflections on organizational research, Miller et al (2004) suggest that there are key three valid reasons why qualitative research is important for organizations. Research often addresses 'how' and 'why' questions which are important for organizations. There are increasing public demands for

organizations to be transparent in their processes and to assure quality in their work. However, efforts to ensure quality and achieve transparent organizational governance often fail and organizations and public bodies are left unable to answer questions when things go wrong. It is certainly true in the case of the HRA and NRES that there is a strong commitment to quality and transparency in their statements in public texts. However, Miller et al point out that there may often be a gap between official directives and unofficial practices. It may be that organizations can focus on outcomes as tests of their efficiency for example but the processes at local level which lead to these outcomes is not scrutinized. This is not to say that unofficial means unethical. In the context of RECs, the outcome arrived at may be couched in the required language but the debate and process of how the decision was arrived at, the means by which a judgement is made, is beyond the scope of research studies which have scrutinized outcome decisions. The focus has been on the 'end-point' rather than the processes by which outcomes are arrived at for example, Dixon-Woods and Angell (2009).

The second important feature Miller et al (2004) note is that qualitative research allows for 'discovery', factors which were unanticipated or not thought to be relevant. Data can arise through accident and allows a response to unanticipated opportunities because it is flexible and iterative. In addition, data can arise unexpectedly through accident and through discernment in unstructured research. I certainly have found data in unexpected sources and in unexpected ways. Early on in my fieldwork, I attended a conference of the Association of Research Ethics Committees. This is an annual conference, which committee members and administrators attend from NRES RECs, University RECs and local Research and Development RECS. I made notes on the speakers but also found myself making notes on some of the discussions in which I was involved and the audience responses to speakers (some of whom were executive members of NRES including the Director). These revealed tensions within the audience about the status of qualitative research and moral concerns about the ethics of research in developing countries. I have also found that by regularly accessing the NRES website I have gained insights into what the organization sees as its purpose, I have accessed their training materials and have attended one of their training days for new committee members. Miller et al do introduce a note of caution here. Though the unstructured nature of qualitative research can accidently provide data, one must consider rigour

– in my own research I need to justify the inclusion of this data and think through how to ensure rigour in its analysis.

Lastly, Miller et al (2004) highlight how the context stripping of quantitative research, which aims to nullify context and situational effects, is replaced in qualitative research by a concern to place context and complexity at the centre of research. This is important for the potential impact of research. There are implications for the methods employed. Mishler (1986) presented a critique of traditional interview techniques for example. His critique highlighted the fact that interviews are not neutral and that structured interviewing serves to decontextualize people and their responses from their daily lives. My interviews were structured by a framework of initial questions which could keep the interview on track but I allowed the interview to take its own direction as I felt I was in the position of learner in the interview process. Mishler describes this as one type of relationship which enables a sharing of power between researcher and interviewee. I also tried to maintain this stance in observations.

The context in this research is crucial. How participants construct their social worlds is important and this has benefits to organisations because understanding the practical order of how things are done, achieved, outcomes reached and so can link to an organisation's practice dilemmas or problems and provide clues into how change can be brought about. For example, NRES has a concern with consistency in the RECs. Evidence for this can be found in the Minutes of Ethical Adviser meetings (which in the interests of transparency are available on the HRA/NRES website). These Minutes are interesting because the discussion includes the question of what consistency means. Research which looks at how decisions are arrived at in the context of the committee potentially may assist the organisation or at least provide some insights into this concern – does consistency refer to the level of debate, to outcome, to committees following certain practices in the reviewing process, consistency in who does what? The overarching organization is the HRA and NRES who administer and oversee the RECs. However, the REC is a crucial part of how research is reviewed and so RECs do constitute a representation of the 'organisation'.

I have argued that qualitative research on organizations is relevant particularly in its potential to illuminate the workings of organizations and its openness in the process of research to discovery. However, this left me feeling that this methodology did not quite satisfy what I wanted to achieve in the study. Ethnography is about the discovery of social worlds using methods such as observation and interview. Institutional ethnography also gives prominence to the role of texts in co-ordination people's activities. The following sections provide an explanation of how ethnography as a methodology and its methods corresponded to the aims of the research.

4.6 Ethnographic approaches

In orthodox ethnography, cultural and social reality is 'out there' and independent of human thought and values. Classic ethnography seeks to objectively capture and represent this social reality. Interpretive ethnography presents a challenge to this view of reality and describes a theoretical perspective which views cultural and social reality as a textual construction influenced by historical formations and contemporary developments (Denzin, 1997). Interpretive ethnography as a language is a construct used to create and narrate the researcher's self and the researched world. My collection of and descriptions of what I found in the course of the research data are influenced both by my role as a PhD researcher and by my desire to create a coherent narrative about the world I observed. I return to a discussion of this in the discussion of my approach to data collection. However, it is relevant here because it assisted me in connecting to the broader and wider significance of the study. The regulation of research ethics is viewed as created by historical forces (with their foundations in the Nuremberg Code and the Declaration of Helsinki) and its current practices are both produced and maintained by cultural forces which (in contemporary society) are dominated by a preoccupation with risk and procedure. The significance of my research is that starts with the local but has to connect to broader social themes if it is to be of any consequence. Connecting to these cultural forces and identifying how these influence and are influenced by what happens in the day-to-day work of ethical regulation is part of the project. I now want to show how the above influences were distilled into the ethnographic methods which I employed, particularly those of institutional ethnography.

Ethnographic approaches are typically described as shedding light on, uncovering or discovering social worlds, with ethnographers generally using observational methods (as participant or not) in conducting the research (Miller,1997). Traditionally, participation and immersion were seen as integral to ethnography. For Brewer (2000) ethnography is the study of people in naturally occurring settings or 'fields' using methods of data collection which capture their social meanings and ordinary activities. The direct participation in the setting and/or the activity allows the researcher to collect data in a systematic manner. Though it is important to adopt a systematic approach, I am unsure about the link between participation and systematic collection of data. On setting out to research as participant or not, it is always unclear what dilemmas and challenges may occur in the field and which may get in the way of a systematic approach. More appealing to me is Eberle and Meader's account (2011) which describes ethnography as taking into account the furniture, the architecture, spatial arrangements, interactions and documents produced in the field which suggests the possibility of a vivid evocation of the world which is entered with the physical (the furniture and architecture) being an integral part of the whole experience of collecting data. In my observations over the course of this PhD, I have experienced how important the surroundings are, the spatial arrangements of RECs are important. Committees group around a conference table bringing formality to the proceedings, nameplates are displayed in front of committee members which distinguish the hierarchy and category of membership, and the interactions and use of documents are all treated as data in this study.

Ethnographies of RECs are challenging due to the timing of RECs and the frequency of 'capacity' studies' being reviewed. At the start of my study during negotiations, it was agreed that if I concentrated on a small number of RECs that I would attend observations of a larger group of RECs when capacity studies were due to be reviewed. Previous studies of internal decision-making in RECs in the UK have involved attending a small number of RECs for repeated observations (Hedgecoe, 2012) and this is in line with Stark's research on Institutional Review Boards in the United States (2012). These have not had a particular focus on 'capacity' studies though these authors might refer to decision- making about consent. Although there may be a potential difficulty in the sampling strategy I adopted (attending RECs for single observations of a larger number of RECs) in achieving Geertz's 'rich

description', (Geertz,1973) I discuss in the next chapter, that Geertz describes also how in the act of interpreting the researcher has to hold two concepts 'experience-near' and 'experience-distant' simultaneously. I would argue that I was able to maintain these positions. I was aiming for immersion and familiarity with the social world of ethical regulation not in the REC exclusively though of course this was an integral part of the review process.

Ethnographic research derives from early anthropological research where immersion and participation were key to describing and discovering 'cultures'. Iconic ethnographies involved immersion sometimes for many months and participation (in some cases covert) was a crucial way of accessing data (Humphreys 1970, Rosenhan1973). However, there are alternative perspectives about whether ethnographic research has to be characterised by immersion and participation and qualitative researchers do not necessarily take a constricted view. For Delamont (2004), even the terminology is equivocal as ethnography, participant observation and fieldwork are used interchangeably. What characterises these is that they involve spending long periods watching and talking to people with the common purpose of finding out how they view their world. For Hammersley and Atkinson (2007) a strong feature is the emphasis on exploring the nature of social phenomena rather than setting out to test hypotheses. For these authors a sense on getting involved and getting to know the field is crucial but this may not involve participant involvement or immersion.

The research I have undertaken is ethnographic. I have aimed to describe, explore and discover and I attempt to 'map' the work of a particular culture. An important part of the process of locating the study in the most relevant methodological paradigm has been the definition of the field and the extension of the field from the REC to institutionalised ethical regulation with the REC being where review takes place.

4.7 Constructing the field

The 'field' in ethnographic study has traditionally been viewed as a clearly bounded site. It has been viewed as unproblematic which is surprising as the 'field' is an indispensable part of an ethnographic study. Given that textbooks describe access, handling relationships in the field and handling field notes, the problems of

delineating a field are usually absent from textbooks (Nadaia and Maeder, 2005). In sociological ethnography - research objects are derived from theoretical knowledge and questions. The field needs to be constructed by the researcher and is seldom 'out there' in a concrete way. Nadaia and Maeder go on to argue that sociological ethnography has to deal with 'fuzzy fields' by which they mean that social worlds are contexts for certain processes, actions and ideas and these have to be located (in this study, the social world is the REC). This however is the *concrete* location of the study, the location where observable interactions, discussions and so on take place but this location is not the ethnographic field. Nadai and Maeder propose that a theoretical clarification of the object of the study is required. I had to delineate a field which was 'fuzzy'. It was fuzzy because the abstract research object is formal ethics review. A tangible field of ethics review does not therefore exist. However, the REC is a physical site where the review of research takes place – as such, they are crucial components in the achievement of ethical regulation and the way it is accomplished in real time. Therefore, the REC has been a significant and indispensable **site** where I have been able to observe decision-making processes and debate about capacity and other concepts but he wider context of ethical regulation is relevant. Geertz makes a similar point when he says that, 'the locus of study is not the object of study' (Geertz, 1973:22).

I have argued that ethnographic fields are 'social worlds' – for me the social world was in the Research Ethics Committee though it has been necessary in the discussion to contextualise this focus in the wider field of ethical regulation of research. Though REC members themselves are not responsible for ethical regulation, they nevertheless play an important part in the achieving, bringing about the ethical approval of research, and have an important but (I argue) little understood role in shaping and influencing ethical practice. Data derived from observations of RECs, researchers and reviewers as well as the information on the NRES website and the documents used in REC decision-making. These are all components of the wider field of ethical regulation of research. I have so far outlined some ethnographies and theorists which were influential and I will return to some of the key elements in my interpretation of the data. I have described how institutional ethnography is relevant to this study as ethics review is constituted, brought to life, debated and so on in RECs which are legitimised by an overarching organisation –

the HRA. I want to move on now to discuss how my investigation extends beyond organisation into an inquiry which makes connections with institutionalised ethics. I now attempt to show how institutional ethnography illuminated my approach to the research and to my understanding of what I wanted to do.

4.8 Institutional Ethnography - borrowing principles from Dorothy E Smith

'. inquiry begins where people are and proceeds from there to discoveries that are for them, for us, the workings of a social that extends beyond any one of us'
(Smith, 2006: 3)

Dorothy Smith introduced the term 'institutional ethnography' in 1987 with a 'sociology for women' written about experiences of mothers' work at home in relation to the schooling of their children. Smith avoids asserting definite methodological frameworks but views inquiry, discovery and learning as central to the ethnographic project. For Smith, each project varies in method and she does not view institutional ethnography as orthodoxy but what distinguishes institutional ethnography is that it is driven to discovering how things are actually put together and how they work. The ideas of institutional ethnography are based on encounter with the everyday, the ongoing activities which shape people's activities. Importantly though, she offers an exciting epistemological theory about how knowledge from the everyday connects to and is informed by wider social discovery exposing for example, which kinds of knowledge are privileged and which excluded or ignored.

Smith viewed some of the principles employed in her research as having wide application. What Smith did was to show how women were outside the frame of (men's) views of the world in which particular versions of knowledge are passed off as or taken to be universal. Women in her work may not share opinions and views of the world but their standpoint constitutes a critical position in relation to knowledge because it is outside of the main frame.

For Smith, the standpoint of the actors in the situation being investigated is the starting point. The everyday world becomes all-important. The way the actors view their social worlds is all-important. I am not arguing that research ethics committee members or researchers as actors in the social world of ethical regulation occupy the same position as 'other' and outside of dominant social relations in the same ways

as Smith described in relation to women. What I am arguing is that the way to generate new knowledge about this subject is to start with the key players (committee members) involved in the work of 'doing' ethical regulation and with those who have to work at getting their research approved (researchers). Therefore, for me, discovery may be made by starting with the questions of 'what happens' and how does ethical regulation work? The study has sought to answer these questions by the use of observation and interviews as methods.

In the next section (4.9) I highlight ideas about the methods and theory which I view as central to Smith's work to illuminate what I have done in my study.

4.9 Theoretical relevance

Epistemologically, the ethnographic project extends people's ordinary everyday knowledge to the social. For my study, inquiry transcends the local debate and decision-making and connects the day-to-day knowledge making that committee members and researchers are engaged in with wider social dimensions. The challenge of making meaning for me in this study is two-fold:

- Describing what is said, done, acted out at RECs and what researchers and committee members say about their work in interviews.
- Uncovering what is taken for granted and every day and viewing that as significant in creating knowledge about ethical regulation and capacity.

This perspective that inquiry begins and ends with the everyday seems somewhat at odds with what I have argued about delineation of the field where I explained that my focus on the RECs as a site of study extended inevitably to ethical regulation. Though my site is the everyday of decision-making in the REC and interviews with those players involved (committee members and researchers), the study was to some extent theoretically informed by wider concerns with ethical regulation and with concepts of capacity and consent. As I have tried to argue above, the field is always constructed. Smith's approach has illuminated my engagement with the sites and shown how wider societal concerns influence institutions at a local level and that the local level in turn produces and reproduces particular ideas and knowledge, in this case, about ethical research.

I do not think Smith would exclude the place of theory in constructing a field of sociological research or inquiry. She does however emphasise that whatever the field is, inquiry begins where people are engaged in the work or practices under investigation. Smith seems to argue that effective research practices are more important than methodological dogma, it is not that you have to be immersed in the field for a prolonged period but that different types of engagement are required in different contexts. Research strategies may evolve as the researcher engages with the work and these vary. The researcher also inevitably varies in relation to what s/he is responsive to, what s/he attends to. I now turn attention to the particular principles adapted from Smith which influenced my methods

4.9.1 The standpoint of actors - rooting research in the social situation

Smith emphasises the importance of 'standpoint' which means that the research (as well as taking account of one's own standpoint) tries to see things from the standpoint of the people being researched. The approach does not mean that the research is tied to one theoretical explanation but commits the researcher to particular theoretical practices which look at the actualities of everyday life. There is a dedication to pay attention to everyday experience where work happens and there is then a subsequent mapping which shows how work is tied together. A way of describing research in institutional ethnography is to say that to 'understand our lives or the lives of other people we must find the actual determinations of those life conditions and "map them." (Campbell and Gregor, 2008:17).

By observing the REC which is central to regulation, I was able to generate data on the everyday understandings of committee members about what they were doing, how they were achieving decisions, their understandings of capacity, consent and vulnerability. Uncovering the everyday – practical reasoning of individuals.

Later I look in more detail at the REC. I describe the idiosyncrasies of the committees, the deliberations with each other and with the researcher and dissonances between what people say in the committee and what they say to me in interview outside of the REC. I offer explanations of these practices in order to show what influences judgements and decisions.

4.9.2 Problematics

Problematics have a technical meaning in institutional ethnography. They do not refer to the research questions or to assumed problems or difficulties but rather possible sets of questions (or 'puzzles') which may be present at the outset and certainly emerge from the research project as it evolves. So, conceptualising the problematics requires some knowledge of the field of study and they may adapt and change as the study progresses. The mechanics of how I did this and analysed texts (talk, interactions, debate, practices in the REC and in interviews) is described in the data section. My data was created from these texts. Smith demands that in analysis researchers look for the problematic. Establishing the 'problematic' was clear at the outset of this study and was rooted in a concern about research being 'blocked' with people deemed to lack capacity by current regulatory processes and requirements. There was also a problematic in the authority and power of RECs who could veto research. These have remained but the problematics have developed and been modified over the course of the study.

> *'That looking up from where you are, or from the where of some people whose experience of and in the everyday you've learned from and developed as the problematic of your study – it's that looking up and into as a process of investigation, of progressive discovering, and assembling what you've got as a base from which to move to investigating further and more widely that's the key to institutional ethnography'*
> (Smith, 2006:5)

It was certainly true that the problematics in this study evolved as I progressed and interacted with more RECs and spoke to more of the key players involved. Interviews allowed me to test out impressions gained at observations but also to ask in more depth about specific questions of capacity and consent. These in turn influenced the 'problematics' and informed the next observation. The problematics, which emerged from the interpretation of my observations and interviews, were about the activity of the REC, how authoritative decisions were achieved and how RECs' work was connected to and with trust. Again, these are explored later in the thesis.

4.9.3 Analysis of Texts

Smith stresses the importance of texts and their role in organisations. Text in this study means understandings, verbal, written, social practices, discourses of risk, vulnerability and so on. Smith developed ideas about the explicit use of texts as

documents (2006). She explained how incorporating texts into ethnographic work enables the researcher to 'reach beyond the locally observable into the social relations and organisation that permeates and controls the local' (p 66). In this recent work, Smith is referring to words, images or sounds which are observable and writes specifically about how documents and their functions can be incorporated into research. Ethical regulation is saturated with 'texts' which intend to guide or advise everyone involved – the researcher, the committee member, the public, the potential participants. It would have been difficult to avoid the incorporation of these kinds of reproducible texts in this study.

Using the everyday, micro-level activity, to make connections to the social has been important. For me wider social questions about our views about and tolerance of risk, of public trust and transparency in public institutions are linked to my findings. They have both shaped the ways in which ethics in research are currently regulated and they shape and influence or 'frame' the discussions which take place in RECs and the ways in which committee members and researchers talk about research with people in general and in specifically governed ways with those who lack capacity.

The collection of data was with some key problematics already defined, but these developed through my engagement with the field. 'Problematics' for Smith are the important building blocks which shape focus in the field.

4.9.4 Developing the problematics

These emerged from the overall aim of the study. They did not replace the aims but emerged as important as the research progressed. In Smith's explanation; '*it's that looking up and into as a process of investigation, of progressive discovering, and assembling what you've got as a base from which to move to investigating further and more widely that's the key to institutional ethnography.*'(2006: 5).

These evolve and are modified as the research or investigation progresses. These problematics or 'puzzles' complement and enrich the objectives of my research. Conventionally, these questions or arise following the literature review. Certainly, a review of the literature indicated that there was limited knowledge of how NHSRECs work in practice and that further information about this field of activity would be beneficial to the research community and might aid development of committees'

work. However, institutional ethnography acknowledges that questions also emerge or are refined once the researcher is in the field.

Table 3 showing the research question, aims, objectives and problematics is on the following page.

Table 3: The research question, aims, objectives and the emerging problematics or 'puzzles'

Research question: How does ethics review 'work' in the real-life setting of a REC?	

Overall aims:
 	
   1.   To provide an interpretive ethnographic description and 'mapping' of the everyday work of RECs by use of institutional ethnography.
   2.   To illuminate processes in the review of ethics in research.
   3. To promote a reflexive approach in the further development of NHSRECs	

Objectives	Problematics
Primary: 1. To investigate *how* RECs reach opinions in their review of research applications. 2. To explore *how* research applications (including capacity and consent) are operationalized (use of requirements in practice) in meetings; and, 3. To investigate *how* research applications (including capacity and consent) are conceptualized (thought about and discussed) in meetings, by members and by researchers. 4. To describe ethics review in NHSRECs from the perspective of those who live it, experience it and talk about it. 5. To analyse ethics review in order to provide a 'mapping' of processes in the REC. **Secondary Objectives:** 6. To explore *whether* there are differences in the review of qualitative and quantitative research. 7. To investigate the experiences of researchers of attending for ethics review and their conceptions of consent.	How do reviewers make sense of what they are doing and how do researchers make sense of ethical regulation? How much do RECs rely on texts, procedures? How are practices of RECs constituted by and constitutive of dominant ideas/discourses for example, about vulnerability, safeguarding participants, moral obligations to 'good' research? What do members consider to be 'good' research? How does the work of the REC produce/influence/contribute to knowledge and understanding about ethics in research more widely? What are the ways in which consent and capacity are understood in ethics review? What part does trust play?

In the research then I started with the REC in order to look in detail at the work and at how what committees do might link to wider, social dimensions. This connecting to wider social contexts is an important part of interpreting data in institutional ethnography and develops as the research progresses.

I now consider the methods in the study.

4.10 Methods
Common methods employed in ethnographies are observation and interviews.

4.10.1 Observation
Observation as a research method implies that it is something more than the observation we do each day of the world around us. Ethnographic research is characterized by regular and repeated observation of people and situations in order to respond to a theoretical question about the nature or behaviour of a social organization. Gold (1958) distinguished four observation 'stances' or categories of researcher roles, in a typology which included 'complete observer' where the ethnographer is detached from the setting and neither seen nor noticed, with the implication that this provides objectivity, to 'complete participant' where the observer disappears into the setting perhaps to the extent of being covert in the researcher role. Participation to a greater or lesser extent is inevitable. In my observations, I was openly a researcher but not a member of the group as I did not participate, however in order to observe I had to interact with co-ordinators leading up to the meeting and on the day, with Chairs and committee members and with researchers. I chatted to researchers before the meeting, I spoke to Chairs and committee members in breaks and sometimes after the meeting. I did not participate in the discussion or decision-making although this was sometimes difficult. I was not a member of the committee so was careful not to reveal my feelings, and tried to maintain a neutral countenance all the way through (difficult!). I was conscious that committee members were looking at me for reactions and at times I was addressed directly after a discussion and asked what I made of the debate and discussion. I had not quite anticipated all of the qualities I would need.

Angrosino (2008) describes the qualities required by an observer with even minimal interaction. The first of these is language skills especially where the language used

is different to your own. In the sense of technical language, this was certainly true for me and there was a certain amount of 'jargon' which I had to become familiar with. Being explicitly aware of 'mundane details' was important. These are details which in everyday observation, we might filter out but which became important in observing the REC because gestures, seating arrangements, who had a voice, who contributed most and so on all provided me with insights into the social relations within committees. Angrosino also refers to 'good memory' because it is not always possible to record at the time, on the spot. For me this might be replaced with speedwriting because I was unable to record but I also needed to remember details after the meetings, which I was not able to record in the meeting. This especially linked to the approaches made to me and asides which were outside of the formal business. Observational data only comes to life if placed in a narrative so Angrosino claims that writing skills are an essential quality. The second part of the thesis attempts a coherent narrative building up an account of the REC which describes *what* happens through to *how* it happens. In negotiating access and consent to attend each committee meeting, I had to remain 'neutral' or marginal in the eyes of the committee. Hammersley and Atkinson (2007) described how:

> *'Marginality is not an easy position to maintain, however, because it engenders a continual sense of insecurity… many fieldworkers report that they experience some degree of discomfort by virtue of their 'odd', 'strange', or 'marginal' position'.*
> (Hammersley and Atkinson 2007:89).

This discomfort was often very real for me as I was made to feel 'strange' by some committee members. I reassured REC members that I was not there to evaluate in any way and yet my position (usually at the conference table, though sometimes just behind) meant that this was difficult.

4.10.2 Challenges in the observations

Hammersley and Atkinson (2007) described how most researchers in the field experience a degree of discomfort due to their strange or marginal position. It was difficult at times to maintain distance because I had to make some connection (in a comparatively short space of time) at the observation so that I had a good chance of them allowing me to do a follow-up interview. Hammersley and Atkinson also refer to a sense of betrayal (to those who have been observed) which I did not experience at the time but I have felt at times when appearing critical in writing up. Early on in the fieldwork, observations of the work of ethical regulation at meetings revealed

differences but key similarities. As I became more familiar with the ways that reviewers had of understanding, discussing applications, making judgements and reaching decisions, patterns began to emerge which were not articulated but implicit. Identifying these 'common-sense' and everyday ways of doing ethics review involved a great deal of unpacking and analysis. Altheide and Johnson comment that immersion and concrete detail are necessary for researchers to ascertain tacit knowledge which is the "largely unarticulated, contextual understanding that is often manifested in nods, silences, humour, and naughty nuances" (Altheide & Johnson, 1994:492).

Campbell and Gregor (2008) note some distinctions between being an observer when the observer is in a familiar field (such as a social worker or nurse) when practices are very well known, and being an observer when the field is unfamiliar. Collecting data in these circumstances is a challenge, however, because some 'problematics' or questions are carried into the site of observation, the researcher is looking for elements which appear to relate to those problematics. This is how the methods of institutional ethnography assisted me. I went into each field with a frame of questions which guided the data collected. As I went along, I paid increasing attention to 'useful' data, filtering out what was irrelevant. Of course, what this means is that I was not a neutral observer. I have not claimed to be neutral and have been open about subjectivity in the research and thesis. It remained the case however that I needed an element of objective structure in which I could frame my observations and the following chapter on data collection describes some of the ways in which I managed the recording of data. Using observation as a method is challenging and one can end up with a lot of data – Campbell and Gregor comment that it is typically the case that 'very little, but very specific data is needed for an analysis in institutional ethnography' (p77).

4.10.3 Interviews

Literature has usually advised caution in using telephone interviews because of the lack of opportunity to establish rapport and the absence of visual cues and mannerisms which may contribute to the interview. However, there are practical benefits in terms of travel costs and time. The opportunity for interviewing members of committees and researchers on the day was extremely limited. RECs run to a tight

schedule and researchers attend just for their study and then leave. I was always able to make contact with committee members on the day as the lead reviewers were identifiable as were the Chairs. I had chance for a conversation with the researcher(s) as we were often waiting outside of the meeting together. Nobody I approached refused the request to do a telephone interview, in fact some members pursued me to give me their contact details even though I was (initially) confining myself to Chairs and reviewers. In practice, these distinctions (between lead reviewers and committee members became blurred). It would not have been practical for me to travel back to REC locations to conduct interviews as I attended RECs across England, often some distance away.

Irvine et al (2010) used conversation analysis techniques to closely examine differences between face to face and telephone interviews. They noted that telephone interviews may be used for practical reasons (as in my case) or for ethical reasons when the protection of identity of the research participant might be needed. The aim of their study was to look at implications for researchers and considerations which might be helpful for researchers using the telephone mode for qualitative research interviews. They established that there were interactional differences but that these should not lead to rejecting the use of the telephone. Some of the differences they described were that face-to-face interviews were usually of longer duration with the participants talking more. In telephone interviews, the researcher was relatively more dominant and also indicated that a topic area was delicate or sensitive to the interviewee. It was suggested that researchers may need to be prepared to encourage participants to elaborate. Reflecting on my interviewing experiences, it was sometimes difficult to keep interviewees on track because of the lack of visual cues and this may have led to more prompts and 'reminders' of the questions or topics. This may have interrupted the flow.

4.10.4 Experiences of interviewing researchers

These took place over the telephone. At the time of interview, I always reminded researchers of the purpose of my research and reiterated the details on the Participant (Researcher) Information Sheets that I was not involved with the decision-making of the committee. Sometimes the interviews were long because they wanted to talk about the particular challenges of their study and I then had to

work to keep a focus. Researchers varied in how much they wanted to say in relation to my questions about capacity and their experience of attending the REC.

4.10.5 Interviewing Chairs and reviewers
These tended to be longer interviews. To answer my questions about capacity and vulnerability, the context of the study reviewed was often a useful way in to talking about these concepts. This meant a lot of backward and forward discussion of the details of the particular study before we could move on to talk about these concepts in a more general way.

4.10.6 *Ad hoc* interviews
There were discussions over tea, conversations with researchers outside committee rooms, even a long conversation with a Chair on a train journey home. DeVault and McCoy (2006) writing about institutional ethnography show how interviewing might best be called 'talking to people' (p756) because there is a continuum from formal times to interview and serendipitous moments which come about as a result of being involved in the research. This strongly resonated with me as some of the connections made during the observations spun off into agreements to be interviewed. Though these were followed up by email contact to arrange a formal interview). For example, I learnt much about processes from an enthusiastic co-ordinator over tea and then a follow up telephone interview which s/he consented to me conducting. Content of discussions which were outside of formal and consented interviews were not used as data but allowed me to gain valuable insights into the work of reviewing and this was part of the 'immersion' in the field so frequently described as a component of ethnography.

Institutional ethnography aims to get at the everyday competence of people in organisations, how people accomplish their daily work. Because these are so commonplace it was necessary to 'know accurately' (Campbell and Gregor, 2009, p 78) so checking out and asking what seemed obvious questions became important. For example, asking what 'lay' meant seemed at first a strange (or obvious) question to reviewers and co-ordinators, but this question in fact lead to an important point about committee membership and one which when probed, they found problematic to address fully.

I now address governance and ethical approval for the study. I discuss recruitment and sampling. I analyse the ethical considerations in the study using a framework which draws on Gelling's (2016) suggestions of what reviewers want to be reassured of in review.

4.11 Ethics, governance and access approval for the study

The access approval, institutional approval and access arrangements to the field were as follows. This tables show these distinct processes. However, as will be seen later in the findings and analysis, design and ethics are inexorably linked. For example, there needs to be clarity of design before full implications for research subjects can be properly addressed.

Table 4: Ethics approval process

Stages	Narrative
• Scientific review	Scientific review of this study was undertaken by my Lead Supervisor at the start of the PhD and reviewed internally by the Executive Committee of the School of Nursing, Midwifery and Social Work at the University of Salford.
• Institutional approval	Given favourable opinion by the University of Salford's Research Ethics Committee (Reference HSCR11/17) in January 2011. Detailed letters and information sheets requesting consent to interviews. (Appendix 4) In addition, an informed consent form was prepared (Appendix 4) but in fact email consent was sought in practice.

Table 5: Organisational permissions process

Stages	Narrative
• Initial access approval	Following negotiations with NRES, I gained the permission of the Director of NRES to carry out the research. Discussions were with Deputy Head of Operations and a member of Ethics Advisory Committee. Design outline agreed.
• Ongoing correspondence with NRES	Approval of wording on Information Sheets and letters. Close attention given to full information, consent, opt-out for each potential participant. (Appendix 4)
• Detailed discussion of administrative support for the study prior to commencing.	Administrative support details worked out with (national) co-ordinator (who was based locally) who notified REC co-ordinators of the study at co-ordinator training days in order for them to be made aware of the study. Further minor modifications to letters. and information sheets in order for co-ordinators to facilitate sending out of information sheets and letters dealing with consent.
• Ongoing oversight	I kept co-ordinator informed of stages of research. Original consultants have been informed that study is complete.

4.12 Design of the study
The process was agreed as detailed below.

4.12.1 Recruitment and arrangements for consent for each participant
Co-ordinator based centrally alerted me of potential study applications and dates of REC.

If there was potential for me to attend, local co-ordinators sent out letters to Chair, committee members and researchers attending.

This ensured confidentiality as any potential recruit to the study can communicate their wishes to be involved/not involved to the co-ordinator.

Co-ordinators alerted me regarding consent/not consenting to my attendance

I was informed by NRES of RECs where 'capacity' studies were due to be heard. The period of notice I received about these varied. I then contacted regional co-ordinators and sent out letters and information sheets.

Observations were arranged, dependent upon:

(i) How much notice I was given.

(ii) Speed of consent decisions being communicated to me.

(iii) Practicalities of arranging travel.

The drawbacks of this were that I sometimes missed the opportunity for hearing potential studies of interest and there was no systematic access to committees. The sole selection criterion was that RECs were 'flagged' for capacity studies. On the other hand, I did not select the committee meetings directly and was therefore unable to directly influence the sample of RECs. Furthermore, I did not include/exclude particular types of study and I consequently heard an eclectic range of study applications in both subject and research approach.

Researcher interviews were again, not selected but dependent on the meetings I attended and the decision to consent to interview. It is also reasonable to assume that some researchers did not respond due to time restraints.

4.12.2 Sampling method
Morse (2001) emphasises the importance of critically examining sample size and ensuring a fit with disciplinary purpose. The sample was purposive in that recruits to the study were relevant and involved in review as either reviewers or researchers. This is what Nolas (2011) refers to as being relevant to the phenomenon under investigation. However, the sample is also 'convenient;' in that participants recruited were accessible and available (Morse, 2007) and included those RECs it was possible for me to travel to (RECs were not all local and some at considerable distance). The sampling became more purposeful as I progressed through the research in that I wanted to 'check out' emerging themes with a cross section of reviewers about different types of studies. The purpose of research needs to be congruent with sample size. In this study, which is about rich description and detail, illuminating the intricacies of forming opinions in ethics review, a bigger sample would have risked losing the nuanced understanding and the analysis undertaken

would be potentially superficial. However, it is important to acknowledge that in a small study such as this, which has been designed to access depth, some aspects of review may only have come to light if a greater number of participants and RECs had been included. The design was agreed as follows.

4.12.3 Design
Stage 1: Observations

- Participants: Panel members (reviewers) and research applicants. Access to the REC meetings is in order to see the panel in action. This is expected to provide recorded observation of how the panel carries out its functions, interactions between panel members, interactions with the researcher, how roles are negotiated, who speaks at the meeting, who speaks to the researcher, how decisions are arrived at, and if there are disagreements among panel members how these are resolved.

- The committees are those which NRES have designated as Mental Capacity Act 'flagged' RECs. The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred. In these 'flagged' RECs, panel members have undergone additional training in order to deal with issues of capacity, specifically approval for studies which fall under requirements in Section 30 of the Mental Capacity Act 2005.

- Flagged RECs consider a number of applications from researchers when they sit. Not all of the applications considered will be have capacity issues. Committees typically hear a range of applications in one sitting.

- Study to include England and Wales only.

- Letters sent via NRES to Chairs of all flagged RECs stating that I will be observing committee panel meetings for research purposes and that I may wish to follow up observation with interviews of either Chair or reviewers for particular projects. Letters to include confidentiality statements, clear opt-out options, purpose of observation.

- NRES will alert me when committees which are to consider projects with issues of capacity, usually with approximately two-week notice. At this point letters sent to research applicants (via NRES with appointment letter) stating that I will be observing panel and that I may contact again if I wish to follow up

with interview. Again, letters to include confidentiality statements, clear opt-out options, purpose of observation.

Stage 2: Interviews

- Participants are Chairs and/or reviewers and researchers.
- It is likely that some of the applications will highlight interesting issues relating to capacity and consent. In this case, I will interview members of the committee and the Researcher.
- Detailed information sheets to be provided at interview stage for Reviewers/ Chairs and researchers if to be followed up with interviews. These are likely to be projects which have been considered for approval by RECs and which specifically fall under S30 MCA.
- Information sheets at this level to be more detailed and to address purpose of research issues of confidentiality, anonymity, reporting of serious breaches of ethical approval, opt-out etc. Also included is that some reference may be made to the study which is undergoing review in order to make sense of discussions.
- The study then is observational and interview based.

4.12.4 Data collection, coding and analysis
This is dealt with in depth in Chapter 5.

4.13 Analysis of ethics in the study
This section deals with the ethical considerations relevant to the study. Many professional bodies and disciplines have produced codes and statements which enable researchers to think through ethical challenges (Wiles, 2013). In respect of my own profession as a social worker, the broad standards for conduct, performance and ethics are outlined by the Health and Care Professions Council. These are relevant to acting as a professional in research but they say little directly about research practice. As this research is sociological, reference is made to the Statement on Ethical Practice of the British Sociological Association (BSA, 2002) which is concerned with research practice. This statement acknowledges that it does not:

> *'...provide a set of recipes for resolving ethical choices and dilemmas, but recognizes that it will be necessary to make such choices on the basis of principles and values, and the (often conflicting) interests of those involved.'*
>
> *(BSA, 2002: p1)*

The emphasis on ethical *practice* in the BSA statement corresponds closely to the approach taken throughout with my supervisors. Applying for review and seeking ethical approval was one element of acting ethically in the project as a whole and any ongoing conflicts and dilemmas were discussed fully as the research progressed and during its writing up. Generally, codes of professional associations such as the BSA demonstrate a shift in emphasis from the high principles of the Nuremberg Code and the Declaration of Helsinki to a more pragmatic approach which regulates and guides the professional ethical conduct of researchers (Ransome, 2013).

The formal review of ethics is concerned with ensuring that people are protected in research and RECs have been described recently as follows:

> *'Research ethics committees have an important role in balancing the risks and benefits of proposed research projects, and it can be helpful for researchers to understand the main issues that research ethics committees will consider during their deliberations. Research ethics committees will focus on: the potential risks to research participants; the potential risks to researchers; the requirement for freely given informed consent; and the potential of the study to generate findings of value.'*
> *(Gelling, 2016: 43)*

Taking each of these considerations in turn (risks to participants; risks to researchers; freely given informed consent; potential to generate findings of value) I use these as a framework and reflect upon how these were addressed in the study. I link the statements to overarching principles.

4.13.1 'potential risks to research participants' - balancing risks and benefits

Risks to participants are generally weighed up in the balance by reference to principles of beneficence and non-maleficence. Beauchamp and Childress (2013) in their discussion of biomedical ethics, define several types of risk to include, 'physical, psychological, financial and legal' and, as 'possible future harm, where harm is defined as a setback to interests, particularly in life, health and welfare.'(p230). Reviewing the ethics of research includes weighing up the potential of risk by balancing up harms and benefits. Benefit is a probabilistic term so that 'probable

benefit' is the proper contrast to risk. Thus, argue Beauchamp and Childress, we can best,

> *'...conceive risk-benefit relations in terms of a ratio between the probability and magnitude of an anticipated benefit and the probability and magnitude of an anticipated harm'*
>
> (2013:230)

In other words, both risks and benefits have to be assessed as 'probabilities' as certainty in both is unknown. Transposing this understanding to research ethics and this study in particular, probable harms here were that committee members may have felt unable to exercise autonomy. Researchers may not intend to be coercive but in fact contexts of work can mean that people feel unable to refuse to take part in research if it is seen by the organisation as important. I was aware that members of committees and researchers may view my research as evaluative and be uncertain of my value position. After all, I had approval to undertake the study from the Head of NRES operations and the Director of NRES and I was asked to include this information in the information sheets explicitly. While important to demonstrate permissions, it could have appeared to some committee members that I represented NRES in some way. Even if not direct coercion, it needs to be acknowledged that this could have been perceived as influence to participate. It is also possible that this factor may have put some committees off participating in the study.

NRES did not see any major ethical concerns with the study. They grasped the purpose and were facilitative. It could be argued that they might have adopted a more protective stance towards the committees and their members. There was a risk that participants felt pressured to take part in the study and (given the concerns referred to above) experienced a level of restrictiveness in exercising autonomy when reaching a decisions about whether to participate. In a parallel situation when undertaking research with social work and other practitioners, I caution dissertation students to consider issues of coercion and pressure from employers in their research projects. In other words, practitioner research which is often seen as straightforward and less ethically complex than research with service-users and patients, does in fact require as much consideration of potential 'risks' as with any other vulnerable group.

Researchers have a responsibility to research participants and though researchers are committed to the advancement of knowledge, this does not override the rights of participants (British Sociological Association, Statement of Ethical Practice, 2002). In this study, potential risks were that committee members might feel scrutinised or that their work was being evaluated. For researchers, interviewed following the observations, they may have felt vulnerable in relation to their understanding of ethical issues or their performance. Even though my interaction with participants was brief there was a personal connection with participants and I felt a responsibility to them.

In relation to probable benefits, it was difficult to claim that the research would directly benefit committee members and researchers who participated. One cannot set out in qualitative research knowing what (if any) insights will be gained or knowing for certain that there will be no harm (Johnson, 2004). However, there are obligations on the part of researchers to participants and these may mitigate against the potentially disturbing effects of research. Research relationships should be characterised, whenever possible, by trust and integrity (BSA, 2004) and there are definite obligations to feedback findings to those who participate which I intend to do in ways which are most meaningful to participants. In this way, potential benefits can be maximised by sharing the findings. Some commentators point out that participation in research can bring about unexpected benefits. Participants may welcome the opportunity to air their views and feel that they and their interests may be better understood or more accurately represented (Iphofen, 2009). In this research, participants were not only willing to participate; they were interested and engaged, keen to elaborate on their perspective and views during interviews.

As will be seen, later in the thesis, my findings revealed that committee members consistently saw researchers as being vulnerable. Homan (1991) highlighted how participation can be a strain for those conducting the research as well as subjects (participants) and can be 'lonely, arduous, inescapable and dangerous' (p166). Investigating RECs was not dangerous but was certainly lonely and arduous at times given the travelling and management of a complex study. Attending committees felt comfortable to me as I was familiar with formal settings from my social work practice (giving evidence at Magistrates' Courts and Mental Health Review Tribunals) and

from my work as an academic through attending formal meetings including as a member of a research ethics committee. Homan (1991) highlights that a considerable source of strain may come from the participants who may feel resentment or wish to discredit findings from the research. Some of the description on experience in the field and power illustrates this, though overwhelmingly, my experiences were positive.

4.13.2 'freely given, informed consent'

This of course relates to the principle of autonomy. In a philosophical sense notions of consent are integral to autonomy and a core element of the social contract of the European enlightenment (Kittay, 2007) and integral to this is treating people with respect and dignity. Once consent is gained, it must be managed and negotiated throughout the research and considered at each stage. As the literature review in this thesis discusses in depth, consent is not a straightforward matter for reviewers or researchers. The challenge for me as the researcher was that as well as legal and regulatory compliance, there was a need to balance a range of (potentially) competing interests which Wiles (2013) summarises as follows: the best interests of the research participants, the aims of the research and the interests of formal or informal gatekeepers (p25). I would argue that there is a significant challenge for researchers in having to both operationalise (conform to regulations) and be reflexive about consent in ongoing ethical research practice. This section on ethics attempts to show how regulation governing research was adhered to but also demonstrates an honest and reflexive account of some of the potential (or inherent) dilemmas which existed.

I raised the issue of seeking consent with the University Ethics Committee. They accepted that individual consent forms would be difficult to gain at the observations. However, it was anticipated that interviewees would sign either a consent form or the Participant Information Sheet which requested a signature on meeting for interview. In the course of the research, these were not completed as I did not conduct face-to-face interviews. I acknowledge however that it is important to have a record of consent. Informed consent was achieved through the provision of information sheets and verbal agreement on the day of the observation and via email.

Informed consent necessarily requires that information is provided and that there is a process for gaining consent. I could not achieve a signed consent form on the day of the observation as researchers would usually leave immediately and committee members were dealing with the business of review. I was often able to discuss the possibilities for an interview over coffee breaks and members would pass on their details for follow-up contact or they would give the co-ordinator permission to provide me with personal contact details.

People who did not consent to participate in the research opted out by not responding to my requests over email. Consent was taken therefore via electronic means (emails).

4.13.3 The process of 'informing' participants and gaining consent
Prior to observations

Letters and information sheets were sent out with paperwork to committee members and to researchers with letter of invitation to the committee. Each individual potential participant was notified of my study via local co-ordinators and was able to respond if they did not consent to my attendance or to interviews. They were fully informed about the study and voluntary consent to participation was detailed in letters and information sheets at both stages of the research – observation and interviews. Prior to observations:

- Letter to Chairs
- Letter to individual committee members
- Letter to researchers

Although I was advised to address a separate letter to Chairs of committees by NRES administrators, it must be stressed that individual letters to all members of each committee were also sent out**.** This was to ensure that Chairs did not make a decision about participation on behalf of members (in English Law, it is not permissible to consent on behalf of another person). Rather, this was intended to enable the Chair and members to discuss their views about whether they should consent to participate prior to that decision being communicated to me.

Key content of letters and information sheets endeavoured to give as much information as possible to the potential participants in order that they may be fully informed in order to make a decision. As noted earlier in the thesis,

> *'This process (of consent) is much more than provision of an information sheet and a signature on a consent form and a recent review of evidence indicated (not surprisingly) that talking one–to–one was the most effective way to provide information that was understood.'*

(HRA, 2013)

I feel that there was time for one-to -one questions about the purpose of the study so that participants were informed in order to make a decision whether to consent to take part or not. (This happened on the day or prior to each telephone interview). There were possibly fewer opportunities for individual questions at observations because meetings were so pressured and though all committee members had received information sheets, it is possible that they arrived on the day of the meeting not having read about the study. If invited, I spoke at the start of the meetings and explained the purpose of the study and answered questions.

Consent prior to interviews

Following observations, information sheets were provided to people who had agreed to be observed (usually via co-ordinators) including committee members and researchers requesting consent for an interview. It was not assumed that because participants had agreed to an observation that they would consent to an interview. In addition, further information about the interviews and what they were likely to include was important in ensuring participants were fully informed. The information sheets for interviews asked for a signature for consent purposes on meeting as at that point it was envisaged that I could conduct face-to-face interviews. In the event interviews were conducted by telephone and consent received via email. At this stage, there were:

- Information sheets to Chairs and committee members
- Information sheets to researchers

All letters to participants and Participant Information Sheets (and the prepared Informed Consent form) are provided in Appendix 4.

In this study, as well as letters, consent to interviews was checked out directly with every single participant. Examples of consent emails are included as in Appendix 5. In addition, the design of the study and the support from NRES meant that every individual member of the committees observed was informed about the study ahead of the meetings which meant that if any single member did not want to participate then the observation would not take place. Iphofen (2009) raises a dilemma for qualitative researchers in 'fully informing' prospective participants in that when gathering qualitative data, the participant may not fully know what they are consenting to because the researcher may not be clear. The research may move in unanticipated ways and explore unexpected areas. In this way, the commitment may be to 'fully inform' at the outset of the research (as required by an ethics committee) with any significant changes to the study being communicated to those concerned.

Although I highlight below some of the ethical concerns connected to the involvement of NRES, there were undoubtedly advantages to their administrative support. Firstly, I could not have contacted every individual in the way that co-ordinators did by sending out relevant forms and secondly, I feel it may have lessened any obligation individuals felt to take part. There were certainly committees and researchers who did not consent to observation. I was informed by the co-ordinators of this. Sometimes reassurances were needed but on other occasions I was not informed of the reason or I simply did not receive a response. In any case, there was no need to communicate directly with me as the researcher and this may have been an advantage. If any committee, individual member or researcher did not want to be involved, they did not have any need to correspond directly with me. Similarly, individual consent to interview was entirely voluntary and people who did not want to be interviewed either told the co-ordinator or did not respond to the requests made.

4.13.4 'potential of the study to generate findings of value '
My interpretation of this statement places its significance in context of the principle of justice. Accounts of the principle of justice in biomedical ethics and health more generally, usually interpret justice as fair, equitable and appropriate treatment in the light of what is due or owed to persons (Beauchamp and Childress, 2013: 250). Each of the above statements from Gelling's quote relate to justice in its widest sense.

However, justice in research also includes the right of citizens to take part in research and therefore there is a corresponding need for justification of the research. This is because any burden or potential risk to participants must be weighed up in the balance with the scientific value, design and purpose of the research.

In this thesis, I have made clear the origins of the study, the objectives of the study and the reasons for the methodology explaining also how methods selected were aligned to the overall question. The purpose of the research has been explained and I have avoided making ambitious claims for the potential of findings to influence development and practice in ethics review. Rather, I am modest in my claims. This is because although the question is highly relevant to our understanding of review and the meaning of ethical research, one does not set out in qualitative research being certain of what will be found. The intention is for the findings to illuminate, influence and inform. Much depends on the quality of interpretation and skill of a researcher. This realistic approach demonstrates integrity and emphasises potential rather than making grand claims of research which may not be achievable, as findings are unknowable, when starting out to research. The study claims therefore to have potential to increase knowledge and understanding in this area.

Finally, in this section, I draw out any relevant ethical issues in the relationship with NRES.

4.14 Relationship with NRES

On balance, NRES were committed to facilitating the research in their commitment to transparency and development. My responsibilities here were to be open about the methods and aims of the research. Even though NRES might use different terminology at times there were some clear guiding principles which were adhered to. These come from the British Sociological Association (BSA) Statement of Ethical Practice, 2004 which provides helpful guidance to their members on working with sponsors and funders. Though NRES neither sponsored nor funded, this guidance in my view is relevant when working with any organization that is hosting or supporting research. The statement has resonance for me because of the nature of my inquiry which is sociological in nature.

The first point relates to pre-empting outcomes and negotiations about research. Researchers should not accept conditions that are contingent on particular outcomes or findings. Particular methods should not be required. NRES did not make these

demands. They did not determine the methodology. They were solely involved in thinking through the practical issues of how the methods could be implemented. The second point concerns relationships and responsibilities. Research should be undertaken with a view to providing information or explanation and not constrained to reaching particular conclusions or prescribing particular courses of action. This was not a condition of my research and neither was it a commitment which I made to NRES. The research was seen in the wider context of a commitment to development.

The BSA statement also refers to social inquiry being undertaken professionally. Professional and ethical practice was assured by adhering to what had been agreed by NRES. Sound ethical conduct was assured by the circulation of information to each committee, individual members and researchers in attendance by NRES prior to the meetings. I also spoke in person to each REC about the purpose of the research when invited to do so. Consent was sought on the day of the meeting in person with researchers in addition to them receiving the information sheet and letters. NRES did not act as a gatekeeper but supported the administrative process of sending relevant forms. The responsibility for negotiating with individuals about consent, providing full information about the study, answering detailed questions from the members or researchers and generally conducting the research rested with me. The BSA statement highlights an important matter here about devolved responsibilities.

> '*Where sponsors and funders also act directly or indirectly as gatekeepers and control access to participants, researchers should not devolve their responsibility to protect the participants´ interests onto the gatekeeper.*'
>
> (BSA, 2004: Point 56)

In other words, the responsibility for protecting interests is with the researcher and her/his ethical practice.

4.15 Ethics and power

Handbooks for qualitative research and social science research generally highlight the importance of ethics in research with people. The ethical conduct of the researcher is often discussed in the context of power. With the researcher being viewed as powerful and the participant or subject as powerless. I see a fundamental problem with this. Taking a comparatively recent text Somekh and Lewin's 'Theory and Methods in Social Research' (2011) as an example, they describe how knowledge confers power and so researchers have to be mindful of the impact of research on participants. I am not sure who has the knowledge - who is meant to have it? There is an assumption that the researcher has knowledge and researched does not. They go on to discuss how there may be different distributions of power in different kinds of relationship and that this is reflected in the terms used - participant, co-researcher, and informant and so on. They conclude by acknowledging that power differentials are not in the control of the researcher.

There is an assumption here about power - notably, that it is inevitably with the researcher who possesses knowledge. This suggests that power is finite, limited, and dichotomous (power/powerless binary) - you either have it or you do not. Have spent time in my teaching creating ways to encourage social workers to challenge this notion of power - similarities in social work practice, persuading students and social workers that power is exercised rather than possessed and drawing on Foucauldian ideas about power and their application to social work to show the limits in social work practice of dichotomous thinking about power (perpetrator/victim or social worker/ client for example), without denying that there are some situations where practitioners do have knowledge and power in their professional life. Juritzen et al (2011) also talk about the assumed asymmetrical relationship of power in the researcher/researched dyad in their Foucauldian analysis of research ethics committees. Much has also been written about the 'real world' of ethics in research which is in the course of the research negotiated, dynamic and situated.

4.15.1 'Power being exercised in the field' – an example
As an example of how power operated in this study, I offer an example from my research practice which happened early on.

> I arrive after long journey. Co-ordinator very welcoming, introduced me to committee. Having their tea break. Chair makes a big fuss and starts asking why I'm there. They are not informed of anything by central office about these observers coming all the time. Co-ordinator says that she had sent him all relevant letters and information sheets (which I had asked to be sent). Chair and other committee members had clearly not read any of them. One of members says she is concerned about confidentiality and what I'm going to do with information. I explain I'm not there to evaluate, explain purpose of research and say that as it states on my letter, I will withdraw if there are any members who do not wish me to sit in - even at this point. She then says she needs to discuss this privately and can I leave the room.
>
> **Extract: Field notes made immediately following observation Rec A**

Their grievance was with 'central office' and probably nothing to do with me attending but they could, have justifiably not consented to the observation. They did discuss as a committee and decided to let me stay. My intention here is not to suggest that they did not have the right to ask questions but to illustrate:

- The need to negotiate consent each time I attended a committee
- The unexpectedness of what can happen in the field and the need to respond flexibly
- That design can be meticulously planned (all members of committee and researchers would receive letters, information sheets, consent forms prior to me attending) but that this may not happen in practice of the research
- That research does not happen in a vacuum and contexts are influenced by personal and organisational politics which the researcher has no control over

I use this as an example of how as a researcher, I did not feel very powerful at times. I had entered a field of which I knew little - either about the particular dynamics of each committee or the wider institutional politics. RECs are powerful component parts of (institutionalised) ethical regulation. They cannot all act in the same way as they are made up of a group of individuals and reflect the geography and history of where they take place. I had to negotiate access differently with each REC. As the research participants in this study, I experienced them as committees and individuals able to exercise agency in decision-making about consent. I always reiterated that any individual committee member had the right to say that they did not wish to participate and that I would leave.

4.16 Research in practice

4.16.1 Negotiating access with the organisation

I met with the Deputy Head of Operations of NRES and an ethical advisor in September 2011. I outlined the proposed study to them in detail (I had already had some correspondence). This was summarized by them as a study broadly looking at the operationalisation and conceptualization of capacity and consent in the context of how RECs go about their work. My aim in negotiating and agreeing a design was that I wanted to keep the design compact so that the process of knowledge production could be confined to a 'framework' of potential sites. Within those sites, through observations and interviews, the everyday practice, work and procedures could be observed and recorded, in order to discover practices (details of the work) which might not otherwise surface. I also wanted to explain that the record of observation might be about what takes place as well as what is said.

My notes from the meeting reveal that detailed discussion took place about confidentiality, advance consent of participants, anonymity and the stages of the research pre-observation and post-observation. I was encouraged to undertake the research, they were open about how findings might lead to improvements and that the aims of the study corresponded both to the NRES commitment to transparency, quality and improvement I have also noted that the Ethical Advisor thought there may not be sufficient data if the focus was only on RECs suggesting I also interview researcher 'applicants' to committees.

Following the meeting, there was email communication between myself, the Deputy Head of Operations and an Ethical Adviser who sat on NRES's Ethics Advisory Committee. Subsequently, permission was given by the Director of NRES. (Some examples of the communication are in Appendix 2). The last email prohibiting the use of recording was a disappointment and meant I had to think carefully about an alternative way of recording.

4.16.2 Conducting the research in practice

Negotiating access through formal channels (NRES) was one thing but in fact I had to negotiate access with each committee and as I have illustrated above this sometimes presented challenges. The design of the study has been pragmatic in that I wanted a 'window in' to the RECs and therefore access to the RECs and the design of the study had to be negotiated with NRES. Committee meetings are

usually hidden, taking place behind closed doors and the discussions leading to decision-making are private. This is not to suggest that committee meetings are secretive as decision outcomes (and appeal processes) are transparent in HRA approval systems, but *how* the decisions are arrived at is not often the focus of research attention. Review processes may be transparent, that is, not secretive. However, there are limitations in notions of transparency in public institutions. Onora O'Neill's philosophical commentary on transparency describes a 'revolution' in the demand for transparency and accountability in public institutions. She warns that increasing transparency does not inevitably lead to greater accountability (O'Neill, 2002). Transparency then should mean that we can assess information made transparent not have access to information. The HRA (and previously NRES) have been influenced by this drive to greater transparency but I would argue that the mass of information available on their website does not necessarily mean that they (in common with other public institutions) are accountable. For O'Neill, the provision of information in itself has to be in the context of meaningful explanation, otherwise it remains simply, the provision of information. Notwithstanding this, the HRA has made considerable efforts to make the information provided as accessible as possible to the research community and provides personal assistance via co-ordinators if needed, to aid understanding of the processes for application and review.

4.16.3 Modifying design

Although I had met with the Deputy Head of Operations for NRES and an Ethical Adviser, I also met with the national administrator responsible for the work of co-ordinators of RECs across England. She gave me invaluable advice and alerted all the co-ordinators across England and Wales of my study. She notified me every month of all the RECs in England and Wales where 'Adult Capacity' studies were scheduled for review.

 She was able to tell me some of the 'custom and practice', the contexts which surrounded the running of the RECs and the realities of 'on-the ground' access. There was a gap between her pragmatic approach based in the realities of the day to day and the advice from the Deputy Head of Operations and Ethics Advisor I had met with initially. The co-ordinators' support of the project was invaluable and I would

have been unable to conduct the study without them. It would for example have been impossible for me to send out letters and information sheets directly to individual participants due to confidentiality.

One key piece of advice she gave me was to amend wording of the letters I had prepared for Chairs so that I was 'requesting permission' to attend the REC. She suggested that this was politically advisable as simply stating that I had permission of NRES may upset some Chairs who had local control of their RECS. It became apparent that Chairs in the different localities varied in both their approach to observers and in the level of influence exerted over the committees. I had been assured that RECs were used to observers for a range of purposes, for example, training purposes, quality assurance, new recruits to committees and so on. This highlighted the need for me to clearly distinguish my research from 'evaluation' which I did at each observation and at the beginning of each interview. It is also important to state that consent was not sought from the Chair on behalf of the committee members. Each member received letters. However, the advice I received was to 'request permission' and this was a courtesy. I felt that this was important in that having permission from NRES to conduct the research was not to be confused with a presumption that committees would consent to the research. Letters being sent out provided the opportunity for discussion between Chairs and committee members in reaching a view about whether to participate. A measure of the effectiveness of consent seeking in the study might be indicated by the fact that not all of the committees approached, consented to participation. On the day of meetings, Chairs always introduced me to researchers and verbally asked permission of them for me to remain for discussions.

At the time of writing, any study in which the applicant has ticked the box asking about involvement of participants who lack capacity, will automatically be allocated centrally to a flagged committee. These are the studies I 'heard' and observed. Other studies may well have issues and pose questions relating to capacity (for example, what if person loses capacity during the course of the research? How will capacity be assessed and consent taken?). The studies I was concerned with then were listed as 'lack of capacity' studies. I also heard other studies which discussed capacity and consent issues in detail.

4.17 Conclusion

In this chapter, I have described an iterative and heuristic approach to methodology. I have shown how the desire to inquire and discover particular questions led particular decisions being made about methodologies and methods. I hope that I have shown a line of development from thinking about investigating organisations to ethnography through to institutional ethnography. These have all had a part to play in shaping the design, data collection and interpretation. I have also described some of exigencies which impacted on design, which is always imperfect because we cannot control access to the field. I have illustrated the ethical concerns inherent in the study. I have given an account of how I delineated the 'field' and attempted to draw some parameters around the object of inquiry. The focus throughout is on 'how' questions in the everyday practice of ethical regulation. In a sense it is about the 'concrete' part of ethical regulation, looking at the practical work of reviewing the ethics of research. There is no sense in which the study sets out to uncover truth or make judgements about what REC reviewers do or decide. How they make judgements and how they make decisions is the more relevant concern in the study. The uncovering of the everyday is the ethnographic focus of the study and the interpretive task is to illuminate processes and show how these extend and have wider significance.

In the next chapter, I describe the data I went on to collect, my approach to the analysis and interpretation of that data, drawing on the methodological approaches described here. It follows a more orthodox route with a detailed description of the data. It also identifies the broad methodological paradigm (interpretive ethnography) within which the research is located and which guides the analysis.

Chapter 5: Data and approach to analysis

5.1 Introduction

The aim of this chapter is to describe the data collected and to then describe how I approached the management and preliminary analysis of that data. Keeping in mind the reflexive approach adopted in the thesis (and study), I describe some of the experiences in the field. I then give an account of how I organised the data. The chapter reveals some of the tensions I experienced at this stage of the research. I wanted to maintain transparency and credibility in the process of coding and analysis and initially saw this as separate activity to the rest of the project. However, analysis is interwoven with other aspects of the research process and is therefore not always a distinct phase (Bryman and Burgess, 1994:218). Handling the data and coding was important as a means of surveying what I had collected and the process (including use of NVivo) identified preliminary categories and helped to deepen my understanding of what was happening in the RECs once I had amassed significant quantity of material. Nevertheless, I was analysing and trying to make sense of data from the first observation. The conceptual framework I held in mind was a constant focus on the *how* of ethical regulation and the *doing* of the work in line with the aims of institutional ethnography. Lastly, in this chapter I locate the study in a broad interpretive ethnographic paradigm which starts from the premise that interpreting cultures is not a search for truth but a search for meaning (Geertz, 1973).

5.2 The collection of data

The NRES coordinator at Manchester, which is where the central NRES offices were located, sent me details of any flagged RECs who were reviewing 'capacity' studies each month. Some months none were forwarded to me, on other occasions there might be two or three listed. RECs were therefore randomly selected at that point, rather than systematically randomized. Scotland and Wales have slightly different requirements to England so I only went to RECs in England. The selection was determined by whether there were certain types of studies (capacity) being reviewed at certain types of REC (those that were flagged). I was also constrained by other commitments. I attended the RECs which were on dates when I was not committed to teaching. Distance travelled was also a factor because I had to be able to make the trip in a day. Sometimes coordinators, who all had their jobs to get on with, did

not confirm arrangements in time or had not heard back from Chairs or researchers. Co-ordinators varied in the authority and influence they had. Sometimes coordinators made the decision about whether I could attend or not. Co-ordinators deferred to the Chairs in most cases.

I did the majority of observations over the period of 18 months. I did two following preliminary analysis of the data. I visited RECs once except in two cases because there were a group of capacity cases to be reviewed at the same meeting. There were nine observations in all.

Table 6: Methods and type of data generated

Method Observation	Method Interviews committee members	Method Interviews Researchers
Observation 1 REC A	2	1
Observation 2 *REC B*	2	1
Observation 3 *REC C*	0	Informal only
Observation 4 *REC D*	2	1
Observation 5 *REC E*	2	2
Observation 6 REC *F*	2	1
Observation 7 REC *F (2)*		Informal only
Completed within 12-month period		
Observation 8 *REC G*	1	Informal only
Observation 9 *REC B (2)*	1	2
Completed after preliminary coding and analysis of data		
Total = 9	Total = 12	Total = 8
Type of data generated: Written observation notes and sketches and transcripts		

However, as is typical in ethnography, these formal methods were not the only way in which data was collected. I was immersed in and engaged with the field in other ways which I recorded as field notes and which also form part of the data.

Table 7: Additional engagement methods and data types

Method/type of engagement	Number
Informal discussions with researchers on day of observation	14
Discussion with co-ordinators	8
Extended interviews with co-ordinators	3
Type of data generated: Field-notes and transcripts	

I also included in my field-notes, any other interaction I had with committee members outside of the formal meeting. For example, over tea breaks and in one case, an extended discussion with a Chair on the train journey home. Informal discussions assisted in providing understanding of the field though these are not reproduced in the thesis.

5.3 Breakdown of process of the observations.

Observation comprised three stages for each application

- committee discussion of application
- questions to researcher when researcher came in
- follow-up discussion to decision when researcher leaves meeting

In addition,

- informal talk with Chairs or committee members in committee breaks
- informal talk with researchers on the day, for example while they and I were waiting for the slots Interviews conducted

These assisted with my familiarity of the field and informed the study. However, analysis draws on formal interviews.

For each observation there were follow–up interviews with committee members and reviewers of the study – some of whom were Chairs. There also follow- up interviews with researchers who attended committee. There were ten separate approaches to RECs via NRES to request observations. Two RECs refused to let me observe them. There were two committees whose members did not engage with interviews despite several attempts to contact directly and via the co-ordinator.

5.4 Sources of data

There are potential difficulties in using multiple methods resulting in different data sources. Hammersley and Atkinson (2007) warn that it is a mistake to assume that an aggregation of data from different sources will straightforwardly lead to a more complete picture. The different sources did however lead to a richer and more nuanced picture. Observations were conducted in formal settings which to some extent were bound by committee protocols but which were simultaneously idiosyncratic, chaotic and not always particularly ordered within those constraints. Nevertheless, all meetings followed a particular sequence which contained the messiness. The description of these messy and complex meetings is important and I go on in the next chapter to set the scene and evoke the atmosphere of these meetings. However, there were important reasons for behaviour to be circumscribed in the REC. Researchers wanted approval. The REC is the body charged with judging research as ethical or not. In addition, committee members may hold views which they would not express in a meeting. Conducting interviews allowed all participants to express their views and connect to their thinking about key concepts in the study – vulnerability, consent and capacity as well as commenting on REC processes.

5.4.1 Records collected

In ethnography importance is attached to recording. Hammersley and Atkinson (2007) suggested four types of records.

- Condensed accounts which are jottings made as soon as possible after fieldwork, or preferably during it, recording snippets of conversation, routine and significant incidents when and how others reacted.
- Expanded accounts, made when the ethnographer is out of the setting and has more time.
- A fieldwork journal noting the ethnographer's own feelings and responses and commenting on aspects of the research process.
- Analytic notes record ideas and insights that arise when sorting data, thus beginning the interpretative process.

My own records were not separated out precisely in this way but consisted of a range of condensed notes, lengthier perceptions following the observations and later

the beginning of interpretation when I began to notice patterns in the data collected. There were different styles of notes for observations and interviews.

5.4.2 Records of observations

These correlated to notes made in the field but were not 'condensed'. Whereas in some settings where the researcher is participant, these notes would of necessity need to be in a shortened form and written opportunistically. Johnson (1997) refers to retreating to the sluice, bathroom or kitchen to make notes whilst working as a bank nurse and researcher to conduct an ethnographic study on a medical ward. I was often sitting (rather than being physically active) at a committee meeting for between 1 – 3 hours. I could be open about recording as everyone knew I was there as a researcher/observer. My notes then were more often lengthy demanding focus and concentration. The audio recording of committee meetings was not permitted by NRES and so notes had to be written at the time of the meeting. The recording of data was adapted from an approach previously used in an observational study of attribution of cause of death in children by staff in an Accident & Emergency department (May-Chahall et al, 2004). This provided a simple framework for recording. Observation data consisted of notes taken at the time of the REC meeting which would be structured and notes taken after the meeting which were unstructured. The notes taken at the meeting consist of a written record of who is speaking, acting: what (doing and saying); the type of interaction or exchange, for example between committee members, to researcher and my own perception of what I think is happening. Unstructured notes taken afterwards consisted of my perceptions of what took place.

Who is speaking	What is said	Type of interaction/what is happening?
Immediately following meeting – perceptions of what took place		

My 'expanded accounts' were also a 'fieldwork journal' and these notes were made following meetings (usually on the train home). These included my perceptions of what had happened at the observation, anything significant or unusual, differences and similarities between committees and a note of any comments made outside of

the formality of the meeting. These might include coordinators', Chairs' or researcher comments. Emotions and feelings about the events of the day were also included. I included here notes about the dynamics of the meeting which I recorded in very informal language, for example, 'show-off Chairs' and impressionistic comments on the surroundings for example. These correlated to Hammersley and Atkinson's 'fieldwork journal'. The 'analytic notes' will be referred to later in the description of how I analysed the data.

In addition to these accounts, I drew small sketches or diagrams when I felt I was able (depending on my proximity to committee members). These simply indicated seating positions of members, where the Chair and Co-ordinator sat and the 'status' (if it was revealed) of committee members, for example, lay members, statisticians, lawyers, nurses, patient representatives and doctors. The diagrams also showed who contributed most in the meeting and between which members most of the dialogue took place.

5.5 Interview schedules

Interviews were conducted as soon as possible after the committee had met but not on the day of the meeting. There were some key outline questions asked of researchers and reviewers but the process of interviews was also organic and followed the direction of the interview.

There were two interview schedules – one for researchers and one for committee members. These were a series of prepared questions, prompts that I adapted according to who was being interviewed and the context. Questions were slightly different for researchers and committee members. Interviews lasted from 30 minutes to one and a half hours. Due to the distances travelled and the location of interviewees, I offered to conduct interviews over the phone or on Skype. Questions to both researchers and reviewers related to process and to consent and its associated requirements. A further question was asked about if they felt anyone was particularly vulnerable in research. Kelly (2013) described a continuum in qualitative interviewing with informality and natural conversation at one end and standardised, structured interviews at the other. I used the schedules to keep the interviews focussed when on the telephone but spontaneous interviews which happened in the field were informal and unstructured. I was conscious that reviewers and researchers

would want to represent themselves in particular ways. I felt that researchers were sometimes initially wary because I might be checking out how sophisticated their understanding was of ethics. However, as the interviews progressed, researchers became engaged in nuanced discussions about their dilemmas. Similarly, my expectation was that reviewers would shape their answers to indicate that they were doing what they thought was required of them. So governed by the terminology of procedure are committee members, that the content of our discussions was often couched in that language. Again, as interviews continued people were likely to talk about uncertainty in the processes and decision- making they were part of. This was assisted by open questions and being open about where the interview might lead. I also slightly changed the focus of questions as I went along. When asking the question: 'How do you go about making a decision?' responses usually included comments on the researcher so I extended that question to ask about the attendance of the researcher as this was clearly of importance to reviewers.

See table showing interview questions on following page.

Table 8: Interview schedules

Committee members
Process questions • What made you think in the application(s) in the meeting I observed that there should be a favourable or unfavourable outcome? • What do you take into account when making a decision? • How do you go about making a decision when you are reviewing? (Extended – presence of the researcher) • How do you use the procedures in reaching a decision? • Do you want to say anything about the process, the way the committee works? (Extended – the remit of the REC? lay membership, allocation) Capacity/consent questions • What is your understanding of capacity and consent in the context of research ethics? • Do you think anybody is particularly vulnerable in research? • Do the requirements (MCA2005) and crib sheet assist you?
Researcher questions

Process questions
 	
  • Could you talk about your experience of attending the REC and the process? (extended – and the application process)?
 	
Capacity/consent questions
 	
  • What did you consider in relation to capacity and consent in your study? (extended – previous studies)
 	
  • Did the requirements assist you? (either in application or in previous research)
 	
  • Do you have particular ideas of who is vulnerable in research?

5.6 Coding

The analytic notes made on sorting the data came about as a result of the transcribing process. Perceptions, observations were made at the time of transcribing both field and interview notes. This process itself constituted a

preliminary analysis and I began to see links in the data and looked at where emerging items were occurring.

Table 9: Data types used in analysis

1	observation notes
2	interview records-committee members including Chairs
3	interview records- researchers
4	field-notes – these included perceptions recorded in field-notes during observation, immediately following and ongoing commentary I kept in journals and then on transcribing.

A number of commentators are prescriptive about when analysis should take place with some indicating that researchers begin the process almost on entering the field and others suggesting delaying analysis until a substantial amount of data has been collected. Bryman and Burgess (1995) describe a developmental position on analysis which begins with coding and progresses to conceptualization. Mason (1996) distinguishes between making data amenable to analysis (or coding) and developing the analysis but points out, that the distinction between the two activities becomes blurred because in establishing some preliminary categories I was involved in analytical and creative thinking. Transcribing was an important activity because it allowed me to immerse myself in the records I had amassed and become familiar with them. In looking across the records, I began to see categories emerging which I classed as nodes in the NVivo system. I felt that I began interpreting when I was transcribing moving from passive reading to 'active interpretation' (Silverman, 2013) at this stage. Mason argues that it is important to treat the activities of coding and analysis as distinct in order to emphasize that 'although techniques like indexing and retrieval provide materials with which an analysis can be created and crafted, they do not represent the analysis in and of themselves.' (p91).

Coding is heuristic and a step-forward to more rigorous analysis. It is not simply labelling, but leads from the data to an idea and then from the idea back to the data pertaining to that idea (Richard and Morse, 2007). Saldana comments that 'focused coding' (Saldana, 2009:155) is useful for ethnographic methods as it encourages the

development of major categories without focusing too much on their properties or dimensions. Coding is described as being a word or phrase which has symbolic resonance. For Saldana, the code may be summative or salient but also be an evocative attribute for a portion of the data collected. He cautions that not all qualitative data are conducive to coding and highlights how methodology and the specific context of research influence the process. Coding is performed through our own interpretive, subjective lens. Finally, he notes that coding is a transitional process which takes place between collecting data and extensive data analysis (p5).

In qualitative analysis of data there is a tension between maintaining a rigorous approach and remaining engaged in the field whilst collecting data, coding data and during analysis. A rigorous approach to data at each stage is linked to validity and reliability in a positivist tradition. Hammersley (1992) argues that validity in qualitative research depends on research being credible and plausible as well as relevant and making a contribution to knowledge and understanding. NVivo may suggest and provide evidence of a systematic approach. It helped to organize the data but is limited in analyses and interpretation as it removes crucial context.

Silverman (2001) proposed some guiding principles in approaching data collection and analysis, which I adapted, and though I did not follow these absolutely, they did guide what I did.

- Firstly, the principle that observational research can be both original and valid and involve testing hypotheses in the field (Silverman, 2001: 69). If there was a feature of the committees which seemed significant to me then this heightened my awareness and I was more aware the next time I attended committee to 'test' this out. For example, I noted early on then when queries were raised, particularly by lay members of the committee, then they were expected to be reassured of their concern by the assertion of medical authority. The medical members of the committee (usually in the majority in the RECs which I observed) were able to refer to their own medical practice and reassure the lay member that what was being proposed was fine. I then developed a hypothesis that professional membership was important. I had developed a heightened awareness to this dynamic.

- Comparison. In my initial coding, I paid attention to how often categories had occurred and whether they appeared across sites. I would not want to say that claims made on the interpretation and analysis of data are only valid if occurring in a number of RECs but I have been mindful of how frequently categories occur. I have also looked at similarities and differences of RECs. I was also aware that I compared responses in interviews to how REC members and researchers acted and what they said in the context of the more formal committee meetings.

- Simple tabulations. I did identify references, for example to 'vulnerability', at RECs and then place them in the relevant node. I was then able to count how many times this had occurred in RECs and in interviews. I noted observable (inter)actions and gestures at RECs and considered how frequently they occurred in that context.

- Silverman also highlights the importance of separating out the recording of what is said at meetings and during interviews from interpretation and impressions or sensations (emotional reactions) of the researcher. I did this in a very straightforward way in my notebooks and then in transcribing.

5.6.1 Use of NVivo

I used NVivo to begin 'coding' and this was helpful in describing initial categories (or 'nodes' in NVivo terminology. This involved cutting and pasting chunks of transcripts under different nodes, creating them as I went along. The other advantage of NVivo is that each node can be opened to display which record it occurred in and this enabled me to refer back to where specifically (in which type of record) these nodes had occurred. Potentially, a node could occur in multiple records. NVivo also allowed me to count occurrences of references to the nodes overall. Nevertheless, I found there to be some disadvantages. In order to organize data into nodes, it has to be extracted from transcripts. One of the hazards of this is loss of context so that in further developing analysis, it was necessary for me to go back to the original transcript in order to be sure of meaning. For example, if I had extracted a comment and placed it under 'vulnerability', I had to go back to look at the context including the type of study under discussion, who was making the comment and where it occurred in the live debate in the committee. Bryman and Burgess (1995) comment on how retaining a sense of context seems to be linked to the researcher's theoretical

assumptions. It was certainly true that as I was holding ideas in my head, I wanted to check out many aspects of a particular node and the complexity of this preliminary theorizing (checking, rechecking ideas, going back and forth to records to confirm hunches and so on) could not be performed by the software (as far as I was able to use it).

5.6.2 Initial categories

In this stage I was engaged with the records I had generated through data collection in the field. I generated categories as I went through the data and ended with 25 categories. I did not apply these categories, rather I created them extracting comments, examples from the records kept and placing them into categories. The 'problematics' delineated in the previous section with which I approached the study and which began to emerge influenced the way I selected data for these categories.

Table 10: Initial ordering categories

• Engagement with the study	• Concerns with language and communication
• Design - researcher	• Key points about capacity
• Remit of the committee	• Requirements
• Committee expertise or knowledge	• Reference to professional status
• Considerations of capacity-researcher	• Perception of committee-researcher
• Qualitative and quantitative comments	• Vulnerability
• Notions of harm	• Seeking clarity on requirements
• Confidentiality or anonymity concerns	• Consent concerns in study
• Judgement about researcher	• Concern with design
• Reference to me as observer	• References to paperwork
• Reference to previous studies	• Committee dynamics
• Assertions of medical authority	• Concern with 'good' research
	• Moral and ethical dimensions

5.6.3 Approach to coding

In this section I want to talk about the approach to coding which I adopted. Following Mason (1994) and her distinction between coding and analysis I approached these separately. Mason argued that although the distinctions may become blurred, coding was organising and making data manageable but not analysis in itself. My approach was to code into initial categories (above). This was a laborious task going through transcripts closely and deciding what they represented. Charmaz and Mitchell (2001) discuss the role of grounded theory in ethnography. Their important point, relevant I think to all ethnographic research, is that coding does begin the analysis. Initial coding involves the researcher as this is the stage when one is prompted in 'taking the data apart and to look at them anew with a theoretical eye.' (p165, 2004). I was interacting with the data (as well as the participants in the research) and my theoretical position was holding in mind what was taken-for granted in the discourse used in the REC. Codes arose directly from the words or what I thought was tacit in what was being said. I also was conscious of how the context supported the taken-for granted actions and statements or, how the context was relevant, how it impeded or changed actions and statements.

These questions were very much aligned to the methodological approach described by Smith above in that I wanted to look from the particular to make connections with the social. I was keen to look at the 'everyday' in review. The assumptions which were so dominant that they were not questioned. I was able to expose this through my interviews with researchers and committee members sometimes – but often had to ask myself the question when reviewing and making this preliminary analysis of the data. So, for example, my broad question in interviews – 'do you have any particular views about who is vulnerable in research?' would often be answered in a legalistic way by reference to the MCA. There was a taken for granted perception that this was obvious and 'common-sense'- but when probed interviewees would begin a dialogue with me and discuss vulnerability more widely, certainly in more interesting ways not constrained by the taken for granted, almost reflexive need to safeguard. It is only by using this approach to data analysis that the everyday can be revealed and connections made which have wider social relevance. This is a significant theme in the thesis. The ways in which we are all involved in perpetuating the illusion of protection by having procedures in place to claim it has been

accomplished. This will later be tied to concepts of and the meaning of 'institutionalized trust'.

The question about structures and contexts, how they support and impede, was also important because the 'action' of decision-making was embedded in a structure of procedure and regulation (field) and specific context of the REC (site). This again echoes the discussion in the methodology section where I attempted to separate out the site of investigation and the field of investigation. Clearly, it is important in this study to have investigated both but continually interrogating this relationship - how much of what happened in the REC is a product of regulation, and in turn, how does regulation support and impede decision-making in the REC – has a central place in my approach to coding and analysis.

The tension here in coding was that it felt like an attempt to make empirical what was not amenable to an empirical approach. Coding in constructivist research feels like a regressive step to some extent because the activity and process of data collection are not aiming to collect according to certain categories. I did not have a closed questionnaire or schedule as my research tool which I was looking to complete by the collection of facts. Qualitative researchers would take issue with the notion of objectivity as inevitably some theoretical filters or conceptual frameworks are already in place. Schenshul et al (1999) describe how theory operates at different levels of abstraction during the research process. At analysis level, interpreting patterns or looking at associations between types of data, the researcher is using 'low-order' abstraction, extracting information that is most relevant to understanding what is happening. However, ethnographers move up and down levels of abstraction even when collecting data and generating preliminary hypotheses in the field (p15). In other words, even as we are collecting and noting, our field notes themselves are already imbued with some theoretical perspective, I think the codes I created were actually a way of organizing some of my initial 'low-level' theories about what I had observed, seen and heard. As such, some are not concrete codes but more symbolic categories represented in code form. For example, the codes 'reference to professional status' and 'judgement about researcher' represent symbolic meaning - a category which encompasses 'authority, trust' and connects to a theoretical position which seeks to problematize this in the context of ethical regulation. I am

seeking to answer the questions - why are committee members reassured by status? How does professional status confirm ethical conduct?

5.7 Conceptual analysis

A second stage (analysis) was defining concepts. My conceptual framework is about the 'doing' of ethical regulation and some of the categories above were more relevant to this than others. Timmermans (2012) discusses the importance of concepts in qualitative research. His commentary is written out of a concern that sociological research (here he refers to sociology of health and illness) can demonstrate its significance. In order to have an impact research needs to broadcast its relevance beyond other sociologists and directly to health stakeholders and non-social scientists. For Timmerman, concepts are crucial in helping to elucidate recurrent, practical concerns. He argues that rather than concepts which require lengthy explanations, those with 'intuitive relevance' may resonate more widely. I have taken this to mean that concepts should make sense - if my aim is to look at the construction of research ethics and its regulatory processes then I want my description of what I uncover to be intelligible to research communities and to the institutionalized regulators of research ethics (the Health Research Authority and specifically NRES who co-ordinate the RECs). I agree with Timmerman that in order for sociological research to achieve the reframing of dominant perspectives and offer alternatives to what is perceived to be 'reality' then the conceptual analysis has to have relevance in order to ultimately uncover dominant perspectives and conceive of alternative realities.

I would argue that the concepts I have developed have meaning and relevance in research communities and research ethics. I clearly had some key concerns in mind already when commencing the research which I wanted to explore. The concerns which prompted this PhD were bureaucracy, the limitations placed on research with vulnerable groups and the meaning of capacity and consent in research. During the period of this study I have engaged with researchers in discussions about these issues. These have all influenced the conceptual analysis. I mean by this colleagues, informal chats with researchers waiting outside of RECs, conversations which were unconnected to the studies I was observing and colleagues in other Universities. I had contacted the North West Mental Health Research Hub about my research and

they viewed it as important and from their publicity about my PhD, I was contacted by two researchers a psychologist who did research with people with learning disability and a nurse who did research in prisons. I had helpful discussions with all of these people on an informal basis and I do not include these as data. However, I feel confident that the themes I discuss have relevance to and resonate with the research community and have found that people actively want to share their frustration and concerns. I have not been able to 'test out' my concepts with NRES but I certainly found in my observations and interviews with REC committee members that I was discovering data as I went along which were aligned to my key questions. Conceptually the focus is on developing theoretical explanations of work and the 'doing' of ethical regulation in order to extend our knowledge of decision-making. Of 'doing', of practical judgement making and of decision-making and the use of texts.

I want to explore next, my involvement as a researcher collecting data and the subsequent interpretation of data. The purpose of this is to demonstrate a reflexive approach, reflecting on interpretive ethnography to think through my presence in the research. In the section that follows, I begin to define what is particular to the study and how orthodox methods have been used in original ways.

5.7.1 When analysis ends and interpretation begins
Interpretive ethnography can potentially enable a description of shared meaning in a community. This shared meaning is what constitutes reality in a community. In this case, the 'community' are the communities of the REC or the wider community engaged in research which includes researchers and ethics committees. In studying professional knowledge making, researchers need to maintain a balance of engagement with and detachment from the conceptual world of the community being observed. (Smart, 1998). Clifford Geertz saw that interpretive ethnography could describe and interpret culture. By culture he meant the 'webs of significance' which man (sic) has spun.

> *'Believing...... that man is an animal suspended in webs of significance he himself has spun, I take culture to be those webs and the analysis of it to be therefore not an experimental science in search of law but an interpretive one in search of meaning....'*
> (1973: 524)

Geertz describes how in the act of interpreting the researcher has to hold two concepts 'experience-near' and 'experience-distant' simultaneously. The researcher task is seen as taking these concepts and producing an interpretation, illuminating by connecting them. The researcher can be neither imprisoned by the mental horizons of the culture being studied nor immune to the nuances of its existence.

These concepts of 'experience-near' and 'experience-distant' are helpful in the context of the RECs being researched. As an observer one has to be familiar enough to make the experience of observing comfortable for oneself and the committee and to be sympathetic to what is being discussed and each RECs way of seeing. Committee meetings usually lasted 2-3 hours depending on how many capacity studies were being reviewed. Some committees invited me to stay for the duration of the meeting regardless of whether studies were subject to the MCA or not. So, although I did not attend the same committee over a period of time and could not claim the immersion into the field required in classic ethnography, I was able to become briefly familiar with each committee and the way it worked, the similarities between committees and the ways in which they differed. This kind of observation allowed me to have an 'experience-near' in the context of each REC and RECs across England as well as simultaneously allowing me to maintain some distance, permitting me to make comparisons which contributed to the description of committees.

5.8 Writing ethnography

The approach to analysis of findings has been interpretive. Mantzoukas (2012) produced a useful taxonomy distinguishing the features of ethnography, critical ethnography and interpretive ethnography. In this section I use his headings and have paraphrased his descriptions. I explain how I think this study fits with interpretive ethnography. Though some more contemporary ethnographers would take issue with the descriptions here, I have found this process a useful way of distinguishing the distinctiveness of this study.

In this taxonomy, analysis results in a coherent narrative constructed of different, complex and connecting discursive issues and the analysis continues when the reader is involved in deconstructing and reconstructing the narrative. The data in this

study derived from different 'sites' and from different methods of inquiry (observations, interviews) and these have been juxtaposed, looking at relationships between for example researcher interviews and committee member interviews. The analysis has drawn on diverse influences in approach. Themes emerged and interpretation of data began sometimes immediately in my recording of observations and at other specific points along the way. Denzin (1997) refers to 'messy texts' which he describes as moving back and forth between description, interpretation and voice. The messy text 'produces local, situated knowledge about the practices of a given group and its culture.......The messy text re-creates a social world as a site at which identities and local cultures are negotiated and given meaning.' (p225).

I explored Smith's (2006) conception of 'texts' in the field as sources of data where 'text' in this study means understandings, verbal, written, social practices, discourses of risk, vulnerability and so on in the field of ethical regulation. Myers (2013) argues that the premise of interpretive researchers is that access to reality (whether given or socially constructed) is through social constructions such as language, consciousness and shared meanings. The interpretive paradigm is underpinned by observation and interpretation, thus to observe is to collect information about events, while to interpret is to make meaning of that information. In this study, access has been to the real-life events of REC meetings' in which discussion and talk is focused on making objective decisions about research based on guidance and some of my 'making meaning' is about my judgment and interpretation of the gap between this and the reality of what took place.

I did not approach the study from the perspective of uncovering 'truth'. I did not set out to evaluate, as I had no idea of what the committee meeting ought to be (except perhaps some view of what it should not be given my own experiences!). I was not measuring the performance of the committee against any set criteria. I did not set out to show that committees made bad decisions as this would infer that I had an idea in my mind of what that would be. I did want to look at whether regulation limited the scope of research especially with those who lacked capacity to consent and in this way, it could be argued that I was searching for meaning. As I explained above however, interpretive ethnography seemed to me to fit with the difficulty of having an interpretive framework and some problematics in mind before I even entered the field

and certainly once in the throes of data collection, it was impossible to put these aside. I think remaining open to what could not be codified meant remaining open to surprise and there were some significant 'cultural moments' which lead me to think about issues I had not anticipated, for example trust and the extent of the coordinator role.

5.9 Credibility

This study was not a large-scale ethnography. The observations I conducted in the field and details of the interviews are detailed above. The data generated were sufficient to provide useful insights into the workings of RECs. Instead of drawing specific and concrete conclusions leading to recommendations, I have offered detailed analysis and description of what I observed. Multiple methods were employed to gather data. Frequently, what happened in one REC was repeated in another. Consequently, the phenomena I observed and my emerging interpretations were confirmed in each setting over the nine observations. In addition, what I observed happening in observations was also borne out in the accounts given by interviewees. An example of this was my observation of the importance of the attendance of the researcher applicant. All reviewers saw it as central to their decision-making that they could see and speak to the researcher. This in turn led me to a consideration of what was really happening. For example, how and why was the presence of the researcher so important?

Triangulation in a pure sense was not a method I employed in analysis. Rather than one source of data corroborating what was found in another, my interpretation presents data drawn from observations, field-notes and interviews as evidence of my arguments. In addition, I have drawn on a range of perspectives to illuminate my interpretation of data. In a presentation of quality criteria for qualitative research, Tracy (2010) suggests that 'crystallization' rather than triangulation may be more appropriate for the practice of using multiple data sources and lenses and when research is motivated by post-structural and performative assumptions.

> *'Crystallization encourages researchers to gather multiple types of data and employ various methods, multiple researchers, and numerous theoretical frameworks. However, it assumes that the goal of doing so is not to provide researchers with a more valid singular truth, but to open up a more complex, in-depth, but still thoroughly partial, understanding of the issue.'* (p844)

5.10 Conclusion

The overall analysis of findings in part two attempts a coherent narrative constructed of different, complex and connecting discursive issues engaging the reader in deconstructing and reconstructing the narrative through a backwards and forwards reporting of data analysis and interpretation. The conceptual framework I pursue in the ethnography which follows derives from institutional ethnography and relates to *how RECs work* and *how they do their work*. I have attempted to be reflexive throughout the interpretation of findings and have used a range of literature to illuminate in an attempt to build a persuasive discussion.

The following chapters present what I found to be significant and have meaning in the work of RECs.

- The 'doing' of review – the work of committees (rich description of ethics review).
- The practical strategies employed by committees to make sense of applications – making judgements.
- The use of texts in RECs – making decisions.

These now form the basis of the interpretation of findings in the thesis.

Part Two: Mapping ethical regulation

Chapter 6: Describing the REC – setting the scene

6.1 Introduction

This chapter is descriptive and may at times appear anecdotal, however, there is a theoretical context and purpose. This relates to Smith's insistence that institutional ethnography relies on 'mapping' what is happening in organizations or between people (1987) emphasizing that research is located where things 'happen'. This mapping has as its aim the unearthing of the everyday, common assumptions, talk, processes and so on, which belong to the field of study. As Campbell and Gregor (2008) put it:

> *'People's lives happen in real time and in real locations to real people. Institutional ethnographers explore the actual world in which people live, work, love, laugh and cry.'* (p17)

This focus of attention on the 'actual' is part of a wider project, that of finding the 'invisible' which underlies what is happening beneath the surface of the everyday and common-place. The researcher has to find ways of looking at what is really happening in order to tell the story and 'map'. In order for me to discover what was really happening I needed first to describe some of the 'goings on' at the RECs.

> *'Once they grasp 'how to look', their (researchers) storytelling becomes more focused for a particular analysis, one that is theorised'*
> (Campbell and Gregor: 18)

So this chapter sets out my attempt to understand the REC leading to the particular analyses which I present in chapters 6 and 7. I have previously discussed the auto-ethnographic elements in this study, beginning with its origins in my own attendance at a REC. Institutional ethnography also acknowledges that researchers do not stand outside of the world being researched and though I was an outsider as a researcher and not a full participant at the meetings, some of the content of this chapter gives attention to the ways in which I was inhabiting and interacting with the world of each REC. I use different bodies of literature to analyse different aspects of the committees.

Finally, further theoretical justification for the descriptive nature of this chapter derives from Garfinkel and the perspective that seeing 'sociologically' requires a

'focus on the routine details that comprise the coherence of activities' (Garfinkel and Rawls, 2005: 6). It is through the descriptions of the mundane and routine that I am then able to offer an analysis of how these details matter for ethical regulation. This chapter then 'sets the scene' and contextualizes the meetings as well as providing background to how the later interpretation and analysis (which are the subject of the subsequent chapters) emerged. It describes the REC and some of the typical ways in which they worked detailing:

- Physical features and location
- Atmosphere and dynamics in the RECs – two 'stand-out' incidents
- Membership categories – expert and lay members
- Allocation of applications to reviewers
- Participation in the meetings
- Sequence of meetings
- Outcomes of meetings

During the observations of meetings, I watched and recorded the meetings in note-form, usually taking a place at the conference table though in one the Chair suggested I sat just outside so that I could see everything. This was easier as I did not have to think about my writing/sketches distracting the committee or the researcher when they were being questioned. *Mise-en-scene* can be translated literally as 'putting on stage' but can also refer to the setting or surroundings of an event. In this chapter I want to evoke the performance and spectacle of the REC as a production or 'putting on' of an event drawing on some of the interactions with me as the observer/researcher and between committee members. This chapter aims to provide a description of the REC as I experienced it and to describe some of the ways in which the REC functions in order to achieve its aims of reaching decisions about the ethical approval of research. There was a sequential organization to the meetings, which I noted, and I argue that this sequence helps to achieve the business of the REC (reviewing applications) but also provides a perhaps superficial uniformity of procedure across the committees which in turn supports the notion of objectivity in decision-making. As I observed I looked for patterns in interactions between Chair, committee members and researcher/applicant. I made notes of who was speaking so that I could later evaluate who contributed most

6.2 Locations of meetings.

Table 11: Location of meetings

Observation number and code letter for committee	Location
1 REC meeting A	Hospice in small town but researchers came from large metropolitan area.
2 REC meeting B	Located in major national teaching hospital – psychiatric specialism
3 REC meeting C	Large city teaching hospital
4 REC meeting D	Large city teaching hospital
5 REC meeting E	Teaching hospital - spinal injuries specialism
6 REC meeting F	Large teaching hospital
7 REC meeting G	Major national teaching hospital – cancer specialism.
8 REC meeting H	Located in major national teaching hospital – psychiatric specialism

Note: REC meeting observation D and F were the same REC, both of which were held in the same location. REC meeting observation B and H were the same REC but held in different locations.

The settings are important in that the RECs did feel overwhelmingly medical. The criticisms levelled at bureaucracy and about the dominance of biomedical concerns in the review requirements (Dingwall, 2006; Stanley and Wise, 2010) would certainly be confirmed for researchers coming to the RECs to seek approval for research outside of health and medicine simply by virtue of where they have to attend. The dominance is certainly reinforced in the *doing* of review, the spaces where review happens are 'medical'. This can be daunting for researchers whose research is not primarily medical and does not sit within typical biomedical research paradigms.

A further consideration in the significance of location is raised by Hedgecoe (2012). Describing the role of local knowledge in review, he noted how networks of relationships can develop when a REC is located at a particular institution with

committee members becoming familiar with research, the facilities to support researchers and gaining knowledge of the researchers themselves. This 'local knowledge' where committees have strong local connections can assist review (p673). Of the committees included in the study, REC B did feel it had a 'home' in the hospital in which it was located and this was commented on positively.

> Reviewer/ Chair: 'We're independent from the ____Institute but we're very proud of what goes on there. We're proud to be contributing to (research in) difficult situations'.

However, though this local connection and corresponding accumulation of knowledge may still be true of local Trust RECs, the NHSRECs which I attended ('flagged' for capacity RECs which fulfil the independent function required by the Declaration of Helsinki (World Medical Association, 2000)) are nationally coordinated by NRES. This means that they are usually covering a large geographical area. They may have historical local links to the local Trust within which they are located, as in REC B above, but even in the period of this study, RECs have been reconfigured and locations changed. Their geographical reach has been widened with reconfiguration. This means that committee members are less likely to have the local connections and importantly the local knowledge described by Hedgecoe (2012). Lastly, the location of the meetings in the table above (in hospitals) may reflect the sample rather than this being more widespread or typical.

6.3 Welcome to the REC!

All RECs had a Chair and committees were large – frequently over ten members though membership might be wider than that. The tone of the meeting was set by the Chair. Mostly, Chairs were positive and well used to observers at the meetings. Some Chairs asked me to further explain the purpose of the study to the meeting.

The operation of power and authority in the RECs seemed heightened at the point I entered the REC. I became aware as the observations went on how much members relied on impressions of the researchers and how they made judgements about trust. This was what was happening when I went in to the meetings. **Just as reviewers preferred to see the researchers whose applications they were reviewing, they wanted the chance to weigh me up and decide on trustworthiness.** They did this by seeing me, by asking questions about the research. Some members were warier

than others and probed more about my intentions in the study. However, even when one reviewer appeared to be hostile in her questioning of my intentions in the research, s/he later was generous with time and our interview was one of the lengthiest conducted. On reflection, the recruitment of the committee members could have been improved. I was not able to contact committee members directly as this was done via co-ordinators. Ideally, I would have liked more time to discuss and explain (in person) the aims of my research to committees prior to observations. I think this would have been helpful in providing the opportunity for increased participation, for example, influencing and shaping the research as it progressed. Instead, the preliminary discussions I was able to have with the RECs seemed rushed given the time constraints within which REC members have to work on the day of the meetings. Furthermore, information about the project was sent out via co-ordinators along with the paperwork for the REC. Given the volume of applications received by members, it was understandable that they had further questions about my research. Given this, I think members understandably wanted to know more about the research and check out my researcher credentials. There was no suggestion that they did not consent to me observing in any of their comments or questions. They were seeking clarity about the research from me in person. (This paralleled what I discuss later in relation to trusting the researcher in the course of review). The RECs I was permitted to attend always acknowledged my presence and noted that I was allowed to observe. It was very much a case of the individual REC giving me permission to remain on the day.

My perception of the committees I attended was that they had a dramatic quality in the way in which meetings can. I was reminded of ward rounds I attended as a social worker which were led by a psychiatrist and which involved much posturing with registrars and Consultants debating diagnoses. Atkinson's work (1995), referred to in the first part of this thesis, demonstrates how interaction between doctors (rather than between doctors and patients) produces medical knowledge. Atkinson emphasised how clinical opinions are produced socially through interactions and how local settings influence which diagnostic and treatment decisions are reached. Members performed to each other, to the co-ordinator present and to the researcher during meetings. The analysis of interactions in Table 11 shows the frequency of

interactions and who these were between (Chair to committee member, committee members to researchers, for example).

Talking about performance leads to a consideration of 'drama' and particularly Goffman's dramaturgical perspective. This perspective introduced in Goffman's 'Presentation of the Self' describes the elements of performance in any interactional setting. Smith (2005) describes dramaturgy as an extension of the metaphor 'all the world's a stage' and that this metaphor is used by Goffman to illuminate aspects of the 'performance' of social interaction. Smith goes on to explain that Goffman did not view dramaturgical action as somehow false or insincere. REC members do not learn scripts of how to behave, what to say and are not acutely conscious of the effect of what they say. However, what I viewed as performance and dramatic effect are ways in which people present and manage themselves during the course of meetings and in order to achieve the business necessary.

> *'Individuals do not learn scripts that allow them to know in advance what they will do and what the effect will be. There is just not enough time for that. Rather, individuals are socialized 'fill in' and 'manage' any part they assume. Everyday conduct derives not from a script but being the kind of person who enacts and sustains the standards of conduct and appearance of their social group'.*
> (Smith 2006:43)

I also have to acknowledge the possible effect of my presence as an observer on how committees acted. I cannot judge whether their behaviour was modified or changed due to me being there. Certainly, the REC becomes immediately 'public' because there is an observer present, someone who is not a regular participant in the proceedings.

6.4 Membership categories – expert and lay members

As an ethnographer in this research, 'knowing about' the membership of RECs was difficult. They appeared to be medically dominated and yet this was not explicitly acknowledged in the HRA information. For example, this extract from the HRA's website on membership explains what 'lay' and 'lay plus' means but does not describe what a non-lay member is.

> *Each NHS Research Ethics Committee is made up of between 12 and 18 volunteer members. At least one-third of the members must be 'lay'; half of*

the lay members must be 'lay plus' members. Lay members are people who are not registered healthcare professionals and do not conduct clinical research. Lay plus members are people who have never been care professionals, researchers in a care field, or chairs, members or directors of care service bodies or organisations providing care. The remainder of the committee are expert members, who are specialists including doctors, other healthcare professionals and academics. Each Committee has a Chair, a Vice Chair and an Alternate Vice Chair'.
(Health Research Authority, 2014)

My interpretation of this official text on membership is that it is intended to show a commitment to openness. While not suggesting that it deliberately misleads, this extract provides an example of what Manson and O'Neill (2007) have articulated (as I understand her) the need for public institutions to be transparent, here showing that the REC membership is open and includes experts and non-experts. However, as Manson and O'Neill go on to explain, transparency often merely takes the form of 'information giving' without any responsibility being taken for how understandable the information is. Information is provided and this is proof that the organization is transparent. The extract provides limited real-life description of the membership of the RECs. Its intention is to authenticate the REC as open in membership and transparent in its process of forming a REC. The classification of 'lay' and 'lay-plus' is unclear while the other side of the binary, 'non-lay' is defined by 'expertise' and examples are provided of these. Given the history of RECs which are mostly situated in hospitals, and are after all, *NHS* RECs, the majority of members are medical. It was difficult to discover in the field what was meant by 'lay'. It was not always possible to establish the type of membership when I attended for observations. One co-ordinator who I interviewed said that in practice 'lay' often simply meant 'not medical'. The committee reviewers I interviewed were not all health-related professionals. Those who told me they were lay (because they would often point this out at the start of the interview) described themselves as statisticians, philosophers, ex-circuit judges, business people, social workers and so on. Nevertheless, the potential for expert members to influence has been noted:

'The constitution of committees is also interesting as a factor which could undermine their very rationale. For example, there are currently more 'expert' than 'lay' members on any one committee so, if it were ever to come to a stand-off between the two groups so defined, the experts would probably win the day'.
(Edwards, 2011:149)

However, in my observations, the identification of a committee member as lay did not mean necessarily that their input was less valued. Other forms of expertise were brought into the discussion. At one observation, I noted that the Chair encouraged non-health-related members to participate and that contributions were taken seriously.

> Good that the lay concerns were raised and given time even more time than the other concerns from the clinicians present on the committee. All members listened and points were raised with researcher directly by Chair later.
> **Field-notes extract: REC B**

This was usual, as was the appeal to expertise from other non-medical members as appropriate. There was respect for the lay members' contribution and though medical members dominated, Chairs were generally fair in ensuring lay members' perspectives were included.

> The researcher was saying contradictory things about incapacity and exclusion and inclusion. The lay member sought clarity on these.
>
> **Extract: Field-notes REC E**

In another observation, the lead reviewer (a lay member) was very concerned about the difference in attention that the control group in a pharmaceutical study were going to receive. The Chair was a medic.

> Lead Reviewer: A thorough application but I need some clarity from the researchers. Does the control group have less cover (attention)? There is a moral dilemma. What if the staff notice a discrepancy between the two services? If there is a problem will it be left or corrected in the control group?
> Chair: In my Trust… (what the researchers are doing) …. this is normal Trust policy.
> Lead Reviewer: Will the medicine regime have the impact that the pharmacists think regarding the length of stay?
> Chair: Well it's still real science even if what you do is disprove your hypothesis. One of my patients this morning … (Recounts story) …. it's a nightmare at the coalface.
> **Observation: REC A**

In this exchange, the reviewer was raising a serious point about equipoise. Here the research was into the introduction of a new medicine regime for patients admitted in an emergency and whether a new regime has an impact on length of hospital stay.

The lead reviewer is concerned that staff would face a dilemma if one regime were working much better than the other was. Equipoise is the term used to describe the situation when researchers face a particular ethical dilemma. Typically, this happens in experimental research with trials which use a control group (the Randomized Control Trial) when evidence (or none) for both treatments is roughly equivalent. In this case, concern was being expressed that if it was discovered during the trial that the medicine regime was superior with better outcomes for patient that this would pose a dilemma for the researchers. The second reviewer of the application was concerned that the control group might be denied the attention to medicines that the experimental group would receive.

However, the Chair again intervened to reassure saying that the control group would be getting standard, NICE (National Institute of Clinical Excellence) treatment whilst the experimental group would be offered 'top-drawer' treatment.

The reviewer was raising questions which might have seemed surmountable and obvious to those with a medical background on the REC but s/he was raising important matters which developed the discussion and meant it became more critical. The debate was not simply based on the accuracy of the application or the 'science' but the lay member was imagining the doing of the research and the potential difficulties- both practical and moral.

The Chair's (medical) perspectives appeared to me to close down discussion of complexity. On the other hand, because business needs to be done and decisions made and in this case because s/he was confident about practice in A&E, reassurances were given which lead to an outcome of 'favourable with conditions'. This might be viewed as dependence on expertise. The Chair in this case happened to have experience of A&E and so could comment on common practices which set a context for this pharmaceutical study. Hedgecoe (2008) refers to this when discussing committees' attitudes to qualitative research. He notes how committee members query specific practices and allow experts in the area to clarify and provide context. So rather than concluding that medical expertise dominates, I would suggest that medical expertise seems to dominate because of the historical foundations of RECs and their physical location (hospitals, clinics). It is expertise which is utilized in the difficult business of arriving at a judgement. Other types of expertise were

referred to or used to support concerns. Lay members, when interviewed, did not express feelings of exclusion and certainly felt that they were valued.

> JM: Can you tell me about the process of making decisions?
> Reviewer: Well, the Lead Reviewer reads and highlights any issues in the application, everybody reads the application. The Lead Reviewer is allocated – this is spread about. We try to allocate according to background. Everyone can express their views though. Lay views are just as important. We don't weigh the views of a medic more highly than a lay. It's a collective view.
> **Interview with reviewer: REC B**

I am not underestimating the dominance of medical authority and certainly members claimed legitimacy by asserting professional authority, however this was not specifically medical. It is probably expertise which is valued in the decision-making process. Stark's (2012) description of Institutional Review Boards (IRBs) in the United Sates, notes that governments appoint both civil servants and those with specialized knowledge. 'Civil servants become agile in using a narrow set of regulations, and gradually, in the course of doing their jobs, they become *rule experts*.' (20012, p3). These are the coordinators. Co-ordinators definitely had an in-depth knowledge of procedure and capacity requirements. On the other hand, Stark goes on to explain that temporary bureaucrats, (the term used by the anthropologist Donald Brenneis is 'nonce-bureaucrats' in the sense that they are 'here for now'), have their main job elsewhere but are used as temporary bureaucrats due to their knowledge and expertise. In the United Kingdom, these temporary bureaucrats may be defined as 'lay' or 'medical'. (Brenneis (1994) was writing about another bureaucratic institution – the National Research Council in the United States).

Institutional Review Boards (IRBs) are the formal review Boards in the United States which are located usually in academic institutions or health facilities. These function to review research, weighing up benefits and risks in similar ways to RECs in this country. Stark draws attention to the bureaucratic nature of such institutions which are charged with making decisions about matters which are largely about human experience and not easily made quantifiable. Rules are developed which try to impose regulation and order. Given that the decisions which need to be made in IRBs require more than an application of rules but *judgement,* knowledgeable bureaucrats are also needed. Stark argues that two mandates run in parallel here.

Rule experts mandated to provide expertise on rules, and nonce-bureaucrats who are mandated to use discretion. In one sense then, in the United Kingdom, all members of the REC are 'nonce-bureaucrats' because they have expertise outside of the REC which is meant to provide them with knowledge and skills to make judgements on research. They become familiar with the rules but are heavily dependent on coordinators for help on the rules and regulations. Co-ordinators are the equivalent 'rule-experts'.

Stark argues that the expertise in these roles is important in that they provide legitimacy to the REC. The roles described resonate with the differing roles in the RECs which I observed. In my observations, coordinators were also able to advise on how rules could be 'bent' in order to support the judgement of the REC members. I discuss this in more detail later but the relationship between Chairs and coordinators was often one of complexity with an interplay of 'rules' and 'expertise' leading to a decision. The roles were not oppositional but complimentary and co-ordinators exercised considerable authority whilst performing a supporting role. Their role however was often to outline how a particular decision could be granted, what was needed in the application, what was missing or needed to be revised. However, the rule experts only ever supported the judgement of the committee members.

6.5 The significance of 'good science'

There were particular understandings of 'good science' that were revealed in observations and interviews. My questions during interviews did not address design or the quality of research but these were part of the responses.

> JM: How do you go about making a decision, what do you do when you read an application?
> Reviewer: I would look at the quality of research first, for example, are there well-defined objects, how will outcomes be managed. Most people are not evil who are doing research.
> JM: Do you have any views of who might be vulnerable in research?
> Reviewer: Well there are certain categories like children or people with mental problems. ……. As a community, we have a responsibility not to authorize a study if it is only for the sake of achieving a higher degree. Research involves human beings. It sounds pompous, but it is our duty. People with dementia for example, we have to do our utmost to ensure that they are not used for

something that is not worthwhile. Design is not our concern however bad research or bad science is not ethical.
Interview with reviewer: REC B

Institutional ethnography does not set out to blame the individuals involved in organizations and bureaucracies, but attempts through analysis, to reveal ruling concepts. An important ruling or overarching concept here is that of 'proper research'. This was referred to in the observations and in my interviews variously as 'good science' or 'good research'. I say more about this concept in the following chapters. However, here I am claiming that the membership of the REC is significant in that it serves to maintain this category of 'proper research'. This 'proper research' is maintained by a membership which is largely medical and where 'lay' means non-medical. The medical members could express their views with certainty about what research means, ('well it's still science even if you disprove….'). The implication being that they understand research and could explain its crucial elements to lay members. Evidence of this was also in interviews. Committee members talked about 'good science' as 'ethical' and that they were unable to separate these out in review.

Social science researchers, who it has been seen, have expressed concerns about the dominance of biomedical approaches and uncertainty about the expertise on qualitative research. They are concerned that there is a limited understanding of the range of research which lies outside of the biomedical frame. The view that proper or 'good' science is biomedical science and that its methods are tried and tested, transparent and obvious needs to be open to challenge and it is the presence of lay members which can potentially 'trouble' this view. It is also important to state that when reviewers referred to 'good science' they did not mean that they were reviewing the science of studies but seemed to be suggesting that they needed to be convinced that the study was worthwhile. This was an important component of weighing up risks and harms in the balance in reaching a decision. Reviewers did not claim to be making evaluations of the science, but its 'moral worth' given that researchers do not have a right (as a matter of course) to undertake research.

6.6 The allocation of applications to reviewers and objectivity

Objectivity is an important ruling concept in ethics review. The lay/non-lay question is important in relation to this. The public website pronouncements are intended to demonstrate objectivity achieved in part by the inclusion of lay members. There are

even distinctions between lay and lay plus. In the everyday world of the REC, there was a straightforward practical understanding/working of this. Lay meant non-medical. Medical members did not feel the need to assert their knowledge where lay members did. The ruling concept here which is hardly acknowledged is the 'objectivity' of decision-making. The overarching rules about the composition of RECs are presumably intended to fulfil this requirement for objectivity when what happens in practice is that the RECs just work with what they have. There was no clear process for how Chairs allocated applications for review. I was told by various committee members that Chairs would usually try to assign studies which suited the particular areas of expertise. Everyone I interviewed was keen to point out the value of lay members.

In interviews, committee members were usually happy with the way meetings were chaired and the allocation of applications to lead reviewers.

> It's a good friendly team. In other meetings I've been to, lay members are viewed as second-class.
> **Interview with reviewer: REC A**

> In general, there are two reviewers. It's not always a good idea if there are two reviewers from similar backgrounds - there needs to be a spread on the committee in membership, lay and clinical for example.
> **Interview with reviewer: REC E**

One new committee member was unsure how members were selected as lead reviewers.

> Are they selected according to experience by the Chair or does the Secretary allocate on the advice of the Chair? Even if you don't have specific knowledge or experience, you can still comment on ethics.'
> **Interview with reviewer 1: REC E**

Lay members were seen as important to the process of decision-making.

> We negotiate a decision. People are encouraged to participate. The Mental Capacity Act covers a massive area of research – emergency work, old age psychiatry, unconscious people – we need the wide spectrum of perspectives on the committee.
> **Interview with reviewer 2: REC E**

The reviewers I interviewed were not all medical but those who told me they were lay were generally not from a medical background. The range of expertise represented by these members was drawn upon in REC discussions. When I interviewed two

reviewers following one REC, the dietician identified herself as a lay member whilst the other, a pharmacologist did not. In relation to the study reviewed (which was a psychiatric study), neither was 'expert' and yet there seemed to be an unspoken hierarchy here of lay simply meaning 'not medical' or not or 'not medical enough.' I am not suggesting that the status of members is a problem for RECs and the ways in which they operate. There did not seem to be a standard way of allocating applications for review. Particular expertise was valued but there was also an acknowledgement of the value of a breadth of experience. However, the lay issue was not seen as straightforward.

> JM: How do you go about allocating applications?
> Chair: Well the REC managers allocate – they sometimes consult with the Chair. We assume that by the end of a year all members can review. It's fairly indiscriminate. Lay members are included. And all MCA (capacity) applications are included. There's no difference in allocation. There used to be someone we used a lot for capacity studies because he developed an interest – but he wasn't a psychiatrist. Most of the committee can deal with most of the applications.
> JM: Can you describe what lay means?
> Chair: Well it's tricky to define- have you seen the 'lay-plus' issue?
> JM: Does lay mean 'not medical' – that's what a coordinator explained to me.
> Chair: Yes, that's probably it. I am lay because I'm not a medic though I worked for the NHS. We have a retired teacher who is 'lay-plus'. We had a barrister who was lay.
> **Interview with Chair: REC H**

Lay members may be valued and included in allocation but this question of what lay membership is, is significant. What is unacknowledged is the dominance of medicine and scientific concerns. The official discourse is one of openness and the aim of wide membership is indicated by the 1/3 lay membership. However, by terming members as 'lay' the issue of dominance of certain professions (usually medicine) is not addressed. The implications of this are that there is a model of research review in which there is a privileging of quantitative and positivist research (especially medical) at a time when NHS ethics review is being extended to all kinds of research. Again, I am not concerned with identifying negative attitudes among reviewers (for example towards their 'lay' colleagues or to qualitative research). However, there is an important point here in this unravelling of lay and expert. The very idea of 'lay' implies that there is a pre-existing 'expert' version of what research really is. Currently, that expert version is predominantly medical. This is an example of what Smith terms 'relations of ruling'. Overarching ways of understanding about

what constitutes science and research are embedded in official discourse, in documentation, in web-based information, in the 'rules' adhered to in committees. To extend this analysis, lay membership also seemed to me to be required in order to show evidence of objectivity. The HRA may attempt to draw on a diverse range of backgrounds in the RECs. The co-ordinator who I interviewed about this said that in practice lay often simply meant 'not medical'. Given this dominance and the fact that RECs (particularly flagged for capacity RECs) need to review all research whether medical or not, the lay issue becomes crucial. The theory informing institutional ethnography would suggest that the settings investigated are organized and ruled in definite ways (Campbell and Gregor, 2008). Examining the detail of connections between people in the setting and across settings is important in helping to establish links and highlighting relations of ruling. This means that a critical analysis of this practice of appointing membership and apportioning who is counted as 'lay' would lead to a questioning of the purpose(s) of this practice and raise questions about why committees ae constituted in these ways. I propose that the lay membership issue is crucial in demonstrating objectivity. Objectivity can be referred to here as a 'ruling concept'. What I mean by this is that objectivity is a powerful concept with an extensive reach. 'Objectivity' seems unproblematic – who would not want an objective review system? Further, the players themselves repeat that lay contributions are valued and imperative in decision-making. Yet the everyday working out of who is lay or not is at the same time complicated and practical. In the end, decisions are made as the RECs 'work with what they've got' on the day of the meeting or who REC coordinators know will be attending. It seemed important to all those interviewed to point out the lack of a formal hierarchy. However, the hierarchies were present but unacknowledged. Again, institutional ethnography assures us that settings are organized and ruled in particular ways which might not be fully acknowledged and realised by participants.

6.7 Participation - who talks in meetings?

REC meetings are large. It was difficult to keep track of membership categories and it was extremely difficult to keep pace with the discussion. However, in my observations, I kept note of who spoke and the frequency of interactions between members. I did this in my observation notes and by small sketches. In fact, discussion invariably only included a minority of members.

'The alternative allocation case'

RECs I observed appointed two reviewers. However, there was one exception to this in the sample. REC D was different and did not appoint two lead reviewers. The justification for this was that all members had read the application and therefore committee members were more familiar with it.

> She said that their approach had not been encouraged by NRES. However, she had checked this out many times with the committee and they see advantages to adhering to this approach. However, my perception was that the committee meeting had still been dominated by two members in particular though this might have been because they had most relevant experience. However, there was a lot of discussion and debate in this committee and it seemed a more collaborative process. The Chair was inclusive and checked back with the committee asked questions for clarification as they went along in their deliberations.
> **Field-notes extract: REC A**

When I interviewed her, the Chair was evidently proud of the way the REC managed reviews.

> Our decisions are negotiated. We are asked each year (by NRES) if we want to change our system. There are only two RECs in the country which operate the way we do. I always ask the committee but we don't want to change. New people are encouraged to participate.
> **Interview with Chair: REC D**

This was supported by one of the committee members I interviewed: 'We gel as a team. There are no dominant members and we have a good Chair.'

In order to examine who spoke and who was involved in discussions in RECs I have reproduced the turns taken at meetings to speak and who spoke in the tables below. The following is a comparison of a meeting where two lead reviewers are appointed to review and the REC where lead reviewers were not appointed by the Chair. These have not revealed a great deal of difference in how many people contribute to the discussion and in fact show some important similarities.

Table 12: Participation in meetings

REC E Two Lead Reviewers appointed	
PRELIMINARY DISCUSSION Chair-LR1–LR2–LR1-LR2-PMA-LR1-LR2LR1-LR2-LR1-LR2LR1-LR2LR1-PMB-LR2	5
RESEARCHER ENTERS WITH R&D LEAD Chair-L&DLEAD-LR1-RESEARCHER-CHAIR-LR1-PMC-LR1-RESEARCHER-LR1-R&DLEAD-PMC-R&DLEAD-LR1-PMC-LR1-R&DLEAD-LR2-RESEARCHER-LR2-LR1-RESEARCHER-R2-RESEARCHER-PMC-RESEARCHER-PM3-RESEARCHER-LR1-RESEARCHER-CHAIR-PMC-LR2	6
RESEARCHER AND R&D LEAD LEAVE	
DISCUSSION LEADING TO DECISION CHAIR-PMD-LR1-CHAIR-PME-LR2-CHAIR-LR1-PME-PMF	6
DECISION MADE	
REC C No Lead Reviewers appointed	
Chair-PMA-PMB-PMC-PMC-PMA-PMB-CHAIR-PMA-PMB/PMA-CHAIR-PMA-CHAIR-PMB-PMD-CHAIRGROUP RESPONSE-CHAIR-PMA=CHAIR-PMB=CHAIR-PMB-CHAIR-PMA-PME-PMB-PMA-PME-PMB-CHAIR-PM1-PMF-CHAIR Agreed that questions to go through PMA	7
RESEARCHER ENTERS	
CHAIR-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-CHAIR-RESEARCHER-CHAIR-CO-ORDINATOR-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-PMB-RESEARCHER-PMA-RESEARCHER-PMA-RESEARCHER-CHAIR-RESEARCHER	5
RESEARCHER LEAVES	
CHAIR-PMD-PMB-PMA-PMB-PMA-CHAIR	5
DECISION MADE	

What the above table shows is that a small number of people are generally involved in debate. There was little difference in the number of people included in the discussions in these RECs so that the allocation or non-allocation of lead reviewers was inconsequential. It did not lead to participation by a greater number of people. It does reveal that the **same** members tended to dominate discussions in RECs whether lay or not.

6.8 The importance of the researcher discussion

What the above analysis does reveal is that the most frequent and longest exchanges are generally with the researcher. Even though the same dominant members might be speaking, there is a lot of checking out, allowing time for the researcher to clarify points, explaining their research.

The following extract shows a typical exchange. The study compared women who had recently given birth who had mental health problems. The comparison was between women treated at home and those treated in a Mother & Baby Unit. The readmission rates to hospital were to be compared. In the preliminary discussion, the Lead Reviewers (LR 1 and 2) were concerned about the number of questions in the questionnaire and the intrusive nature of the questions. They also had concerns about anonymity given that interviews would be videoed.

Extract from observation notes: REC D

Who	What was said	What is happening
LR 1	The paperwork says that the videos wouldn't be identifiable – how can this be the case?	
Researcher	They will be anonymously labelled….	Unclear response
LR1	If you don't know then say.	Aggressive tone?
LR1	Is supporters a new word for carers?	
Researcher	Well people don't want to be called carer – they are wives, husbands etc.	
LR2	What about upsetting people? The questions are intrusive (have you been sexually abused, have you experienced domestic violence?)	
Researcher	We say that we are trained (psychologists) and we will stop if needed.	
LR2	The Information Sheet talks about you referring to regulatory authorities if needed -people worry – do you mean the Benefits Agency? Police?	
Researcher	We are taking that out.	

This was a back and forth checking with the researcher about design and purpose. This was in order to establish that the prospective research was going to be 'good science', 'good research'. The reviewers were also engaged in 'protection' work. This was a common theme and was where reviewers challenged researchers about the anonymity or confidentiality principles of intended research.

What this told me about the RECs was that the interview with the researcher was of paramount importance in checking the worth of the research. This is the subject of lengthier discussion in the next chapter and relates to the sense that RECs have of preserving 'good science' and the idea of the 'virtuous researcher.'

The 'checking out' was of the integrity of the researcher was of paramount importance. I want to draw attention here to the prevailing concept of 'good science' and how this was worked up in the meetings and checking the integrity of the researcher in the next chapter.

6.9 Sequence of meetings

The sequence of events at the RECs was important in that decision-making was managed and achieved. Committee members move from one focus to the next in considering each application. This can be shown as three stages:

Stage 1	Discussion of application by the REC
Stage 2	Interview/discussion with the researcher
Stage 3	Discussion leading to decision

This sequence supports the achievement of the business. Sequencing enabled:
- Disagreement to be managed
- Outcomes to be achieved
- Containment of the discussion

The organization of meetings could seem chaotic at times. There is so much business to get through and researchers arrived early or late and so on. However, the sequence above coordinated the work of the meetings. Beyond this local co-

ordination though lies another kind of co-ordination or ruling. Smith's idea of 'ruling relations' provides a way of viewing this sequence as the ways in which texts (requirements) are ways in which work can be coordinated across sites. 'Relations of ruling' may be described as forms of bureaucracy, administration and management which also include,

> '...the complex of discourses, scientific, technical, and cultural, that intersect, interpenetrate, and co-ordinate the multiple sites of ruling.'
> (Smith, 1990:6)

The concept of 'ruling relations' describes the ways in which people's everyday work is coordinated and influenced. Of course, when Smith referred to 'multiple sites' she was not referring only to multiple sites in the way in which I am referring to them. She was talking about extensive sites of activity for example in a health domain sites might include networks of clinics, hospitals, pharmacies. Here I use sites in a limited way to mean the local RECs because this idea assists in making the point that meetings followed certain patterns in order to accomplish the business of ethics review. Each group of members was different but was committed to the same expectations. I want to next explore the relationships between the everyday ways in which committees made decisions and the official 'texts' in the form of requirements. I will go on to explain later in the thesis how overarching understandings of ethical principles found in texts co-ordinate and limit the ways in which we think about ethics.

People activate 'texts' (Smith, 1999) but the overarching texts produced by the Health Research Authority as procedural requirements also co-ordinate the action at committees. Each REC was different but each REC followed the sequences I have described. This enabled the work to be done. There was room for debate but the debate was brought to a decision which was shaped by the procedural requirements. The requirements for review or what happened at the REC are not published anywhere as a sequence. Applications are reviewed, researchers are welcomed and encouraged to attend. Apart from this there is nothing officially written about what should take place in the meetings and yet the sequence described above was followed in each of the nine RECs I observed.

The sequence itself is influenced by the requirements set out in the governance framework. It ensures that RECs can be seen to have observed protocol and objectivity. However, this objectivity is somewhat superficial as RECs are idiosyncratic, use judgement and discretion when making judgements. This can be seen in the following section about review outcomes.

6.10 Outcomes

I did not observe any committee declare an application unfavourable. However, I did not observe any applications being given favourable approval. All outcomes were favourable with conditions. What does this suggest? At the very least this means that research was influenced, changed in some way at the anticipatory stage. Whether this means the research needed to be substantively changed or superficially changed in order for the application to comply with requirements could only be accurately reported on by studying the letters sent to researchers and this was beyond the scope of the study. However, from observations it appeared that many suggestions referred to wording on forms to clarify information provided to participants.

An example of how incidental or random (as opposed to objective and consistent) decisions could be was illustrated by REC C where a decision was seemingly completely reversed. This meeting was reviewing a study which intended to track health outcomes for people with a condition similar to Downs Syndrome over a period of contact with services. The Chair had acted as one of the two lead reviewers.

> Lead Reviewer: I gave up the will to live with this one. The researcher hasn't got a grip of capacity. They would need a lot of help. I think it's a reject. No effort has been made to become aware of capacity issues.
> Chair: There is an association with Downs and because of this, some people may lack capacity or lose capacity during the course of the study. There are no ethical issues with the study but a lack of understanding of the Mental Capacity Act. Arrangements to comply with section 32 and 33 are not there. They need to think about role of consultees – no person can consult for another adult in English law – the consultee can only give an opinion Arrangements will have to be made to comply with the Act. Also, the participant could have capacity and then lose it – consent doesn't survive the loss of capacity. They need to think about what happens if the research

participant loses capacity. We need information sheets and consultee information sheets.

It's a provisional or reject depending on the researcher response. It is permissible but the execution of the application is hopeless.

Extracts from observation notes: REC C

However, when the researcher came in, the Chair's language was more conciliatory. He said that there were 'no problems' with the study but that there had been difficulties in the execution of the application. The researcher (a doctor) and nurse who accompanied her were asked lots of questions for clarification of the purpose of the study and about capacity.

Chair: I think it's permissible under the Act as you couldn't carry out research like this on a group who didn't lack capacity.

Researcher: We aren't doing anything outside of what we would do clinically. We want to keep the information on the health difficulties of people – the aim is to get early help to people.

Following a discussion of the details of consultees with the researcher, this resulted in the decision being 'provisional'. This

Chair: Having met her, I'm swaying to a provisional opinion.

One committee member suggested this change was because the researcher was inexperienced. The Chair maintained that he had been convinced that she was a naive researcher who need a lot of advice and suggested a detailed letter be sent indicating everything which need to be included in the application. At this impasse, I was feeling uncomfortable. However, another committee member who had been silent said:

The outcome won't change whether it is a provisional or a reject – she needs to do it again whatever.

Extracts from observation notes: REC C

(Of course, the correct terminology is favourable, favourable with conditions or unfavourable – not reject). This was true but made me wonder then why any applications should be reviewed as rejected. Even if a study is given an unfavourable decision, there is generally an expectation (and encouragement) that the researcher

will make another application. This exchange is significant because it demonstrates how important the presence of the researcher is. If the researcher had not turned up (and she was very late, but still accommodated) the outcome would certainly have been 'unfavourable'. In the end the application still has to be correct – but a further question is how the application can reflect the practice of the research. Everybody agreed here that this was a naïve researcher who would need a lot of assistance and detail to help her in her re-application. There were no concerns expressed about whether this naivety would be problematic in the field. My observations concluded that RECs make judgements based on pragmatics. This extract evidences a stark example of that. The application which has to demonstrate adherence to abstract principles and rules was clearly a disaster in this case, but the judgement in the 'here and now' of the REC business was that the research (and researcher) were worthwhile and the research should be supported.

The HRA portrays research governance as officially as well as legally sanctioned with the REC as central to a controlled and efficient system. The above extract provides insight into how discretion is an important factor in decision-making. There is discretion over rules. The application and the understanding of capacity requirements may have been inadequate but the committee viewed the research as important. They were convinced in this by worth of the research but also the researcher. There is a careful balance between discretion and procedure. The committee member comment, *'The outcome won't change whether it is a provisional or a reject – she needs to do it again whatever'* was interesting. The point was being made that extensive changes to the application were needed – the application could be either a reject or a favourable with conditions. The committee needed to see the application again. The fact that they did not reject the application signified support and approval. There were no ethical issues the Chair had said – but the paperwork had not demonstrated adherence to requirements. This balancing between rule adherence and discretion is significant in decision making of the REC. I go on to show how this can also be viewed as a tension between *judgement* and *decision*.

6.11 Conclusion

This chapter has provided an introduction to the mapping of ethics review. It has been an attempt to invoke the atmosphere of the RECs as well as to describe how I

saw the committees at work. Inevitably, and in keeping with an ethnographic approach, there were a number of stories which could have been told, a range of matters which could have been deemed as significant. What has been presented here is what I viewed as important and was part of my 'knowing about' committee meetings. I have focused primarily on the processes and composition of RECs before turning in the next chapters to judgement and decision-making. I have emphasised reflexivity throughout the thesis and in this chapter, my portrayal of the reality of meetings has been an ongoing constituting of a particular reality or way of seeing RECs as well as describing them. Though I have not adopted an ethnomethodological approach in this research in that the emphasis is not on the formation of language, Garfinkel's 1986 writing on the ethnomethodology of work (co-authored with Harvey Sacks) has resonance here. He showed how mundane, common sense actions reveal an order that is recognizable to other members of the same organization and in the same situation. The argument is that even the most mundane of practical actions have observable structures (Rawls, 2003). Furthermore, any population can reproduce a scene by reproducing the recognisable practices that identify it as a scene of a particular sort. I am arguing here that the sequencing of work in the REC - provided a familiarity of process and assured members that they were involved in or a part of an overarching system of review. There was also shared language across committees, 'good research', 'good science', 'good design' and so on which members of the REC use as a short-hand. I discuss this in more depth in the next chapter.

This recognisability of terms is how words, actions and discussions about applications were made meaningful. Therefore, despite the RECs being disorganized at times and idiosyncratic, there is a typology which is familiar to all members, in all committees, which is a shorthand way of achieving the practical business. This mitigates against the differences in RECs so that is not necessarily a problem that the committees are not the same or that they do not all operate in the same ways. The sequencing described in this chapter also serves an important purpose. It helps to support an idea of accountability, what Hammersley (2010) has referred to as 'transparent accountability regimes', even if this is in fact illusory. Hammersley contrasts these accountability policies with the alternative of trusting professional researcher judgement.

> *'The fact that, generally speaking, these policies have failed to achieve their goals – and have, generally, undermined good practice and commitment to it – does not terminate belief in the driving ideology. People want to believe that accountability procedures work, because they find the alternative – trusting professional judgment – unacceptable'.*
> (1.9)

Each REC's membership is quite accidental so decisions are made based on the accumulated expertise of the membership on the day and each REC's make-up might be different. The decision that is made ultimately is not an objective decision but one based on who makes up the REC and who the researcher is. Allocation of applications is accidental in that it is very much up to the Chair's discretion with no absolute clarity about this among REC members. REC which did not allocate two lead reviewers showed that this did not necessarily increase involvement. In fact, few members actually contribute to discussion. What I am arguing here is that the RECs are far from objective but they are seen to be accountable because of the ways in which they are driven to function but also by the constraints set in place by the sequence of work. However, what my analysis also revealed was that the exchanges/interaction with the researcher was important in the decision.

Consensus is worked up to and the sequence of events I have outlined supports this. Decision-making is part of a process of 'incremental activities with many intertwined steps' (Halvorsen and Sarangi, 2015: 3). The sequence provides a practical way of making sense of the study and reaching a decision. The mapping of who contributes to discussions indicates that this is negotiable and dynamic within the constraints of the meeting. Far from being excluded from this process, the researcher exchange is crucial and what can be seen in this analysis is that the most exchanges between people occur when the researcher is present and s/he is included in the debate. RECs are generally viewed as being divorced from the real world of research with the process of review regarded as a tricky hurdle. However, all RECs I observed and reviewers whom I interviewed were positive about researchers attending. In fact, they saw it as helping them to make sound decisions. Though it is true that RECs cannot ensure ethical research practice (their influence ends after the REC), Guillemin and Gillam (2004) have suggested that there is a continuity between the procedural and 'ethics in practice' paradigms. Though a researcher's ethical practice only comes to the fore in the domain of practice, they have argued that the

procedural process can enhance practice in the field because researchers are required to think through potential challenges. The values and principles which inform procedural ethics are not radically different from the issues which arise in the doing of research. They are arguing this in the context of criticism of the extension of biomedical approaches to qualitative research. However, as I have previously argued in the thesis, some of the criticisms (about bureaucracy and consent for example) are made by biomedical researchers also. The analysis of data in these findings is that RECs are not so fixed or closed-off as might be thought. They are to some extent permeable. They welcome researchers and by doing this engage with some of the challenges of the doing of research. In addition, much of the debate and subsequent questioning of researchers is about the research, its design and achievability and it worth as 'good research'. Far from trust in professional judgement being 'unacceptable' as Hammersley claims, it is of central importance in the decision-making within the REC.

Finally, the lay membership is a crucial factor in determining the 'bias' and 'orientation' of RECs to a biomedical approach. There is a dominance of medical members and there is a familiarity therefore with quantitative research and a tendency to see this as proper research. However, lay members did make a significant contribution in the REC. Time was given to their views and they opened up debate. The next chapter will deal with how REC members felt about their role and explores further the abstract ways in which committees make sense of abstract ethical principles. I look at some of the strategies employed by the REC to make sense of requirements. I then explore in more depth, the extent of reliance on texts (procedures) especially in relation to consent and capacity in more depth.

Chapter 7: Making judgements – subjectivity at work in ethics review

7.1 Introduction

The previous chapter looked at the day-to-day working *processes* of the REC and how there were routinized ways of doing the work which were reproduced across sites. The shape of the meetings, the ritualized actions, talk and behaviours co-ordinated the work that RECs did and I argued that this assisted the idea of objectivity. This chapter continues the approach of describing and analysing the day-to-day work of the REC showing how the work is achieved through both practical and subjective means. By practical, I mean being pragmatic and using information and knowledge available to members on the day. By subjective I mean the ways in which committee members engage with the research applications, engage with each other and with the researcher. This chapter draws primarily on observations and interviews seeking to elucidate how judgements are made about research applications. The discussion is concerned with judgements rather than decisions, but this is not to suggest that these are discrete actions. The subsequent chapter on texts explicates in more detail how decisions are worked up in the REC with reference to how the procedures are used in practice. Smith (2006) described ethnography as a 'process of investigation, of a progressive discovering, and assembling what you've got as a base from which to move to investigating further;' (p5).

This chapter forms the next part of that 'progressive discovering' and emerged from spending time at RECs, getting familiar with the concerns of reviewers and researchers – being 'immersed' in ethical regulation. It is about objective and subjective ethics work as it happens in the REC meetings. It exposes some of the tensions between concrete procedural matters and the more prosaic and subjective ways in which committee members make sense of applications. The discussion seeks to provide an account of some of the ethical, moral, personal and emotional reactions to research applications which were reviewed. These were often tacit ways in which judgements were made. RECs are faced with having to make sense of applications in the immediacy of a time-limited meeting. Their work is bound by sets of procedures and principles which they have to work within. There was a tension between the outward demonstration of and need for objectivity in ethical regulation

systems and the practical, subjective ways in which applications are discussed and judgements made about them. My intention is to deepen insights into the everyday ethics work of RECs and reveal some of the real-life discussions and practical, connected ways in which ethical regulation actually works. Much of the deliberation leading to decisions was based on the 'ad-hoc' and practical (see Coulter, 1973 in the methodology chapter) sense making of the applications. Coulter proposed that in making psychiatric diagnoses (making decisions) that psychiatrists were not objective but were making judgements. These judgements were social and moral and once made, evidence of symptoms and so on would be made to fit a diagnostic category. In the meetings I observed, I am arguing that reviewers' decisions were based on their *judgement* of the application and *judgement* about the researcher. My own 'making sense' and attempts to map what was happening during observations and what was said in interviews was not immediately apparent as so much of what happens in the REC is clothed in bureaucracy. However, when coding the data, there was a dimension in the decision-making process and REC deliberations that cropped up again and again. This dimension went beyond a straightforward application of requirements to an application and encompassed a range of expressions in interviews of duty, trust, moral obligation, emotion and engagement. Closely linked to this was another frequently occurring theme which I coded as 'good science' which described how the REC had to be satisfied of the worthwhileness of the study under review.

Much of the chapter, in keeping with an ethnographic project, shows how work 'happens' where it happens, the ways in which committee members bring review to life, how they make sense of applications and how their judgements are shaped. Much of what I observed and talked about to reviewers was 'tacit'. What I mean by this can be explained by referring back to the methodology chapter.

> *'Hidden assumptions and meanings guide individuals' actions whether or not participants explicitly say so. However, the significant role of tacit knowledge transcends the immediate surface of speech, texts, or discursive materials. Accessing tacit knowledge takes significant time in the field. The longer researchers are present and closely watching, the more likely they are to notice a culture's values.'*
> (Tracy, 2010 p 843)

Tacit knowledge by its nature is not explicit, it has usually become so familiar that it can be difficult to talk about let alone access. Tracy argues that a criterion of quality for qualitative research is revealing tacit knowledge by showing rather than telling. What I am referring to as tacit is the discernment shown by the committee members, the ways in which they draw on their own moral frameworks to judge research. These shaping practices are not clearly articulated but are tacit in how the committee members make judgements and arrive at decisions. As I spent time observing and listening, I was able to identify REC values. My observations revealed an engagement with the process which went beyond adherence to ethical frameworks. The quotation above explains that the identification of tacit knowledge requires the researcher to go beyond the surface and notice values. The ways in which reviewers engaged with research applications are described under the following headings in this chapter.

- Doing the right thing
- The importance of 'good' design – worthwhile research
- Trust in the researcher
- A moral dilemma 'case'
- Uncertainty and ambiguity about the role
- Situated ethics review

A range of ideas (from Wiles, 2013 (intersections of understandings); Chambliss, 1996 (gap between abstract professional codes and practice); Banks, 2015 (ethics work)) have informed this 'discovering' and my interpretation of what was unfolding. These are briefly described before presenting an analysis of the findings as set out above.

7.2 Intersections- ethical frameworks and individual moral frameworks

Rose Wiles highlighted that there are significant influencing factors in ethical decision-making in research practice. Wiles (2013) describes the factors shaping ethical decision-making in research, which are represented diagrammatically below. She argues that an understanding of these can assist researchers in ethical research. While these influence researcher decisions in the practice of research I would argue that these also of course influence the ethical regulation of research, those making decisions *about* research. I observed how these influencing factors shape decision-making in ethical regulation itself. These were apparent in the

observations of decision-making of the REC and also were revealed in interviews with reviewers.
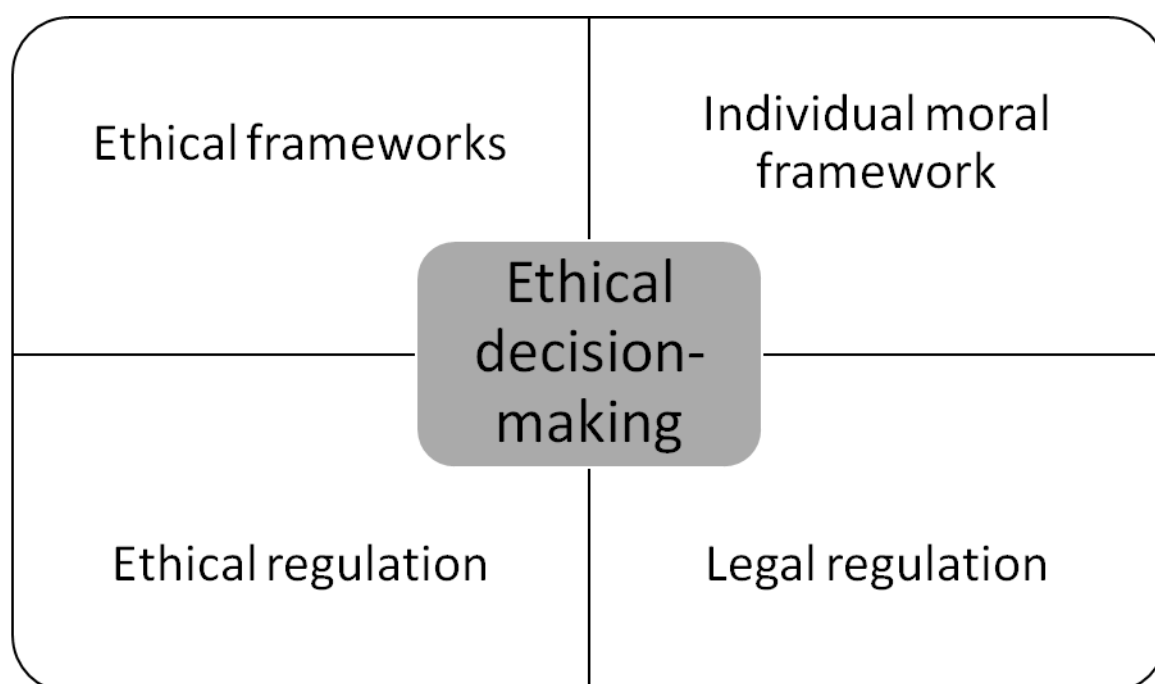
Figure 1: Intersections

Wiles discusses how these elements interact and overlap in a researcher's ethical decision-making. In this chapter I want to focus primarily on the components Wiles describes as 'ethical frameworks' and 'individual moral frameworks' and examine how these interacted and 'worked' in review in the decision-making and judgements of reviewers.

7.2.1 Ethical frameworks

When I refer to individual moral frameworks, I am thinking about people's morality in a broad way. I am referring to people's sense of doing the right thing. Committee members sometimes seemed to me both in observations (though perhaps more in interviews) to come 'off script'. They were expressing their motivation for being involved or explaining how they reached decisions which were unconnected to codified research ethics but rather connected to what they were presented with on the day. I refer to ethical frameworks as distinct from the individually driven frameworks committee members may draw on (specifically here the frameworks which inform ethical regulation). These are also used by RECs in the *deliberate* reflection on moral beliefs which are applicable to the specific cases reviewed by the REC. The formal regulation of research can be viewed as a *codification* of moral

principles. These moral principles are often referred to in the context of biomedical research as beneficence, justice, non-maleficence and autonomy (Beauchamp and Childress, 2013) and discussed above in 3.10.5. Their text set out a framework of prima facie principles. These principles inform the making of judgements in the REC. This is because although there may not be specific and explicit training on the principles for members, they are nevertheless highly influential and (explicitly and implicitly) inform discussions. To illustrate this point, the Integrated Research Application System (IRAS) which comprises the forms, a selection of which are required for each application's specific requirements, summarises the Core Study Information under the following headings:

- Overview of research

- Purpose and design

- Risks and ethical issues

- Research procedures, risks and benefits

- Recruitment and informed consent

- Confidentiality

- Publication and dissemination

These are the areas which the applicant is required to address and which are the subject of review by members of NHSRECs are informed by the Beauchamp and Childress principles. The small set of concepts in Beauchamp and Childress's framework, has been critiqued as a paradigm which is 'widely interpreted and utilized by bioethicists in ways that border on intellectual and moral absolutism' (Fox and Swazey, 2010:278). Fox and Swazey also discuss the hegemony of these principles which are not seen as culturally specific (to the west and in particular the Anglo-American tradition), but universal.

However, though I am arguing that these principles are influential, even dominant, they are not necessarily fore-fronted in reviewers' thinking. So, as will be seen, the principle of non-maleficence may be the overarching principle at stake when reviewers questioned researchers about potential risks to participants, but their

concern was not simply derived from a rational need to consider that moral principle but from a subjective, genuine concern about participants.

There is then a balance here between an ethical framework which informs review and individual 'moral' feeling.

7.2.2 Moral dilemmas and (professional) codes

The gap between subjective ethics and abstracted ethics has been articulated in the context of professional codes and requirements. Chambliss (1996) through an examination of professional nursing codes of ethics, illuminates the limitations of codes of ethics. He referred to the 'social organization' of ethics in nursing in 'Beyond Caring: Hospitals, nurses and the social organization of ethics.' His concern was with the consequences of professional codes of ethics, specifically in nursing. He argued that ethical codes were conjured by remote and powerful decision-makers at some distance from the everyday practicalities which nurses faced in their day-to-day work. The codification of moral values becomes hypothetical, unreal and abstract. Parallel to this, requirements in the review of research also become abstracted from what the reviewers have to do to make sense of applications in the here and now of a committee meeting. What particularly interested me was that Chambliss claimed that the codification becomes intellectually challenging, overly legalistic and 'abstracted' from moral dilemmas in the here and now. Though Chambliss was referring to the United States and the profession of nursing, this resonated with my interpretation of what happened at the REC. At times members became absorbed in the intellectual challenges of interpreting the regulations generally and (the focus of my inquiry) the interpretation of the MCA 2005.However, in making sense of applications, the ethical requirements were often of limited value. Committee members often went back and forth between what ought to happen according to the ethical requirements and what practically needed to happen in order to get a study through review to a favourable decision.

7.3 'Ethics work' – a perspective for understanding what reviewers do

In recent work on professional wisdom, professional ethics and ethics work, Banks (2013, 2016) has described her developing concept of 'ethics work' which has been useful in illuminating the activity of the REC. Though the first part of her paper is concerned with the increased level of accountability in the professions, specifically here, social workers (a discussion which is also relevant to ethical regulation) Banks describes ethics work everyday practice when social workers encounter dilemmas or problems and outlines a mapping of what ethics work might comprise. The important elements of this which I view as relevant to ethics work in the RECs are the notions of performance of 'doing ethical regulation'. Banks describes performance as making visible ethics work and demonstrating oneself doing ethics work. This is part of being accountable and is of course highly relevant to ethical regulation as there is an external and accountability aspect to it. I have also argued in the thesis the need for the work to be 'transparent' which is important for the HRA to assure/reassure the public that research is regulated and scrutinised. REC members do this in part by the performance and rituals of the REC described in the previous chapter, but also by demonstrating that they are 'moral' and so on. That being the case, there is still significant work which takes place in the REC which may be usefully described as ethics work, specifically,

> *'the effort people put into seeing ethical aspects of situations, developing themselves as good practitioners, working out the right course of action and justifying who they are and what they have done.'* (Banks, 2013: 600).

This notion of 'ethics work' is a helpful way of understanding the findings presented in this chapter. The following discussion illustrates how committee members engaged with research applications, how they drew on moral feelings and responsibility in making decisions, how they moved back and forth in RECs between *making sense* of the studies brought to them for review and making *a fit* with the codified moral principles in the form of the ethical requirements in ethical regulation, justifying their decisions.

Committee members arrived pragmatically at decisions regarding approval of research within the restricted (in time, in the form of meeting) context of a REC. As I explain, decisions are based in review on all sorts of factors which then have to be

justified in a practical and efficient way. REC members drew on personal moral frameworks, values, emotions and hunches when making judgements, deciding on the right course of action. What is absent from the influencing factors described above and adapted from Wiles (2013) is the role of emotion or feelings. More difficult to describe and more tacit, they are nevertheless highly important. This chapter attempts to show how these factors interact in ethics review and some of the tacit knowledge employed in decision-making - some of the means which drive the judgements made. So, in this chapter I want to turn to the content of the meetings. During the nine observations, the pace of decision-making was fast. The discussions and deliberations were sometimes difficult to keep up with but I have faithfully reproduced them in part or whole in the following chapters. If I had expected bureaucratic and formal discussion this was confounded quite quickly. Members' own personal moral frameworks permeated the discussions I observed and were also evidenced in the interviews. I initially coded these aspects 'moral dimension'. This was an attempt to categorise what was happening in the discussions; the 'something beyond the requirements' that members drew on which influenced their judgement.

Another term for this would be an individual's own sense of 'doing the right thing'. Policies and requirements rule what happens regarding each application. What happens conforms to the expected course of action (described in the previous chapter) and yet committee members' decisions were often based on personal experiences, emotional responses. Principles (such as beneficence and maleficence) are weighed up in the balance to reach a decision. However, this did not mean that there was an objective use of principles and I would argue that the practical achievement of the work of the REC was achieved partly through subjective means.

7.4 Doing (feeling) the right thing – 'is this okay?'

My field-notes recorded the concern of members with sensitive and moral questions about research. I commented in my notes on how much of the REC discussion was outside of the constraint of requirements and more open questions were raised such as:

Is it right to? Should this happen? What is the purpose?

During interviews, committee members often spoke with reference to their own values or moral frameworks. The following is from an interview with a lead reviewer. The study which had been reviewed was a pilot pharmaceutical study which aimed to make a comparison of a new regime which would entail hospital pharmacists taking over medication as soon as the patient was admitted to hospital from A&E. Some patients may have been unconscious or unable to consent for a range of other reasons which had brought them to A&E. Much of the discussion at the REC meeting was with concern for the control group who would receive pharmacy protocols *'as usual'.* The lead reviewer described himself as lay.

> JM: What factors do you consider in relation to capacity?
>
> LR: The REC guidelines are difficult to keep in mind - I'm a lay member. I ran a motor company. I try to keep in mind what could go wrong for the patient, I try to be creative in my own mind and (I) asked the question what's the worst that can happen?
> In this study if I was incapacitated would I want this to happen? And if I would want it, are there other reasons why someone would not.
> My gut reaction is – is this okay?
> **Interview: Lead Reviewer REC A**

This extract shows how the member drew on personal values in decision-making. The regulations are 'kept in mind' But in order to make moral sense of what would happen in the study, the committee member asks questions of a personal and emotive nature – would I want this to happen? Are there reasons why someone would not? This demonstrates how judgement is at the same time abstract and practical. The ethical requirements are a logical framework, an ethical framework. The committee member is faced with a real situation. The research will involve things happening to real people who are brought into A&E for all sorts of reasons. Some of these people may be unconscious and therefore lack capacity so the committee member is questioning how he would feel if he was included in this pharmaceutical trial at a later date, if he was unable to consent on admission.

Another interviewee demonstrated how committee members think themselves into a situation in order to understand the ethics involved.

> JM: Do you think anybody is particularly vulnerable in research?

PM: in prison studies. It's difficult to see how things play out in context. There is an opportunity for coercion. To think of context, you might be years as a prisoner. But it's hard to imagine myself in that position. (There is the) possibility therefore of skewed results and how can prisoners hope to benefit from the research? These studies require harder thinking.'
Interview with PM: REC B

Individually held values influenced their thinking – this committee member is not saying that research should not take place, for example, in prisons, but that these studies require him to 'think harder'. Ethical principles of 'beneficence' and 'autonomy' are informing his decision making but he is also thinking about context and imagining himself in the same position as a prisoner being researched. Therefore, the judgement which informs decision-making may be located in practice somewhere at the intersection of ethical principles and individual morality. This is above all a practical activity. When I refer to individual moral frameworks, I am thinking about morality in a broad way to describe those feelings and comments expressed by committee members which were unformulated and unconscious. In other words, committee members sometimes seemed to me both in observations (though perhaps more in interviews) to come 'off script'. Their responses to research applications were sometimes emotional or personal and not connected to codified research ethics.

Take this example of an observation which was then followed up with a reviewer of the study. Here I reproduce an extract from my observation of REC B and then an extract from my subsequent interview with the lead reviewer. Taken together, these illustrate how the REC has to ensure it not only meets but also can be seen externally to have met the requirements while committee members may at the same time feel moral obligations which lead to uncertainty about decisions. (External scrutiny is possible because the requirements discussed are minuted and later the co-ordinator composes a letter to the researcher with details from the minutes).

The study being reviewed was exploring use of a novel method of communication with people in a nursing home who had dementia. The committee members began by trying to understand the study and asked about capacity.

Researcher: It's unlikely that they could consent as they have severe dementia and functional communication is a problem. I would check capacity.

Lead Reviewer: Capacity could change day by day.

Committee member 1: Perhaps the work you do could help people regain capacity?

Researcher: I don't think so it's not about regaining functional communication but emotional…

Committee member 2: is it about feeling better?

Researcher: Yes. It's not focused on functional communication.

Lead Reviewer: summarizes the study again – saying it's a new method of communicating

Researcher leaves

Chair: Are we satisfied?

Good – yes, it's good. It's not just the paperwork, it's her attitude.

Co-coordinator: It has to be in line with the Capacity Act.

She reminds the Chair of the key requirements outlined on the checklist.

Extract: Observation REC B

Following this was an interview with the Lead Reviewer.

JM: Were they any concerns you had in relation to consent and capacity?

Lead Reviewer: Yes. Had the researcher fully appreciated diagnosis and prognosis? She still needs to make an assessment in relation to capacity though in advanced dementia, the chances are that realistically, capacity wouldn't be there.

She wanted to get the best form of reaction they could when using this new form of communications. She wanted to know if they were more settled, whether they smiled

People can be very isolated. There may be processes going on that we don't know. It's a great sadness.

Interview extract REC B

Understanding the design of the study meant getting to the heart of what the research might mean.In this case, a form of communication which may make life calmer, or at least less frustrating for people with dementia. So the reviewer is thinking about potential benefit to current participants and future patients. The panle member's comments about isolation and 'great sadness' reveal an empathetic perspective using emotions to connect to applications. These feelings and emotional reactions may have been unconscious during the process of decision-making as it was happening tin the REC. However, there was also a more conscious reflection on values or beliefs.

7.5 Moral responsibility – 'it sounds pompous, but it's our duty'

Interviews with reviewers revealed evidence of a morally reflective attitude in most reviewers and in some cases a sense of moral obligation or duty. In an interview with an experienced reviewer, I asked how he considered capacity and consent in reviewing a dementia study where the researcher was undertaking research for a Master's degree.

> I would look at the quality of research first, for example, are there well-defined objects, how will outcomes be managed. Most people are not evil who are doing research.
> …. there are certain categories like children or people with mental problems. ……. As a community we have a responsibility not to authorize a study if it is only for the sake of achieving a higher degree. Research involves human beings. It sounds pompous, but it is our duty. People with dementia for example, we have to do our utmost to ensure that they are not used for something that is not worthwhile. Design is not our concern however bad research or bad science is not ethical.
> What we do is not paid for, it's a public duty and an honour.
> **Interview extract: REC B**

This interview extract shows how individual morality was important in making decisions. This moral deliberation exceeds the requirement to ensure high quality. The ethical requirements are only given shape and meaning by use of subjective means. The preoccupation with design is connected to obligation to research participants. In a risks and benefits approach, a risk to participants was often expressed by committee members as exposing people to poor research. An element of the Health Research Authority's commitment to the protection of participants was interpreted by reviewers as ensuring the quality of research. The idea of duty was important to another interviewee.

> We have a duty to safeguard interests. We can't just use people for the sake of research. These people don't have people to speak for them and it is our duty to protect patients involved in research.
> **Interview with reviewer: REC E**

Part of that duty was ensuring that 'good' research was approved. This was an example when the ruling concepts of protection came to the fore. This is what RECs are charged to do but there was a moral dimension to this.

7.6 Understanding design

Much of the committee's time was taken up with understanding the practicalities of design. They need to really understand the research and engage with what will happen, what the researcher's role is, what the participants' role is and so on, in

order to be able to make a decision on the ethics of the applications. I was impressed from the first observation with how much time was spent on understanding the design and purpose of each study. Examples from my field-notes repeatedly evidence this:

> Again, impressed by the detail and willingness to try to understand the study
> **Field notes extract: REC A**

> Lots of complicated talk about the processes of how the study would work
> **Field notes extract: REC B**

Much of the discussion at each REC about design related to the requirements for consent but there also seemed to be a need for the PMs to gain an understanding of the study and this was linked to the worthwhileness of the study. This would often be referred to as the 'science'. Whether something could be counted as 'good' science was an important part of the decision-making process.

7.6.1 Understanding design in review
At times the committees were confused by the design and spent time grappling with purpose. For example, on a number of occasions, committees spotted that all kinds of questionnaires were included in applications which sometimes seemed irrelevant to the objectives of the research. This led one reviewer to ask:

> The quality of life questionnaire - what has walking about got to do with the research? The documents don't explain the purpose. Is this a fishing expedition?
> **Observation: REC E**

This reviewer was unhappy with the documentation submitted by the researcher both in terms of its clarity and in terms of number. Some researchers submitted a number of questionnaires as a way of capturing data which strictly lay outside of the scope of the study. The embedded research practice idea of repeatable experiments and the ease of using established clinical outcome protocols such as Health of the Nation Outcomes Scale (HoNOS) (Wing et al, 1998) is a familiar feature of health research but this did not escape the scrutiny of the committee who were questioning the

purpose of each instrument. What was highlighted here was that reviewers may be thought of by the research community as being bureaucratic and overly preoccupied with submitted paperwork but they are actually often concerned with clarity. There is also a moral concern underlying this question with the over-burdening participants. In an interview with an experienced Chair, I asked how much the design influenced decisions.

> It's been a difficult one this. If it's rubbish, then it's rubbish. If it's mildly rubbish, then we're more tolerant. Especially with students – the research isn't going to be saving lives but it won't do any harm….and it might do some good.
> We try not to rewrite research, that isn't our expertise… As long as it isn't a burden.
> **Interview: Chair REC B**

Grappling with design therefore was an integral part of review. The detailed questions though also revealed other concerns. These related to burden on participants but also demonstrated moral reflection. So in the following example, one reviewer was concerned about a control group.

> Are the control group being denied something that would be beneficial not getting the 'top drawer' intervention?

This was the subject of a discussion between reviewers and was specifically raised with the researcher when he came in. The researcher was able to reassure that patients would receive any treatment required and only after initial intervention would they be separated into different streams for pharmaceutical interventions

> Ok - so the patient is fixed first rather than your study. I needed reassurance about that.
> **Observations: REC D**

The following example was a study that concerned children with a visible 'abnormality', conducted by psychologists which aimed to explore whether the use of videos could enhance the quality of carer/ infant relationships and/or interactions by use of playing back the video as part of a therapeutic intervention. The carers' facial expressions toward their infants would be videoed and then the video played so that they (the parents) could learn from them. The researchers had asked to attend this flagged REC to get advice. One of the lead reviewers here was the Chair.

Lead reviewer 1: They seem to have thought of the issues. They have thought this through regarding children. The researchers have asked for advice regarding capacity issues.

Committee member: I have concern about social services involvement. What if they have a bad day during (the course of this research)? If they have a bad day social services may get involved once they're in, you can't get them out. (The) people participating are putting themselves in a vulnerable position. They are being observed when it's acknowledged that this is a difficult thing.

Lead reviewer: (Well) they would be unlikely to act on one incident - it's an experienced child psychologist who is supervising the project.

Observation: REC D

The committee consulted the paperwork and clarified that the group who was being videoed would receive ingoing support and help.

Committee member 1: what if they witnessed something in the control group that caused them concern (in the interaction) and then the research team don't intervene?

Lead Reviewer: the control group will still receive advice and support as well as the group being studied.'

Committee member: I have objections to the questionnaire which may be experienced as pressurising for example it asks about sex life.

Committee member 3: There are too many questionnaires it's overwhelming.

Lead Reviewer: Well, they are standard questionnaire measures

The discussion ends and the researchers come in.

Observation: REC D

This extract shows the kind of detailed questions about design which were raised in committee discussions and how these were linked to burden on research participants and moral questions. Though there were ethical questions about the harms to participants. In this case, emerging from the messy discussion, the following concerns were highlighted:

- exposing the participants to an intrusive video recording
- intrusive and overwhelming numbers of questions
- the potential consequences of participation – the unleashing of social services on to them
- concern about the control group who wouldn't receive the same therapeutic support

Though these concerns are all valid within regulation and refer indirectly to ethical principles of harm, consequences of research and design, the discussion did not feel

bound by the ethical requirements but seemed motivated by moral discomfort about what would happen to participants. In this case, the Lead Reviewer was reassuring the committee members as he did not seem to share their concerns (for example, he said of the two groups 'they'll both receive support – one is gold and one is silver'), the concerns were given time and questions then raised directly with the researchers.

Even when the decision was reached 'favourable with conditions', the committee member concerned with equality of support remained unsure, but a majority decision was reached. The extent to which ethical frameworks or principles can guide decision-making was being tested to its limits in this example. Furthermore, the extract shows that it is through discussion where strong opinions are expressed driven by sometimes very personal and subjective views that a judgement is arrived at. Lastly, the concern with design is still tied to a moral concern. Consider this statement from a Chair (of REC D).

> 'Bad research is bad ethics. We are reviewing the rigour as well as ethics'.

S/he went on to provide the reasons for this.

> 'Mostly people who participate in research are proud and happy to (do so). There is a lot of goodwill. Trust in research is important too'.

So even what appears to be the claim by RECs of more 'rational' aspects of decision-making, the 'review of rigour', are still absolutely bound up with the moral dimension, here that of trustworthy research so that participants' goodwill is not exploited.

These exchanges and contributions from committee members also reveal something about objectivity and subjectivity. Maintaining and perpetuating ideas about good science and design are important in demonstrating RECs as objective adjudicators. The committees need to demonstrate that they are in some ways separate from and disconnected (objective) – their concern is 'good research'. In contrast, what I found was that in fact members are engaged, connected and the process is subjective. In as much as they can be in the confines of a meeting, they are involved in

engagement, with one another, with researchers, with co-ordinators and these relationships all converge in making a decision.

7.7 Trusting the researcher - 'It's kind of subjective – but not'

What I have tried to show so far is that members of RECs made decisions using judgement and discernment. They did not depend solely on protocols and abstract principles (though this was part of their decision-making) but on their own sense of values, their perceptions of what is moral (duty, responsibility), their motivation for doing the work, their own experiences, intuition and perception. I have shown through the data presented that these all take place in the context of lively debate and deliberation. So far, what has been missing is the researcher role in the decision-making process. In the preceding chapter I described a situation where perceptions of a research application were reversed following the exchange with the researcher. I also noted that reviewers said how important it was to the decision-making process that the researcher attended the REC and that all those committee members interviewed were unanimous that it was helpful for the researcher to attend.

During an interview with reviewer from REC B (2) whilst talking about the difficulties of understanding research design she referred to the importance of trust.

> It's not to do with their moral life but when they come in, what they show. Are they trustworthy, do they have integrity and an understanding of what they are doing? It's kind of subjective - but not. (It's) the way they answer questions, their conduct, their modesty, admitting/acknowledging mistakes……….
> It often goes with great ability. They don't know the answers but the project will help find some of them. Because we trust them (even if we don't fully understand the methodology) we will approve…….
> So, (we're) not bogged down with minutiae – willing to trust. It (the minutiae) becomes important if we're not able to trust.
> **Interview with reviewer: REC B (2)**

It is suggested here that the trustworthiness of the researcher is privileged over design. It might be more accurate to say that from my observations, when there were doubts about the research, the impression made by the researcher was a crucial factor in making a judgement about the application.

During an observation in REC C, this judgement-making about the researcher was demonstrated in the exchange with the researcher and subsequent discussion. The

study was of the incidence of co-morbidity (including mental state) in patients admitted to hospital with heart conditions. The range of symptoms to be captured included mental state symptoms as well as physical symptoms. Some participants were likely to have fluctuating capacity or permanent cognitive impairments. The concern of the committee was the requirement in the MCA 2005 that the study could not take place without the inclusion of those lacking capacity.

> Reviewer 1: how would the study be affected if you didn't include people who lacked capacity?
> Researcher: Impairment is frequent in admissions and so this would cause the data to be biased. Some people admitted to the heart unit have dementia for example.
> Reviewer 2: Well some patients might be confused but that would be temporary so you could go back to those patients. Can't you exclude people with long term impairments?
> Researcher: I don't want to do this. Some people will have cognitive impairments.
> Reviewer 3: I struggle with this. If I compare this to my area, learning disability, I'd want to be encouraging about inclusion. People can communicate emotions such as pain and so on.
> Researcher: I don't want to exclude people on that basis. They may well be able to describe their symptoms but they may not be able to consent to research. I could have excluded people but I think that would be the easy option.
> **Extract: Observation REC E (2)**

Here, the REC is pushing the researcher to defend the choices made. They are 'testing out' responses, wanting to be convinced. The subsequent discussion leading up to a decision was a detailed discussion of requirements and concerned whether the research could not be carried out effectively if it was confined to those heart patients who had capacity.

> Chair: The researcher thinks that the research could not be carried out as effectively if confined to those able to give consent – but do we?
> Reviewer 1: S/he wants to include in the pursuit of knowledge so why should we stand in her way?
> Reviewer 2: It's flawed but maybe it's as good as it can be.
> **Extract: Observation REC E (2)**

The application was given a favourable opinion with provisions which included clarifying the role of consultees. This example shows how committees' decisions were based on judgements. - about the research, its worthwhileness and fairness

and judgement of the researcher. RECs use a balance of emotional response and intuition. They seemed to seek a connection (often emotional connection) to the research and they utilize intuition in judging the character of the researcher. Banks' description of Aristotle's concept of the mean is relevant here. She suggests that rather than a mathematical calculation, the 'mean' is when balancing, discernment and judgement is required which 'may involve emotions and intuitions as well as rational calculation' (Banks, 2013 p599). The 'rational calculation' in the context of RECs is the calculation and judgement about the extent to which requirements have been met. The decision making is complex, requiring attention to the detail of design in applications, but even though REC members declare that design is important, they are still drawing on ideas of trust, integrity and other virtues.

7.8 A moral dilemma - case study

The current research context is highly complex and is influenced by wider political and economic factors. I heard for example a high number of studies about dementia reflecting current concern and the desire to improve life experiences for people with dementia. One Chair commented to me that there are 'trends' in the research that comes up for review. In economic terms, some research is inevitably brought about as a result of the availability of funding. Two of the studies involved trials of medical equipment and one of these in particular presented a moral dilemma to REC G.

REC G deliberated for a long time about a trial of a piece of equipment to be trialled at a hospital which they suspected was on lease to the hospital by the company *on the basis* of it being trialled. People benefitting from the equipment were possibly unconscious. The REC had to satisfy themselves that this was of potential benefit to the patients and they were concerned that if it was of benefit that it would continue to be used at the end of the trial. Through thorough interviewing of the researcher, they gleaned that the researcher was convinced that this special equipment could improve the comfort of patients but that the only way to convince the Trust to purchase the equipment was to provide evidence through research. From a feeling of moral discomfort, the committee moved to supporting the research.

Discussion moved back and forth from ethical decisions to moral judgements and revealed the limits of the ethical framework in making a decision. Judgement and the subsequent decision was based on practical and 'real world' considerations.

This was a complex situation for the REC to decide upon. Ethical frameworks in the form of requirements and overarching ethical principles were of limited help. The decision they arrived at was through an open discussion where the moral tensions were acknowledged. They decided in the end to allow the study to proceed (albeit with some conditions in the paperwork) on the basis of patients benefitting from use of the equipment and importantly the research would provide necessary evidence of its efficacy. This example showed how RECs are making decisions based in the everyday – here the political context of purchasing decisions of Trusts was a further ethical element which they drew out and discussed.

The REC might justify its decision by recourse to ethical requirements which were met and by reference to the principle of beneficence but the decision taken was rooted in the practical. The REC made sense of the research and its consequences by weighing up pros and cons of the research taking place or not. They were frank about their moral discomfort about the involvement of the supplier and the reality of the financial constraints in the NHS Trust involved. Johnson and Long discuss research ethics in the real world (2007) but this seemed to be a case of 'real world ethical regulation'. Their judgement was pragmatic and the deliberations leading to a decision were influenced by individual moral frameworks. It could also be said to be a demonstration of the concept of the mean as described by Banks because as well as 'balancing', the committee members did engage in emotional work, thinking through the consequences for real patients who may benefit from the equipment. The ethical framework in the form of requirements and the over-arching principles of beneficence and non-maleficence offered limited guidance to the committee who had to make a judgement about what was presented to them. This kind of judgement provides a pertinent example of Banks' developing idea of 'ethics work' (2013, p599) which she describes as 'conceptualizing the process of practical reasoning in situations where issues of harm, benefits, rights and responsibilities arise'. She explains that 'work' is the effort put into seeing the ethical aspects of situations and

the work of justifying who they (she refers to professionals such as social workers) are and what they have done. This concept of 'ethics work' is a relevant concept to assist understanding of what REC members do.

Ethics work in this context is informed by ethics and procedures, it is informed by overarching principles but in the doing of ethical regulation, it becomes a process of practical reasoning which draws on a spectrum of knowledge. Much of that knowledge is tacit – it comes from feeling, from emotion and a sense of 'doing the right thing'. In weighing up benefits, harm, rights and responsibilities, much of their work in the everyday is subjective based on hunches and their individual and group judgement. Professional ethical codes, and in this context, ethical requirements, are usually influenced or informed by moral values or principles. However, making the decisions required by RECs is dependent upon judgements in the here and now which are separate from and at times quite distant from the ethical requirements. There is also a 'social' aspect to this because judgements are not made by isolated individuals but through talking up in a social group.

At times members became absorbed in the intellectual challenges of interpreting the regulations generally and the interpretation of the MCA 2005. However, in making sense of applications, the ethical frameworks were often of limited value. Committee members often went back and forth between what ought to happen according to the ethical frameworks and what practically needed to happen in order to get a study through review to a favourable decision. Chambliss (1996) noted how the code-makers approach ethics as a logical kind of puzzle and in doing so they miss a prior question of 'what can be done?' asking instead 'what should be done?' (p6). This is a helpful interpretation of what I observed. As I have tried to show in this chapter, in considering applications, REC members used a range of strategies and I would say that their ethics work of reviewing research often occupied a liminal space between the 'what can be done?' and 'what should be done? RECs are bound by the convention of thinking through the four biomedical principles which inform the procedures. These principles inform the requirements and the procedures. Yet in making sense of applications, they needed to step outside of that in order to bring meaning for themselves to the process of making judgements which lead to a decision. There was a delicate interweaving of the need to address what should be

done, what is permitted and the question of what can be done. This happened when the members were convinced of the merit of the research.

7.9 Uncertainty – committee members' expressions of ambiguity

Though the review process is dominated by procedure and bureaucracy, RECs occupy a liminal position. The practical business of decision-making requires them to negotiate a highly bureaucratised and in relation to capacity, legalistic system which is difficult to make sense of by use solely of the procedures. They use 'emotions and intuitions as well as rational calculation' (Banks, 2013 p599). Though they can ultimately defend and rationalize their decisions, they arrive at them in myriad ways and there was some level of consciousness about this when I spoke to committee members.

One reviewer during interview was discussing how much the requirements influenced his decisions. Whilst s/he described the process of reaching a decision as 'easy', s/he said:

> People listen to the debate. The options come out of the debate. Common agreement comes out of the discussion. Things are fixable because of sufficient discussion time. Usually our decisions are contingent – it's not favourable or unfavourable.
> **Interview with reviewer: REC A**

Whilst it is certainly the case that RECs find applications to be 'unfavourable' – I did not observe any decisions which did not require further work on the application for the researchers. One committee member talked at length about her perception of the REC role and her acknowledgement of grey areas and concern that the process did not become purely procedural.

> RECs are steeped in governance and procedure. We (the REC) try to step outside of this. Debate about governance and ethics should be part of the REC. For example, we are clear about clinical treatment of 16 year olds because of Gillick competence, but there is a grey area when it comes to research and 16 year olds.
> **Interview with reviewer: REC C**

Decisions, she said, were: *'driven by the membership of the REC where there are divergent views'*. And she did not see that review was simply a bureaucratic process.

It's a burdensome process (ethics review). It becomes a bureaucratic process. We need to get people to think about issues more broadly *before* the paperwork. Research institutions need to think this through. (Researchers need to think outside of this) - even routine procedures on non-vulnerable groups can be problematic.

There is a risk that people may see things as routine and may not appreciate the impact of research. We need to get people to think more broadly *before* the paperwork.

Interview with reviewer: REC C

RECs did not see their role simply as 'rubber-stamping research. There was a wider purpose which was to provoke awareness among researchers. Another reviewer talked about how the ethical requirements in the MCA (2005) and how procedures were not an easy fit with the ethical quandaries which were presented by the applications. This was a committee member who described herself as 'lay'. At the start of the interview she was sure that the requirements and the capacity checklist used was helpful but then became more hesitant and uncertain as the interview progressed. Her responses show how committee members were often holding two incommensurate positions - that of having to comply (in the same way as the researchers) and reduce complexity to bureaucratic requirements whilst feeling doubt and uncertainty about their decision-making. In other words, thinking solely about what 'ought to be done could lead to uncertainty about whether decisions were 'right'.

JM: What is your understanding of capacity and consent in the context of the REC?

PM: Our job is to refer to the checklist (note, the brief checklist provided by NRES is analysed in Chapter 7 of the thesis). Consent is informed, it's not just 'agree', and it's understanding the implications of something. The bar is higher for a research participant than if a patient was getting treatment from a GP or dentist. I try not to muddle the two – capacity in medicine and capacity in research.

JM: The checklist is helpful then?

PM: Yes, we need a checklist, a directive. We are not a legal committee but are charged with a legal decision. We have to be satisfied that we have followed the law. We might think (something) is unethical but it satisfies the link, for example the research is linked to the impairing condition. Legal checklist and an ethical decision – these are not always compatible.

JM: Are you sometimes left unsure ethically?

PM: Yes, what is legal is not ethical.

That study we reviewed, I'm still not sure. We drew out the legal requirements (from the researcher). We teased out bits to satisfy, we fed him the answers.

I'm not sure we can always trust the researcher to do what they say. It depends on the answers and the way they give them. Will they conduct the research ethically? What if things go wrong?

Some disciplines are better at giving legal answers. Psychiatrists and surgeons are used to exam questions (for example). Social workers see more grey areas.

JM: Do the regulations put researchers off involving people who lack capacity?

PM: That's not a question for me. The checklist makes it easier. The hurdles are low. If you can use the language, then you may pass. ….. . Legal checklist and an ethical decision – these are not always compatible.

JM: Are you sometimes left unsure ethically?

PM: Yes, what is legal is not ethical.

Interview with reviewer: REC B (2)

This interviewee expressed how the legal requirements imposed on research do not always equate with ethical requirements or ethical concerns. This committee member was clearly uneasy with the inherent tension here and expressed it succinctly. Masson (2004) almost precisely echoes this, '*there is a close relationship between law and ethics but not everything that is legal is ethical*.' (Masson, 2004:43). Masson goes on to explain that legal requirements are often minimum requirements and cannot be a complete defence of research practice. This also reflects the legal and regulatory dimensions described by Wiles (2013 and see above) in research practice. What is important here is that this sits uncomfortably with the reviewer. She is weighing up legal and ethical aspects in the balance and deciding on the right course of action in this 'ethics work' is not straightforward.

Hammersley has argued that principles in ethical regulation which inform the procedural specifics imply that 'ethical judgements should be derived in a quasi-logical way from given principles' (2015, p445). His key argument is that this falls short of what is required in the field when acting/researching ethically means more than compliance with ethics committees. It is difficult to argue with this and researchers I interviewed supported this view. The 'one-off' nature of ethics review is problematic because researchers are asking for review of prospective research and approval of the research (and consent) is anticipatory. Nevertheless, the difficulties he describes for researchers are equally challenging for reviewers. One Chair asked in our interview - 'How do you measure (decide upon) research that hasn't happened?' The observations of RECs and their discussions presented here show

that in making a decision, that committee members 'think themselves into' the situation of the prospective research. In considering ethical questions, reviewers are used a whole range of means to imagine themselves into the context of research which I have described. Committee members spoke about this directly. The following is an extract from an interview with a committee member (REC C) (also a researcher) who raised the principle of 'non-maleficence'.

> If we're taking blood samples from babies, then the baby screams – there is distress to the baby and the mother (parent) so we have to question how many times we can take blood. What is reasonable? Clinicians may treat these situations in the same way even when in one case the blood tests might be for treatment and in another, for research. What if it's not to do with treatment – it's not clinical judgement but research judgement. The question of burden has to come up.
> **Extract from interview: REC C**

This committee member acknowledges the gap between what is done in review and what is done in research. She provides a vivid example of how difficult it is to decide, in research and review contexts, how much harm is acceptable. This detail demonstrates how the 'quasi-legal' interpretation of principles is a challenge for RECs and that they have to think themselves into the situation of the research. This was a reviewer committed to raising the level of debate in the REC. S/he was distinguishing research and treatment and highlighting why this might matter. Importantly though, this provides a further example of how committee members kept the researched 'in mind' by thinking themselves into the situations of research, the 'situated perspectives' described by Hammersley as crucial in the field (Hammersley, 2015, p 437).

It is difficult for RECs to translate principles straightforwardly into the research practice domain. The reviewers' discussions in the observations and interviews, evidenced how they oscillate between the procedures (which embody fundamental principles) and more practical means of making sense of the application. Much of what has been described in this chapter shows that part of the RECs work is 'thinking themselves into' the situation of the research.

Research cannot make a prospective claim for good or improvement. It can inform and it can equally inform if a hypothesis does not work out as expected. However,

committee members expressed concern that their authority was only in the reviewing, the anticipatory part of the research and they had no authority to compel researchers to publish negative findings. In other words, they could raise anticipatory ethical concerns about the practice of research but not the real-life consequences of research practice. The question I asked about vulnerability was addressed in this way by one interviewee, a committee member.

> JM: Do you think anybody is particularly vulnerable in research?
> PM: Well, the people who volunteer. I ask (researchers) are you going to publish whether good or bad results. On behalf of people who volunteer, the data should be out there, this is a contribution to human knowledge and people should have this whether good or bad. All we could do however is put pressure on.
> **Interview with reviewer: REC E**

7.10 Conclusion

Attempting to locate the work of RECs in existing moral and philosophical frameworks is problematic. They use a range of repeated processes and moral engagement in order to make a judgement about research brought before them to consider. They engage with applications to get at the ethical dimensions of the planned study. Individual members could be said to draw on a range of ethical approaches – deontological and consequentialist but these are implicit rather than explicit in their work. The most obvious and transparent influential approach in the evaluation of applications for review to the REC is principle-based and even more specifically than that, Beauchamp and Childress's principles of autonomy, beneficence, non-maleficence and justice (Beauchamp and Childress, 2012). These have been instrumental in the development of the myriad requirements of NRES and the HRA. However, these principles are too abstract to make sense of the complications encountered in the applications to the REC. Although review decisions are reified in the REC, decisions can only be concrete if other means of sense-making are employed. 'Making sense of' involved thinking about their own personal relationships (I think about a relative) and committee members use themselves in making decisions, thinking through notions of 'public duty' and rights of citizens to participate in research. It is paradoxical that in review processes which are so prescribed, so bureaucratic and requirement bound that so much is left to feeling, to what is *felt* to be moral or ethical conduct. Ethical requirements are made concrete

by use of individual morality and this may be influenced by doing the right thing and a strong sense of duty (deontological) and/or by the consideration of consequences for participants and the prospect of positive outcomes for patients or citizens more widely (consequentialist).

Ethics of care has offered a critique to the broad and established theories of ethics. (1982) identified two types of moral thinking which were an ethics of rights and Gilligan justice and an ethic of care based on connectedness and relationships with and care of others. Gilligan first identified the two polarised views of ethics as male (linked to rights and justice) and female (linked to relationships and connectedness) though she later revised this and refuted charges of her conceptualization as essentialist. The contribution Gilligan made is that her theory of ethics allows us to conceptualize existing ethical frameworks and their derivation. It also allows a particular critique of RECs which I think is helpful. At its very foundation, Banks and Gallagher (2009) summarise Gilligan's (and Noddings' work on pedagogy) as providing an alternative 'moral voice' (p102) to approaches which privilege principles and rational argument. Institutionalized ethical regulation is firmly in what Gilligan typifies as the mode of rights and justice. What this implies is a universal and generic applicability of regulations to all research applications. All of the associated bureaucracy and requirements and the on-line technological application process suggest that a universal approach is possible and achievable with the protection of individual patients at the heart of endeavours to regulate research. This protection is also of a particular kind. Protection is of a 'vulnerable' research participant in an inevitable asymmetric power relationship with the researcher (Juritzen et al, 2011). However, as a counter-narrative to the dominant view that RECs are steeped in bureaucracy, I would argue that RECs do also use to some extent a relationship based and interconnectedness care ethics which Gilligan describes. For Gilligan, ethics of justice associated with rules were juxtaposed with ethics of care which was characterised by concrete circumstances rather than abstractions. In this sense, the ethics of care approach illuminates some aspects of the RECs' work. Each decision is made in the context of each study application and in the context of each idiosyncratic REC. The judgements which lead to decision-making can only be achieved by a certain amount of care for the task they are involved in, thorough close engagement with the study, through their own relationships and through a

strong sense of 'being responsible' (Gilligan, 1982). Nevertheless, their work is contextualised and given legitimacy through reference to abstracted rues and principles.

Lastly, this chapter has illustrated the ways in which committee members draw on moral frameworks, feelings, emotion and personal responsibility in their ethics work. To an extent committee members are immersed and work within bureaucracy and procedure and I discuss this further in the chapter on 'doing' ethical regulation. This demonstrates or justifies their decision-making. Nevertheless, they do voice concerns, unease and uncertainty about their role and this certainly happened in interviews I have argued that these ways of engaging with research applications lead to judgements about the research applications. These are largely unconscious and tacit. Though there is a usually a peer review of the science which informs the REC members' opinions, they still put effort into understanding the science in order to be able to engage in deliberations about whether the science is ethical. REC reviewers did not directly describe how they determined what was good science or worthwhile research, how they did the work of 'ethics review' but I have attempted to reveal the tacit understandings which inform what they do. In response to the ongoing debate about the extent to which RECs are equipped to judge the science of applications, Gelling and Rodriguez (2014) highlight two important points. Firstly, that RECs have a growing awareness that 'bad' science is unethical and secondly, that they are concerned with whether the science is 'right'. My findings have revealed how both of these elements are relevant in current REC practices. The notion of good science was discussed in both observations and interviews. Reviewers were concerned about the 'rightness' of research which they referred to as it being 'worthwhile'. In this context, they also commented on the balancing of needs between a student researcher and the desire to encourage this group of researchers to pursue studies with the need ethically to protect participants from taking part in research which might not have significant outcomes. These are complex judgements to make and are further evidence of the 'ethics work' RECs are engaged in, balancing the concept protection of human beings with the human desire for the pursuit of knowledge. Abstracted requirements and principles are of limited help in this complex balancing of consequences. It is engagement with research and researchers, emotion and subjectivity which inform their judgements. I would argue that these 'subjectivities'

however are not transparent and obvious to them. Much of the evidence of these tacit understandings was drawn from my observations and then from more detailed interviews with individuals

The 'ethics work' concept which has been helpful in the interpretation of what was happening in the REC has two elements- one is the work of identifying the 'ethically salient' features of a situation (Banks, 2013:600) and I have referred in this chapter to the ways in which committee members do this through engagement with the research using emotions, a sense of duty, their feelings of having to morally justify the worthwhileness of the research and so on. For the REC members I saw in action and interviewed, decision-making went beyond adherence to the requirements and the law, indeed a straightforward application of procedures left them feeling uneasy, unsure and troubled. They were also aware of the difficulties with making judgements about prospective research. Nevertheless, what has been presented so far is a partial representation of what happens behind the closed doors of the REC. The second element of Banks' ethics work is 'justifying'. She refers to professionals having to justify their role and what they do as part of 'ethics work'. This second element is what the next chapter turns to. It is how the *judgement*s made become justified as *decisions.* How the RECs demonstrate their objectivity and demonstrate that what they do is impartial, transparent and accountable. Therefore, the next chapter will focus on decision-making and how this depends upon the texts which contextualize and frame their work. It will show how RECs moved back and forth between making sense of the studies and 'making a fit' with capacity and consent requirements.

The analysis of the *doing* of, the work of ethics review deals in more depth with the practical tension between 'what can be done' and 'what should be done' (Chambliss, 1996) especially in relation to consent requirements. It also deals with the 'performance' aspects of the work of RECs, the having to be accountable and transparent and I discuss how texts are used to justify ethical regulation in the committees and how they lend authority to decisions.

Chapter 8: The use of texts in ethics review – making decisions

8.1 Introduction

The previous chapter was concerned with how reviewers understand their work and what helps them to make sense of the applications for review. The doing of that work was shown as somewhat idiosyncratic but I attempted to show how it was 'ethics work' in the sense of individuals identifying the moral and ethical elements in research and bringing their own subjective understandings to the table (literally) in order to make sense of applications. That description of how the work of ethical regulation is locally accomplished is an important part of the ethnographic project. I described how *judgements* were made about the 'worthwhileness' of research. This chapter emphasizes decision-making processes. It seeks to show how decisions are made in ethical regulation and given authority and objective status through texts. Smith (2001) argues that an analysis of texts is essential to institutional ethnography as they are 'of foundational ontological significance to the existence of anything we can call 'large scale organizations' or 'institutions'. I look at a specific text and analyse its significance briefly, then turn to the everyday engagement with texts and procedural requirements in ethical regulation by reviewers and researchers.

This chapter is structured in three parts. I firstly analyse a specific text used in the review process to show its relevance as an authorizing text. I then provide a description and interpretation of findings relating to the use of texts and regulation using concepts derived from Dorothy Smith (specifically her work on texts and institutional ethnography, 2001 and 2006). Lastly, I report on some of the specific difficulties presented by procedures which are encountered by researchers.

The focus on regulation in relation to capacity is maintained but the discussion is contextualized in ethical regulation more broadly. Smith stresses the importance of looking at texts 'at work' (2001, 2006). The brief explanation and analysis of a text provided on the HRA website is chosen because it provides specific guidance to researchers and is 'supplementary' to the substantial submission which is required. It addresses the requirements for research with people lacking capacity and therefore formed an important part of the applications for review which I observed. This then

provides a context for the subsequent discussion in which I report on what happened in the RECs showing instances of reference to the texts. The key problematic addressed in this chapter is that of the reliance of texts – texts 'at work'. I have developed this to include how much they influence or constrain and lend authority to the work of RECs. Interpretive attention remains with the **how** of ethical regulation, the nature of negotiations with a focus on process. Ethical regulation is currently saturated in texts of one kind or another. Therefore, addressing and attempting to explicate the use of texts in regulation is foundational to the study. Regulation is also *situated* in texts and shape decisions in particular ways. Smith did not mean 'texts' as only written artefacts. In this context, what I mean by 'texts' are the range of requirements, paperwork, electronic material and so on which make up the institution of ethical regulation. Given that decisions are based on an electronically submitted application and decisions about capacity issues are made with reference to a crib sheet specifying the MCA requirements, I focus on these primarily and analyse how they were used in the process of arriving at a decision in review. To begin with, I explain how a particular text is used and is significant in the authority of the REC.

8.2 Analysis of a text – the supplementary information form for applications

> *'Texts and documents make possible the appearance of the same set of words, numbers or images in multiple local sites, however differently they may be read and taken up. They provide for the standardized recognisability of people's doings as organizational or institutional as well as for their co-ordination across multiple local settings and times. It is not enough to use texts as sources of information about organizations. Rather, they are to be seen as they enter into people's local practices of writing, drawing, reading, looking and so on. They must be examined as they co-ordinate people's activities.'*
> (Smith, 2001:160)

I use Smith's approach to texts in a particular way in this analysis. Firstly, I view texts as part of telling the story of regulation, part of the 'mapping' project. Secondly, I am attempting to show how they shape and influence decisions in the action of the meetings and how they are understood by both reviewers and researchers. I begin by analysing one important text which is the 'crib-sheet' used at meetings to ensure that capacity requirements have been satisfied. The following reproduced document is the 'supplementary information' required by the HRA in applications to the REC when participants are deemed to lack capacity.

Figure 3: The Capacity Checklist

Section 30 of the Mental Capacity Act 2005: Applications to NHS Research Ethics Committees Supplementary information

1. What impairing condition(s) will the participants have?

2. Please justify the inclusion of participants unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

3. How will the capacity of potential participants to consent to the research be assessed? Who in the research team will make the assessment and what knowledge of the participant or relevant training/experience will they have to enable them to undertake it? Please see Chapter 4 of the MCA Code of Practice for detailed guidance on this issue.

4. Does the research have the potential to benefit participants who are unable to consent for themselves? Yes   No

If Yes, please indicate the nature of this benefit:

MCA1 - supplementary information form (section 30) Version 1, 25 June 2007   2

5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)? Yes   No

If Yes, please explain how the research will achieve this:

6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy? Yes   No

If Yes, please give an assessment below. Highlight any risk, burden, restriction or invasion of privacy specific to these participants and say what will be done to minimise it:

7. What arrangements will be made to identify and consult persons ("consultees") able to advise on the inclusion of each individual participant and on their presumed wishes and feelings?

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

8. Is it possible that a participant might need to be treated urgently as part of the research before it is possible to identify and consult a consultee? Yes, No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants:

9. What arrangements will be made to consult consultees during the course of the research where necessary? What burden could this place on consultees?

10. What steps will you take, if appropriate, to provide potential participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

12. What will be the criteria for withdrawal of participants?

13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort)?

14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant.

MCA1 - supplementary information form (section 30) Version 1, 25 June 2007   3

This text appears in two forms. This version is found on the HRA website and is to be used by researchers and included in the electronic application for ethical approval. The requirements are also distilled into a checklist (paper) which is used in RECs when making a final decision in review about individual applications. The text, as with the rest of the application, is submitted electronically and then hard copies (substantial volumes) are used in the meetings. It is of course only one part of the regulatory texts used, however, it was significant in that it had to be considered in the applications I observed because those studies were directly with participants deemed to lack capacity.

The purpose of the text might first appear to be ambiguous. This is supplementary information but are the questions guidance or directives? In fact, its use is significant because in the everyday activity of review in the REC, it establishes the particular ways in which research can be approved. The RECs refer to it as a way of checking that all is in place. The steps through which the researcher is taken in the list of questions/prompts, actually map out the process of what needs to be done. I described the sequencing of meetings in Chapter 6 at a local level and showed how these sequences were reproduced in every REC. As well as those sequences and patterns, the texts of ethical regulation also co-ordinate work.

In the above example, there is a checklist of requirements which is intended to ensure that the activities of the key agents (researcher, reviewers) are co-ordinated into unified courses of action. All of these conditions must be considered and addressed by researchers and reviewers. The text provides authority to the RECs and has legitimacy. It is lent legitimacy in two ways. Firstly, it is derived from legislation (the MCA 2005 s30) which specifies the conditions under which research can take place with people who lack capacity and secondly, the version and date (from the HRA) distinguish this text as being authoritative.

The text therefore does not simply make suggestions for supplementary information, this information is required. If an area is not adequately addressed, the reviewers feel uneasy and are compelled to address specific questions directly to the researcher at the meeting. In this way, the text does not simply prescribe, it extends its authority to both researcher and reviewer. The content of the text, the series of

questions asked of the researcher becomes a script which regulates the researcher and the reviewer. The terms used are constantly referred to in the REC. Smith puts it like this: 'People's activities and sequences of activities are co-ordinated through the authorized texts of an organization/institution with the work of others similarly co-ordinated' (2001:187). In this way, the work of the institution, in this case institutionalized ethics, is achieved. I have shown in the previous chapter that regulations and procedures are usually abstracted from context. This text illuminates that argument well. Note for example, the use of principles in this extract:

6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

The ethical principles underpinning this statement are of autonomy and harm. Risk and burden were serious considerations for reviewers in the REC but they could not make sense of them unless they imagined themselves into situations using whatever personal resources were available to them. The requirements appear remote and unconnected to research or the everyday practice of reviewing ethics. The other difficulty highlighted is the prospective nature of review. Researchers cannot predict risk or burden in their fieldwork. They can only say at this point that there would not be 'foreseeable' burden or risk. However, the concrete practicalities of working with these requirements are beyond the purpose of texts. This is an authorised text which co-ordinates work, influencing how researchers think about their researchers and reviewers in their assessment of its ethics. The principles which inform the text are presented as functional. They are operational. Matters such as the capacity to consent, which is complex and sometimes difficult to assess, are treated as a technical procedure requiring training with researchers being signposted to yet further guidance.

3. How will the capacity of potential participants to consent to the research be assessed? Who in the research team will make the assessment and what knowledge of the participant or relevant training/experience will they have to enable them to undertake it? Please see Chapter 4 of the MCA Code of Practice for detailed guidance on this issue.

The effect of this part of the supplementary guidance was that in observations, it seemed sufficient for researchers to say they had been trained in consent for this

requirement to be fulfilled. A question often asked of researchers by reviewers was 'Who will take consent' as if this was a straightforward process.

Even when more nuanced queries entered the discussions, the debate was brought to a conclusion with reference to requirements. This was pre-discussion before seeing the researcher and concerned a study on dementia.

> Chair: Is anyone going to be testing capacity. This wording isn't right.
> PM1: Isn't everyone who has dementia lacking capacity?
> PM 2: No, capacity is time and decision specific.
> PM 3: There can be non-verbal ways of communicating if the problem is not being able to speak
> Chair: (trying to summarise) well, the information sheets are needed with the right wording
> Lead Reviewer: The Act has to be complied with.
> **Observation: REC B**

The text itself by providing a sequence of prompts, suggests a direction, a course of action which needs to be followed and this implies a conclusion or resolution. RECs after all reach decisions on approval (or not) of research. The text guides the researchers in their applications and the RECs in their decision-making. It means that people who have never met have a common language which reduces complexity to a set of pronouncements on what ethical regulation is. In this way, texts have the power to determine what is ethical or not. I have shown in the previous chapter how I think reviewers express some ambiguous feelings about this procedural approach, however, in the end, texts do not simply ensure repetition and (attempt) replication of decisions in RECs but they are the way in which the authority and power of RECs is accomplished by the institution. Smith reminds us that texts are foundational and 'deliver power and agency of sometimes extraordinary scope' (2001, p164). Their significance certainly goes beyond the REC. They are fundamental to how research ethics is shaped and structured.

Finally, in this short analysis I want to draw attention to how the text refers to the person being researched. The 'research participant' in the text is the passive subject of all manner of concerns:

Is it possible that a participant might need to be treated urgently?
Describe what steps will be taken to ensure that nothing is done to which participants appear to object?
Does the research have the potential to benefit participants?

The point is made elsewhere in this thesis that limitations on research with 'vulnerable' groups will render them more vulnerable but this text demonstrates how subjects of research become invisible and how these 'incapacitate' groups may also be vulnerable in review itself. The debate about inclusion is side-lined while the more significant question (for the HRA) of protection is prominent. It is understandable that those who lack capacity may need extra protections to be in place. I simply want to highlight here how processes of review through texts play a part in further marginalising vulnerable adults. I now turn to look at how texts worked in practice and supported the judgements made by RECs lending those judgements both authority and the status of decisions.

8.3 Knowing review and regulation through texts

The endeavour of analysing texts and people's work as they do it is a means of extending what people do and their accounts of what they do. It extends ethnography into the processes of institutions and how they act. It helps us to understand how texts can organize and produce people's activities.

What had struck me was that the REC is absolutely central to decision-making and yet apart from the notes on membership and constitution of the REC, there was little knowledge about what takes place. The task of the REC is to make decisions on research but to do this they have to read complex applications which can be overwhelmingly dense and which also need to include consent forms and participant information sheets. In other words, formal, documented texts dominate processes and are also inseparable from the day to day work of the REC and how it 'does' ethics review.

8.3.1 Texts as regulatory

Texts do not achieve the authority to regulate simply by being in existence. The HRA is charged by the UK government to safeguard research, it is informed by legislation (Mental Capacity Act, 2005; Human Rights Act, 1998; Human Fertilisation and Embryology Act, 2008) and by international directives (World Health Authority Helsinki Agreement, continually revised since 1964, most recent October 2013). Members of the REC are invested with authority as RECs are appointed by the Secretary of State.

In 'Institutional Ethnography as Practice', Smith (2006) wrote a useful chapter on how to incorporate texts into ethnographic practice. I have drawn on Smith's suggestions in this section and highlighted some key characteristics of her work on regulatory texts to explicate what happened in the RECs. Smith is keen to show how texts can be seen as part of the action not separate to it. Although she says that she is not describing a method, the chapter identifies some themes or patterns which may be generalizable when accounting for texts in ethnographies of institutions. Specifically, these themes are **establishing concepts or categories**, **expression** of the regulatory text and **recognition** of the categories or concepts.

The categories and concepts I refer to are those which are embedded in ethical regulation and are summarized by Beauchamp's and Childress's principles of beneficence, non-maleficence, justice and autonomy. I see all of the requirements of confidentiality, consent equality, anonymity and so on, which are the everyday language of ethical regulation, as deriving from these principles. These have become embedded in the talk, written texts and procedures of regulation and this can be seen above in the example provided of a text.

The REC is mostly about talk. Deliberations over the applications take place between committee members before the researcher comes in for interview. My purpose here is not to judge the interpretation of requirements or the extent to which RECs safeguard the interests of research participants and uphold principles. Rather as part of my ethnographic project, I have viewed them as Smith says as 'part of the action'.

The talk about the applications in itself helps to **establish the concepts and categories** within ethical regulation. The concepts contained in the regulatory texts (in the form of published requirements) and the applications themselves have no authority unless they are brought into existence through the REC. The underlying ethical concepts in regulation such as consent, safeguarding, anonymity, informed consent cannot actually be brought about as regulating concepts through the mere existence of the correct forms or the use of correct words. It is the process, the action at the REC which helps to establish them as requirements. The deliberations about these particular regulating concepts and categories become an **expression of the ethical requirements.** The process of the REC - discussion, interview with researcher, more discussion and deliberation leading to the decision is the means by which ethical requirements are expressed or upheld. It is the 'doing' which achieves ethical regulation. What I mean here is that the process of deliberating and discussing applications is instrumental in bringing about ethical regulation. The REC is fundamental, its members process and perpetuate the regulation of research.

This work undertaken by the REC members becomes **recognition work**. Invested with authority, the REC members examine the applications in order to find these **recognisable concepts.** If they are not able to be found, then this means that conditions are to be set which the researcher has to meet. Though Smith does not use the term 'recognition work', she examines an academic appeal procedure in university in the United States of which she says:

> *'The text of the (appeal) procedure ……wouldn't be read prescriptively. Rather the reader's work is to find what might be recognisable (n the student's appeal) as a proper instance of its categories.'* (2006:83)

In other words, the procedure exists and the reader has to look for evidence of its categories. I am calling the work of the REC **recognition work** because although I think what they are engaged in is complex and I have argued that their decision-making draws on personal moral thinking and sometimes what is expedient and practical, in the end, their decision has to fit into the recognisable regulatory texts.

The exegesis is not of the regulatory framework (generally, if the committee members need clarification or interpretation, the 'nonce bureaucrats' refer to the 'rule-experts'), the exegesis is of the researcher's application which is 'worked on' to

find recognisable features of the regulatory framework. This is what I am describing as 'recognition work'.

8.4 The importance of the researcher application in review

The application is central to review. The applications are made electronically through an Integrated Research Application System (IRAS) which intended to streamline applications (for example to local Trust Research and Development) for review. At the REC, the printed versions of the application are available, each a small volume of papers with relevant patient information and consent forms included. Usually the reviewers had read the documents before the meeting and generally two lead reviewers will have had a closer reading and formulated questions. There is great emphasis on having a complete set of documents and that each section is completed. In an interview with a reviewer from RECs B a reviewer was discussing an application which I had heard reviewed at the observation.

> We made a provisional decision. On the material we had before us we could not finalise approval. We can't make a judgement unless we have everything in place.
> **Interview with reviewer: REC B**

Other comments made at observations were focused on the written submission. For example, 'this is well-written - a thorough application' or 'the documentation is clear. Caldicott requirements are met.'

It is worth re-stating here that every outcome I heard was 'favourable with conditions'. The conditions always meant amendments to the paperwork. The 'everything in place' might then refer either to concerns with the study which the researcher needed to think through and then reflect in the resubmission or simply that there were no concerns but the paperwork did not reflect what the researcher was doing or the intricacies of the requirements (particularly in relation to capacity and consent) had not been addressed. In an interview, one committee member said:

> The researchers had very detailed involvement but there was a disconnect between what the research was intending to do and what comes across in the paperwork.
> **Interview with reviewer: REC F**

The work of the REC cannot be accomplished unless they are able to recognise the key concepts required in the application. This comment about a 'disconnect' would not have necessarily meant that the reviewers did not understand the research. Neither did the disconnect mean that the paperwork did not reflect what the researcher wanted to do. What this meant was that the researcher had not used the appropriate language or provided the required detail in a particular form of words that meant that the REC could deliver an approve decision. If the reviewers were not able to do the recognition work (because the required elements were not present) then the application would not be approved.

The work is not easy. Reviewers are faced with an overwhelming number of documents for each application. Part of the reality of the decision-making process meant adopting practical strategies: 'Things take a long time to read. I try to distil what I think is going on. I usually outline three things that worry me.'

I had observed more than one reviewer adopting this strategy during my observations. It was effective because it enabled committee members to escape from the constraints of the procedure and connect to the 'feel' of the research and engage with what seemed to be the moral questions involved in the ways which I described in the section on the ethical and moral considerations of committee members.

In addition, there was an ambiguous attitude towards regulations expressed by reviewers. During interviews when asked about their views on regulations and requirements, one committee member said:

> JM How do you go about making a decision?
> PM: I confess that the regulations are irrelevant – it's the underlying ethics that are important.
> Nevertheless, in the same interview said:
> (Regulations) I have no problem with them. I'm going with the flow.
> **Interview: REC B**

This might suggest that the reviewer recognised the uneasy fit of the process of making decisions which feel meaningful and 'ethical' to her/him with the need to demonstrate that requirements have been met. This may seem obvious. How could

an application be reviewed and a decision made if all of the elements were not present? What I am highlighting here is that it is not only the paperwork being in place that counts. It is the concepts and words which are searched for as evidence that ethical standards are being met. This is not easy. My field notes often refer to the challenge of comprehending the study in the context of requirements particularly the requirements to comply with ethical research with people lacking capacity.

> The Chair was trying to wind this up. The applicants and the committee were tying themselves in knots about exclusion and capacity. The research was saying contradictory things about incapacity and exclusion and inclusion. It was good that the lay concerns were raised and given time even more time than the other concerns from the clinicians present on the committee. The Lead Reviewer was a clinician.
> **Field-notes extract: REC E**

Again, at a different meeting:

> My perception here in the last few exchanges the committee seemed to be trying to work out what the essence of the study - they also however seem to be trying to demonstrate their understanding of capacity (perhaps because I'm in the room with them?) So the last question 'is anyone testing capacity?' Is bringing the committee back to issues of capacity?
> **Field notes extract: REC B**

The committees did not find capacity requirements straightforward. On reflection, my comment that they were trying to demonstrate their understanding of capacity to me was apparent but the comment also shows how after long debates trying to get to the purpose of the study, they had to bring the committee back to capacity questions in order to make a decision. The question asked by one of the committee members returns them to requirements. This was an ongoing theme in observations. The desire for the committee to discuss widely had to be returned in the end to requirements. The requirements justify their judgement and their decision-making. The next phase of the committee's recognition work becomes the establishment of concepts.

8.5 Establishing concepts and recognition work

Smith describes how academics using an Academic Appeals Procedure searched for what was recognisable in student applications and looked for instances of its (the procedure's) categories.' (2006:83).

As my observations were all 'flagged committees' looking at capacity studies there were numerous references to the regulations on informed consent and the particular requirements for capacity studies, as well as the usual Information Sheets for participants and consent forms. Along with other regulatory requirements, reviewers would particularly seek clarification on capacity, often referring to the co-ordinators, the civil servants who Stark described as 'agile' in using narrow sets of regulations and who become 'rule experts' (20012:3). The role the co-ordinators play in the REC is described in chapter 5. To reiterate my position, I am arguing that reviewers in RECs did not start by interpreting the requirements but looked at the submitted application for evidence of the requirements and their representation by particular words and concepts. Reference to the text example above would often take place following a more generalized discussion about the application of the kinds described in chapter 6 above. Discussion of the requirements actualizes them. What I mean by this is that they become significant and authoritative through the activity of the REC. Texts do not have the authority in themselves, they are used in particular ways, which makes them important. The discussion itself at the REC is constitutive of the regulatory process.

In this extract form an observation at REC B, a debate about an application is brought into the final stages before seeing the researcher:

> Chair: Has the researcher done everything in relation to consent? (The) staff and consultancy consent forms - I think page 49 is wrong; the letter to the consultee. What about a consent form for the representative?
> Committee member: The representative form is not right it needs to have the wording correct. Is anyone testing capacity?
> Lead Reviewer: The Act has to be complied with…look at page 55….
> **Observation: REC B**

As well as doing recognition work on the application, the committee prepares to ask the researcher some questions:

> Committee member: Can we just refer her to the actual (words that need to go in) rather than asking detailed questions today?

The committee had made a judgement that the research should go ahead but the paperwork would need amending. In order to make a decision, the committee have to continue their recognition work in the interview with the researcher.

Through these kind of exchanges, members of the committee are using familiar and recognisable terms. The discussion itself is an expression of the regulation and accomplishes the process or procedure. So the outcome decision is important of course and especially so for the researchers, but enactment of the procedures is achieved through the deliberations of the committee members using familiar concepts. One could say that ethical regulation is achieved once the REC has had this discussion. At the start of Part Two of the thesis, I referred to Garfinkel's view that seeing 'sociologically' requires a 'focus on the routine details that comprise the coherence of activities' (Garfinkel and Rawls, 2005: 6). Garfinkel's 1967 work (also cited by Smith, 2006) was a study of every day work in a suicide prevention centre. Rather than viewing the repetitiveness of social activities as a way of conforming to rules or norms, Garfinkel described open ended and ongoing activities (in the centre) which produced what participants could recognise as rational processes of how to categorize a death as suicide or not. Participants produce for themselves and others what they can recognise as rational and objective. In the REC, decisions are not objective, judgements made about the ethics of research are not neutral. Objectivity and rationality are 'accomplished' by the activities of the REC and specifically in the talk and discussion of the REC. When a researcher said to me that there was an emphasis on process in the committees, s/he was right. There has to be, as it is through these recognisable processes, using specific words and terminology that all players with an investment are able to feel a sense of assurance that objectivity and rationality are maintained and the review of ethics in research has been achieved.

8.6 Recognition work with the researcher

This leads to another aspect to the REC's work which is that the recognition work continues with the researcher. Usually the Chair will summarize the key points to be raised with the researcher. Although, the committee will have broad questions relating to the complexities of design and the moral concerns outlined in the preceding section, inevitably, part of the questioning will be seeking out evidence and examples of the categories needed.

Chair: We need to see the protocol regarding consent and participants. They (the researchers) are so used to doing this they haven't written it down. It's a very brief document. It needs the words 'adult safeguarding' in the document
Observation extract: REC E

Lead Reviewer: 'It (the paperwork) refers to a family member consenting which is not appropriate. One adult cannot consult for another in English Law. The consultee can give an opinion. The consultee does not consent. Arrangements need to be made to comply with the Mental Capacity Act. (Participants) could have capacity and then lose it. Consent doesn't survive the loss of capacity.'
Observation extract: REC D

Apart from this particular Chair demonstrating her/his knowledge of the law on consent, s/he is identifying this strong theme which emerged in the data, and that is of the committee searching out, working on finding the relevant and prescribed categories. It is not permissible for crucial aspects to be missed out (as here). Often when researchers came in, the committee would pursue directly any concerns about omissions in the application. One reviewer when interviewed talked about how it was possible to 'lead' the researcher into providing the 'correct' responses or responses which would lead to a favourable opinion.

Reviewer: The onus is on the researcher to make the case but I don't know if you noticed but we fed him (the researcher) the lines. We have to draw out the bits to satisfy the legal requirements. We're teasing bit out to satisfy ourselves.
JM: Does the capacity checklist help?
Reviewer: It makes it easier. The hurdles are low. If you use the (correct) language, you can pass'
Interview with reviewer: REC B

This reviewer was uncomfortable with this as she seemed to acknowledge that this was a performance. She expressed some of the wider moral concerns which I discussed in the previous section, for example, expressing concern about what happens when researchers leave sites of research and the vacuum which might be left. However, she also expressed a concern about the diminishment of ethics review through proportionate review and had concerns about studies not being brought for full review to the REC. It seemed that although she could see difficulties with the current review system, she also saw it as worthwhile to have the discussion at a REC.

> Reviewer: What I like is that it is a very human affair. It's a jury. Who's there on the day. We've had problems, we've reviewed capacity incorrectly and we've been challenged.
> **Interview with reviewer: REC B**

But she saw value in seeing researchers at review:

> Reviewer: Will they conduct things ethically? Have they thought through the implications and why it is important to put in checks?
> **Interview with reviewer: REC B**

Every reviewer and committee member I interviewed said they preferred to see the researcher at the REC. This reviewer also spoke extensively about trust and this is a theme discussed in the previous chapters. Reviewers do go on instincts about researchers and whether they can trust them. However, there is a point here about acting ethically.

I have tried to show so far in this section that ethical regulation is reified in part through the various forms of recognition work I have described as taking place in the REC and undertaken by its actors. So far, what I have left out is the role of the researcher.

8.7 Researcher experiences of recognition work – complying with requirements

Finally, in this section I want to turn to the researcher voice and what researchers told me about their engagement with RECs and I want to connect this with the recognition work that I argue took place in the REC. I always met researchers on the day of the meeting. I often had the opportunity to talk to them before they went into the meeting if I was waiting with them outside. Sometimes researchers would start talking to me outside of the REC, even researchers who were unconnected to the studies I was there to hear reviewed. They frequently wanted to talk about past experiences, especially those who were experienced researchers and had been to many RECS. The mood was usually nervous outside of meetings. Researchers often talked about previous difficult experiences. Comments on the process often focused on the lengthy forms, uploading the forms and ease of the process prior to coming to the REC. This was very mixed with some researchers saying that the process was smooth with assistance from local REC coordinators, others feeling that there was

inconsistent advice and that it was difficult to keep ahead of the changes in paperwork required.

I usually took the chance to introduce myself to the researcher involved in the capacity study I had come to observe and then made contact later by telephone. All the researchers agreed to speak to me though they did not all respond to my follow-up contact. On interviewing researchers, I discovered that they had varied views about their experiences of the REC.

Researcher from REC C

This researcher had applied for review of a study which the committee clearly felt was important and they were looking for ways to support the researchers. It was a study for a research register to be built to assist researchers in mental health. In interview with one member of the research team, she said:

> The experience of attending the research ethics committee was useful. It was my first one. They had read in detail the notes. And it was complicated to get your head around the study. There are thousands of records which are anonymous.

She had clearly appreciated the time taken to get things right and include people whatever their diagnosis. On the other hand I had also noticed that researchers when interviewed were often trying to impress upon me that they found the experience positive and that this demonstrated that they were engaged with ethics issues.

Researcher from REC D

In a dementia study, this researcher was concerned that she was going to have to use consultees (to give consent on behalf of a participant) in case the person lost capacity during the course of the research. She found this a difficult demand, especially as she planned to include people who had recently been diagnosed and were likely to have capacity.

> This is a really sensitive area to raise with people who have only recently had a diagnosis of dementia. (I'm not sure) this is a balanced approach. The study is a feasibility study that was only going to be lasting three months and how much deterioration could there be in that time frame?

I will return to the gap between consent requirements and research practice later. Here, I use this as an example of how committee members are searching for key categories in the paperwork - in this case- the provision of consultee, and if it is not visible in the paperwork then it is made a condition of approval.

Another researcher said:

> I wasn't sure what to expect I'd had very different experiences of committees. I thought I might have further questions. I felt I knew the study and I could prepare. The question that surprised me was about Ireland (the Irish study) and the approval of that previous study.
> **Interview: REC E**

This researcher had been asked questions about a similar study in Ireland and the level of detail about the study design and its potential for repeatability. This again showed that part of the recognition work of the REC was to show that the studies reviewed were worthwhile science. The researcher had been prepared to address questions about her own study but not on research that had preceded it.

A researcher following attendance at REC C said: 'On the proxy (consultee) decisions I was struggling'. Another researcher felt that there was a 'preoccupation with process' and told me that generally RECs were viewed as a bureaucratic nightmare with colleagues encouraging his research team (and research teams generally) to use alternative methods (to get through the process).

An experienced researcher who led a research team attended REC H. He had the possible advantage of being a researcher (into substance misuse) in the hospital where the REC was held. He had found RECs difficult but said that in the last few years, they had been helpful and sensitive. He commented directly on the recognition work.

> You're asked a question, you answer it. By attending you can clarify. The follow up letter puts it in writing. It asks for the detail and confirmation of what you've said.
> **Interview with researcher: REC H**

Ethical regulation is accomplished by the REC doing recognition work, and then the researcher providing evidence that they have complied.

Another researcher who again was an experienced researcher was keen to discuss the difficulties.

> Opinion is mixed about whether to attend the REC or not. There is value in attending. Most of the questions and concerns can be addressed and then the follow-up letter asks for detail. Within our team we've had difficult experiences at REC meetings. The Principal Investigator doesn't always want to go so I go as lead of our team. With one particular study, the start of the study was delayed for a year. It got an unfavourable opinion and it was a year before we finally managed to get approval.
> **Interview with researcher: REC H**

As I have explained above, although none of the researchers received an 'unfavourable' opinion, nobody got a 'favourable' opinion either. All decisions were 'favourable with conditions'. This meant a follow up letter and then amendments from the researcher confirming that requirements had been met.

At the beginning of this section, I highlighted themes from Smith's methodology on texts. She did not claim this as a methodology but rather wanted to show how texts were 'part of the action', inseparable from the work of institutions and organisations. I have attempted to show how in the work of the REC, ethical regulation is achieved through recognition work. I have added a further layer to this in showing how the researchers complete the process of recognition work by playing a part in it in their attendance at the REC and then by the follow-up requirements which are put into a letter and which they have to conform to by amending their applications. The interviews with researchers and reviewers though also reveal how there is some 'ethical acting' which takes place. Note the reviewer comments about saying the right things to get through and though researchers most of the time said they had found the process helpful, others certainly found attendance to be an ordeal to be got through. There is a sense in which the process of ethical regulation supports ethical acting rather than acting ethically in research. In a parallel argument, Juritzen et al (2011) argue, (specifically in relation to consent requirements in review but their comments are generalizable to ethical regulation) that a rule–bound obtainment of consent involves a risk of making the process routinized and mechanical, and remote from ethically reflective practice. They identify a risk which may occur where

the focus is moved from acting in an ethical manner to appearing as an ethical actor (researcher) in the ethics review process.

8.8 'Mapping' texts - recognition work and REC processes

Texts are at work in review and operate alongside the judgement-making and ethics work described in the preceding chapter. Judgement and decision-making are not discrete activities in the REC but both are operating alongside each other. However, I want to suggest that this work is co-ordinated by texts in the following ways:

- The recognition work itself establishes the familiar concepts and categories – the principles of ethical research. The doing of this work, the discussion and debate is what accomplishes ethical research.
- The recognition work continues in seeking out expressions of the requirements in the applications. Looking for the recognisable concepts in the form of expression required.
- The recognition work is taken up with the researcher. Further expressions of requirements are explored with the researcher.
- The 'gaps' are detailed in a letter sent from the REC and the researcher closes the gap by responding to the details of the letter by amending her/his application. These gaps are those procedures which have been recognized as not being present in the review.

To reassert an earlier point, all of this recognition work is achieved through talk. The texts are crucial but are only brought to life, into meaning through the discussion in the REC. The talk is with each other and with the researcher. However, ultimately, for the process to meet institutional demands for transparency and trustworthiness, the performance of ethical regulation has to be played out in the context of texts and procedure and importantly, be seen to have been played out. Boden et al suggest that given a backdrop of public unease about medical scandals:

> *'There is an intuitive appeal in that which offers the fantasy of ethical purity through a therapeutic and redeeming process……. There is relief to be gained from effectively abrogating responsibility for safeguarding ethics to a paternalistic external authoritative body in the form of the ethics committee.'*
> (Boden et al, 2009:737)

I have described the part texts play in this processes of this external body and have attempted through my interpretation, to illuminate what actually happens in the

committees in relation to the regulatory texts, which are integral to the processes of regulation. I have used Smith's description of recognizing categories and concepts and termed this 'recognition work'.

I suggest that the dependence on requirements meets the desire for a display of trust and transparency which meets the needs of the 'institution', in this case, the HRA as the responsible public body. The recognition work on texts (the application completed prior to the REC and the capacity checklist used by committee members) is a crucial part of this. It is not just that the work of the committee is accomplished but ethical regulation itself 'happens', is done, through this recognition work in the REC. As Boden et al infer, 'ethical purity' and safeguarding of ethics is (apparently) achieved through the REC processes. I have tried to show in this section the important part that texts play in this system.

8.9 The gap between procedure and research practice

Using Chambliss above, I discussed how ethical codes are often ill matched with the reality of making moral judgements in practice. Here, in the context of ethical regulation ethical requirements are abstract and hypothetical and separated out from the practice of research. The process I outlined above ends abruptly. The researcher sends the changes back as required by the REC and the process is complete. Texts have been worked on, ethical requirements met, ergo, research has ethical approval. However, the research takes place following the completion of this process. There are no follow up checks on ethical conduct in research.

Some committee members commented on this and the fact that following the REC there are no mechanisms for checking that the researcher is doing what s/he said they would do. There is no jurisdiction which enables RECs to direct that negative results be published. However, rather than this exposing the limits of RECs powers, I think it reaffirms the centrality of RECs in decision-making. This authority appears to be located in committee meetings (even though their authority is granted beyond the RECs by overarching regulation) it is the meeting that leads researchers to dread them. They know that they have 'to get through' the REC in order to begin their research. They become complicit in the process in order to gain a favourable outcome. Boden et al (2009) argued that researchers self-regulate and self-

discipline, limiting the scope of their research knowing that they have to negotiate their way through the apparatus of approval.

Some of the researchers I interviewed seemed to be doing just that. They knew that they had to demonstrate compliance with requirements even though they knew that this would be challenging in practice. This suggested a more significant gap than the one which needs to be fulfilled in the mapping process outlined above. The gap between ethical regulation and the complexity of real-life research. One researcher worked with people who had addiction problems. He said of the people she worked with:

> When you approach people, they don't listen (to all the study information). They're keen to participate in research. They want the opportunity to talk about their issues. What if people don't want to sign a consent form? The groups I work with are used to forging signatures. They're concerned that they may declare a crime in my interview with them and that they would have provided a signature on the consent form. It's inflammatory to ask a drug user to sign something.
> **Interview with researcher: REC H**

This highlights some of the realities of consent requirements 'in the field'. This seems to indicate that they attend RECs and comply with the procedures but are acutely aware of the gap between procedure and practice.

The consultee requirements were highlighted as a source of difficulty. A researcher on a longitudinal study on dementia was asked by the REC to ask participants at the start of the study who they would want to have as a personal consultee when they may have lost capacity. She had to agree with this as part of the conditions for approval (she had got a 'favourable with conditions decision' when I had observed the review of her application) but she was uneasy with this.

> I can comply with the requirements but it's not easy to have this conversation with someone at the beginning of their condition, at diagnosis when they still have capacity.
> **Interview with researcher: REC F**

The use of consultees in general was not viewed as straightforward and concerns were expressed by both reviewers and researchers. They talked about how consultees might be either overly protective or permissive. In other words, their

opinion may be influenced by a range of factors which are not connected to the wishes of the potential research participant. The context was also seen as relevant. The perceptions of consultees may be that if their (usually) family member does not participate in research that this may have implications for the services or treatment provided. Consent decisions are 'partial' rather than complete and explicit and situated, rather than objective and distanced (Greenhough, 2007). Findings from observations and interviews in this study appear to evidence this position. This indicates that the procedural requirements for consent are at some considerable distance from seeking and gaining consent in research.

This gap between procedural requirements and the complexities of ethical practice are highlighted by Guillemin and Gillam (2004) who described two domains for ethics. One which they termed 'procedural ethics; which encompasses the regulatory, procedural and technical world of ethics review and the second, 'ethics in practice' which encompasses ethically important moments in practice and the everyday of research ethics. Although they see some worth in review processes, seeing them as potentially an opportunity for researchers to be ethically reflective, they nevertheless see the challenges for researchers in contemporary procedural approaches.

8.10 Conclusion

In this chapter I have argued that texts are foundational to ethics review. I have provided an example of a regularly used text showing how I think a text can regulate and co-ordinate the wok of RECs. I have shown how texts work in the REC describing how committee members engage in **recognition work**. Invested with authority, the REC members examine applications in order to find the recognisable concepts required by the regulatory texts. I have attempted a mapping of the process before highlighting the gap between procedural ethics and ethics in practice. Much of this chapter (as with the last) has been about bringing into view the commonplace work that members of RECs do. One of the challenges institutional ethnography sets itself is to draw out the everyday competence and knowledge of people at work. The aim of this chapter has been to show how REC members skilfully use texts and I have interpreted their work to argue that their tacit use of texts is actually connected to the authoritative aspect of RECs which makes decisions about whether research

happens or not. I have also tried to show the part the researcher plays in this as researchers are also important actors in the work of ethical regulation. I hope that the chapter has moved beyond description and shown that people's knowledge and actions in RECs are in one sense, already organised before they talk about them. What I mean by this is that the ways in which applications are reviewed (talked about, deliberated over) are shaped by the institutional texts. I think the preceding chapter showed that before decision-making comes judgement and RECs resist confining their judgement to prescribed texts engaging in 'ethics work' to connect with moral and ethical elements in research applications but decisions are legitimised by the texts of ethical regulation.

I have begun in this chapter to identify some of the wider social contexts which the work of regulation relates to and I will extend this discussion in the final chapter exploring in particular how regulation is linked to wider social concepts of trust, accountability and transparency. However, to begin with in the penultimate chapter of this thesis, I want to show the mapping of ethical regulation.

Chapter 9: Mapping ethics review

9.1 Introduction

This chapter sets out the substantial findings of the research**.** This ethnography has endeavoured to look at how ethical regulation is socially organised and the analysis has attempted to 'map', weaving a way through what happens and how things happen at these important meetings**.** What appears in the figure below does not indicate a sequentially or hierarchical outline of the work of ethical regulation. All three elements work together and are sometimes indiscernible from each other. I have given attention to both the work and the use of texts through observations and through discussions with the reviewers and researchers involved. This has resulted in a particular account of the work of the REC. It is my version but importantly, the mapping was developed through the observable actions and accounts of people who are engaged in that work.

The mapping is presented graphically followed by explanation of each of the three areas. I then discuss each of the three areas in more detail and articulate their relevance to the overall project.

Figure 4: The mapping of ethical regulation

Mapping ethical regulation in the Research Ethics Committee

1. The ordering of ethics work

Setting, order and membership organise the work of the committee at the micro-level of each committee and across committees.

This assists with need for transparency in proceedings, ideas of fairness, equity and objectivity.

2. Making judgements

Ethics work carried out in the committee is subjective and includes use of emotions - thinking themselves into research.

Sensitive to capacity in its complexity.

Identifying ethical elements in studies.

Relationships - with each other and with the researcher are significant in judging research.

Reviewers engage with overarching principles and the framework of requirements by use of subjective means.

3. Making decisions

Importance of texts - the form of requirements needed in decision-making.

Back and forth activity of judging application and then making a 'fit' with requirements once judgement is made.

Looking for evidence of the required categories in application and researcher.

Working up to a decision.

- The ordering of ethics work: Description of the processes of the REC. RECs are steeped in bureaucracy. The meetings are structured and follow a sequence which assists with achieving the work. Membership is important. Micro-level analysis of who speaks at meetings and the exchange with the researcher is relevant in how deliberations lead to decisions. All RECs are different and yet

the sequences followed ensure that work is co-ordinated across sites. This is also important in demonstrating equity and fairness in the system.

- Making judgements: RECs have to make sense of complex research applications and justify their decisions in the context of a committee meeting. They are compelled to use abstract sets of principles which inform the bureaucratic requirements. Committee members employ various strategies to justify and make sense of abstract ethical principles and requirements. They justify decisions by reference to 'good science', benefits to society and use their own moral frameworks to aid decision-making. Ethics work in this setting comprises an interweaving of principles and individual moral frameworks. This individual aspect of the work of members can be understood by using the perspective of care ethics. This is what closely describes the activity of the REC members. I explain this more fully below.

- Decision-making: RECs use the regulatory texts in particular ways. They need to demonstrate that they have considered requirements but have made a prior judgement about research first and then find evidence of the text's various 'categories' in the application. I refer to this as 'recognition work'. The loop is closed when a letter highlighting gaps is sent to researcher.

9.2 The ordering of ethics work

Interpretation of findings here is descriptive, setting the scene and revealing the rarefied atmosphere of the REC. Its theoretical significance is to demonstrate how the 'liturgy' (Atkinson, 1995) of the REC and the sequenced and routinized ways of 'doing' the work were reproduced across sites. This co-ordinated the work of ethical regulation, and, I argue, that this assisted the idea of objectivity in decision-making.

 Institutional review of research ethics is constrained in time and space by the REC meeting. Just as institutions manage everyday occurrences in a 'decidedly different time-zone' from real life (Wilson and Pence, 2006:212), the ethics of research is organised and controlled through the regulatory system of review. The business of the RECs can only be achieved by following certain sequences of action (including the appointment of reviewers, debate, researcher interview, further debate leading to decision). The settings of RECs influence the atmosphere of meetings, for example,

hospital settings, and formal committee rooms. I have argued that all of these are significant in co-ordinating the work of committees. They assist in practices being reproduced across committees even if the character of each committee is unique. This serves to provide an overarching structure and method for reviewing applications. It could be said that this is the architecture of ethical regulation. This is important because it allows the RECs and the Health Research Authority to establish objectivity in review. The sequence allows debate but also moves the meeting along to a conclusion. The sequence allows time for deliberation and discussion, gives fair hearing to the researcher and then reaches a decision on the application. Fairness is an important part of objectivity and trust in the process. This is easier to see from the outside if all meetings run along similar lines. The HRA website provides information on what the researcher can expect to experience and even if the discussions and questions vary, the process will be broadly the same. 'Meetings are fashioned to establish direction and justification or institutional action' (Nikander 2003) and there is often an 'incremental process' (Boden, 1994) which supports business to be achieved and works up to outcomes. Boden's description of organisations in action is primarily ethnomethodologically focusing on the 'talk' in organisations. She also however acknowledges that how organisations operate as well as the environmental context are vital to our understanding of how organisations reach decisions and achieve institutional outcomes (Boden: 32). Her emphasis, and Dorothy Smith's, is on how work is achieved locally. My account provides a detailed description of every day work of the RECs and highlights parallels in the sequencing of meetings across sites. I show how committee members work together to make a decision. Furthermore, the sequence of meetings makes for a coherent environment and allows business to be conducted fairly speedily and effectively. The work is achieved in what Boden refers to as an 'organisational dance' (p194).

Membership is also significant. Though there is a lay membership, this is simply in practice, nonmedical. Most lay members have skills or knowledge from their own professions. Examples of lay membership were barristers, statisticians and philosophers. With the exception of some who had a business background, of the members I interviewed, most could be said to bring recognisable skills and knowledge with them into the meetings. Stark (2012) calls this the 'cultural authority' of knowledge-producing professions where skills acquired through training in

medicine, science and the humanities are seen as valuable and amenable to transfer. Authority is carried from one setting to another. She refers not only to the physical 'setting' but also to other domains, specifically here, the domains of ethics where these professional experts carry the authority to make judgements on the worthiness of research. Experiences (as a professional) are, 'generally thought to translate into rare abilities to judge the quality, veracity, or ethics of knowledge outside of research settings.' Experts carry authority from one setting to another, for example, 'from the bench to the bedside, the lab to the courtroom, the field to the review committee, and the armchair to the lectern' (Stark, 2012: 31).

Lay membership has significance beyond the committee. The desire for lay members to be included is crucial in countering the 'bias' and 'orientation' of RECs to a biomedical approach. There is a dominance of medical members and there is a familiarity therefore with quantitative research and a tendency to see this as proper research. However, lay members did make a significant contribution in the REC. Time was given to their views and they often opened up debate, raising questions which might have appeared obvious to medical members but which nonetheless brought attention to pertinent issues.

Recognition of and esteem for professional knowledge in membership extended to a recognition of the cultural authority of researchers so that reviewers were more reassured after seeing the researcher at the meetings and were impressed by their 'professional' presentation. I showed how these exchanges with researchers were so significant that they could even revert a decision to reject which had been based on the written application alone. What was evident in the breakdown of exchanges I presented was that a substantial part of each of the meetings I observed was spent on interviewing the researcher. As well as this being to discuss design, there was also a 'testing' of whether the researcher impressed with her/his integrity to carry out ethical research. This was commented on in interviews with reviewers who all saw the presence of the researcher at the meetings as important. As well as 'checking out' details of the research design, they were also checking out whether they could trust the researcher. How reviewers were assessing integrity was difficult to describe. Some of their judgement was based on the researcher as a professional. If they were convincing as a professional or practitioner, then that would reassure

committees. Members have to make a practical judgement based on what is before them. They do not know what the ethics of the applicant would be in a research context unless they have met them at a previous REC or (as sometimes happens) have some knowledge of the setting in which the researcher works. This highlights an important point raised recently by Hammersley (2015) who in a paper about the limits of principlist approaches in research ethics points out that insufficient attention is given to 'the important differences in task between researchers, on the one hand, and health policy-makers and practitioners, on the other.' (p443). In other words, researcher roles and practitioner roles were often conflated.

To conclude, the findings here revealed how order and roles are important in co-ordinating the work of the committees. The focus was on the observable processes, formal and informal in RECs and on what I learnt about the way committees run from participants talking to me. RECs are not so fixed or as closed-off as might be thought. They welcome researchers and by doing this engage to some extent with the challenges of the doing of research. Finally, this thesis stresses the importance of the sites of decision-making as crucial for understanding how regulation works in the unique setting of the REC.

9.3 Making judgements

Reviewers are committed to research. They engage with research, with each other and with researchers in considering applications. Abstract and remote ethical requirements were brought into being by use of, for example, individual morality and emotions and were influenced by a strong sense of duty and/or by the consideration of consequences for participants or the prospect of positive outcomes for patients or citizens more widely. The sense of duty also included a feeling that 'good science' needed to be upheld by which they meant good and worthwhile research. This was above all about judgement and how the committee embers engaged in 'ethics work' (Banks, 2013:599). Committees did not only draw upon a deontological concept of morality based on principles, justice and fairness but their judgement was located simultaneously in an ethics of care domain. I mean by this that they engage with each other and empathise with research participants as far as they can, demonstrating that they do not simply base decisions on principles. Care ethicists view decision making as crucial data for theorising (Collins, 2015).

> *'They point out that when deliberating about what we morally ought to do……we typically take account of the particularities and complexities of the relationships between the unique persons in the dilemma.'*
> *(p4)*

I argue that committee members do move beyond the principle-informed requirements (even though these are a crucial part of decision-making) and they engage with the particular by empathising (imagining themselves in the place of research participants); they feel proud and responsible for what they are doing; and they want to meet the researcher in order to gain an impression of personal trustworthiness). In these ways, members extend from abstract principles to consider 'concrete, particular others in complex webs of relationships' (Gilligan, 2014:4). They are aware of the ethical and moral dimensions in research and within the constraints of a meeting did their best to find out the purpose of the research. In relation to virtue ethics and virtues in reviewers and researchers practice(s), I have elected not to consider that ethical approach in my analysis. The reason for this was outlined in 3.9.3. This is not to say that participants did not display virtuous character traits, but it was beyond the limits of this study to have looked in depth at virtues held and deemed to be important by reviewers and researchers. Nonetheless I have referred to the importance placed by reviewers on 'researcher integrity' and how they sought to be convinced of that by talking to the researcher at committee meetings.

My interpretation of findings here highlighted the processes and range of strategies used by committee members when making judgements in the REC by using examples from observations and interviews. Judgement making is distinguished from decision-making. An important discovery in this ethnography was that committee members use all kinds of practical means to do their work. I used a concept form Banks (2015, 2016) 'ethics work' to explain this and suggest that in this case, ethics work comprises the drawing out of ethical dimensions and the justification of decisions by recourse to requirements in the form of the texts.

Findings revealed how much of reviewers' every day knowledge is tacit by which I mean that it arose from feeling their way around research, from emotion and from a sense of 'doing the right thing'. In weighing up benefits, harm, rights and responsibilities, much of their work in the everyday is subjective based on hunches and their individual and group judgement. Professional ethical codes, and in this

context, ethical requirements, are usually influenced or informed by moral values or principles. However, making these codes alive and meaningful depends upon the reviewers making sense of the applications in front of them often in quite practical ways. The official decisions required to be made by RECs are dependent upon judgements in the here and now which are separate from and at times quite distant from the ethical requirements. There is also a 'social' aspect to this because judgements are not made by isolated individuals but through talking up in a social group.

Chambliss's (1996) observation of the gap between abstracted ethical codes in the nursing profession and the practicalities in the concrete ethical decision-making required in the practice of nursing was useful here. This connects to a wider issue which concerns the larger institutional structure of the Health Research Authority. The bureaucracy indicates that there is a rational, technical way to make decisions. That principles inform requirements and these can assist in decision-making. This bureaucratic rationality directly influences reviewers as can be seen in my discussion of texts, but on their own, these procedures do not get the job done. Banks describes ethics work as follows:

> '…. 'Ethics' relates to matters of harm and benefit, rights and responsibilities and good and bad qualities of character. I am using the term 'work' in this context to cover the psychological and bodily processes of noticing, attending, thinking, interacting and performing.'
> (Banks, 2016:36)

This description of ethics work, particularly 'noticing', 'attending' and 'interacting' is aligned to a care ethics approach by which I mean an approach which is relational in practice and where the right or wrong thing to do is derived from the situation and relationships (Collins, 2016). I have noted how reviewers demonstrated care for what they did, respected their colleagues' positions and showed care in the relationships with researchers. However, there are boundaries here and the explanations of ethics work and ethics of care as frameworks to understand RECs' work are partial, not explanatory of the whole. It is important to note for example that the value of the relationships here is context-specific. In Collins' terms the relationships are instrumental:

'The instrumental value derives from the consequences of the relationship, most commonly consequences for participants.'
(Collins, 2016: 22)

The relationships and care are a means to ensuring practical work is achieved. There is an investment in the relationships which hold 'value' (Collins: 41) here but I am not suggesting that this describes other aspects of value (subjective, personal, non-functional) which might be placed on relationships. Nevertheless, ethics work and its relationship to care ethics is a further insight offered here to illuminate some of the ways in which the everyday work of RECs is achieved.

I describe the myriad ways in which reviewers do the work of making judgements about applications. Some of these are *ad hoc* dependent upon information available at the time, some depend on subjective weighing up of risks and harms. I also show how reviewers 'think themselves' into the situation of the research using their imagination to think prospectively what might be the pitfalls of the research. I argue that judgements are made first before decisions. Judgment making is incremental and often not coherent, depending as it does on the ability of reviewers to identify and engage with the moral or ethical issues presented. Again, (Boden, 1994) notes that, '…. Decisions, as identifiable items, become clear only *after* their constitution.' Judgements which lead up to decisions are not 'the crisp, goal-orientated, value-maximising assumptions of many theories of rational action' (Boden: 183), rather, they more likely reflect the genuine motivation of REC members to be as fair as possible in making decisions. Their motivations are often based on ideas of duty and a concern for research as well as research participants. There was a tension between the need for a demonstration of objectivity and the subjective ways in which applications were discussed and judgements made about them. I have attempted to deepen insights into the everyday work of REC and to reveal some of the practical ways in which ethical regulation worked in the REC.

Interestingly, just as Guillemin and Gillam (2004) refer to reflexive ethics in the *practice* of research and Banks and Williams (2005) suggest practising ethical reflexivity to assist in professional social welfare work, I would suggest that there is a need for reflexivity among reviewers. So much of their work is done in a taken-for-

granted way that they see what they do as obvious. The purpose of this ethnography was not to look at outcomes or quality of decision-making but a conscious reflexive scrutiny of activity and practices in the REC may reveal helpful knowledge to reviewers themselves.

Finally, the analysis in this chapter is partial. It is impossible to do 'ethics work' in this highly regulated domain without reference to the texts. The evidence for this was in the expressions of concern by researchers about ethical requirements and consent, particularly the use of consultees and aspects of confidentiality. Researchers expressed contrasting views. Some found the REC helpful while most saw it as a hurdle to be negotiated. Though unknowable, as far as this research extends, researchers may regulate their research, set parameters upon it, or even avoid areas of work which interface with 'vulnerable groups'.

9.4 Judgements, decisions and reflective equilibrium

I have described in the mapping in this chapter a process of back and forth deliberation which builds to a decision. The concept of reflective equilibrium enables a further possible interpretation of what I found occurring in the REC. The philosophical term, reflective equilibrium was first described by John Rawls in a 'Theory of Justice' (1971). He used the term to describe a considered and deliberated way of bringing into balance considered principles, judgements and theories into a state of harmony. The term has wide application and is used in bioethics and clinical ethics as a way of thinking through moral questions. It has been described as a method of reflection for moral problems (Van Willigenberg, 2007). 'Wide' reflective equilibrium (which Rawls referred to following his original discussion) incorporates a 'wide' scope of judgements, principles, rules, moral beliefs in reaching a balanced assessment of a particular moral problem. For Beauchamp and Childress (2012) reflective equilibrium is a useful concept. Accounts from 'the top' (principles, rules) and 'the bottom' (cases and particular judgements) both need supplementation.

> 'Neither general principles nor paradigm cases adequately guide the formation of justified moral beliefs in some circumstances.' (p404)

They support reflective equilibrium which they depict as a way of reflectively testing moral beliefs, principles, judgements and theories with a goal of making them

coherent. Justification of a set of moral beliefs or a theory comes about when the coherence of a range of beliefs is maximised.

> *The goal of reflective equilibrium is to match, prune, and adjust considered judgements, their specifications, and other beliefs to render them coherent.'* (p405)

Thinking about this in a research context, 'considered judgements' may be judgements which we all may broadly agree on, such as protection of research participants from harm but this may not be an absolute principle when we consider possible conflicts or particular cases. For example, in my findings above, a reviewer questioned what is acceptable burden using the example of blood tests. S/he said:

> If we're taking blood samples from babies, then the baby screams – there is distress to the baby and the mother (parent) so we have to question how many times we can take blood. What is reasonable? Clinicians may treat these situations in the same way even when in one case the blood tests might be for treatment and in another, for research. What if it's not to do with treatment – it's not clinical judgement but research judgement. The question of burden has to come up.
> **Extract from interview: REC C**

Here the interviewee was referring to the distinction between different levels of acceptable hurt or burden in clinical and research contexts. It highlights also how 'absolutes' have to be altered or changed in the course of moral reflection. The principle of protection from harm can be described as a 'considered judgement' which we might all subscribe to. Beauchamp and Childress describe these as acceptable starting premises but not absolute principles.

Further, my analysis revealed how reviewers use a range of personal beliefs, knowledge and emotions as well as procedure and principles, and bring all of these to bear on the questions they are debating.

> *'According to the reflective equilibrium approach, a warranted solution to a practical moral problem is reached by questioning the tenability and relevance of all sorts of beliefs, none of which is immune to revision'.*

(Van Willigenberg,2007:207)

This is relevant to my findings in two ways. Firstly, the inclusion of a range of (diverse) beliefs and values in deliberations which seemed at times to be disorganised and 'messy', with reviewers going back and forth in their discussions.

Secondly, the practical application which reflective equilibrium seems to me to have at its centre, where dominant seemingly self-evident principles do not dictate one's moral decision making and reasoning about problems though they may indeed play a part in that reasoning. The concept of reflective equilibrium also describes the effort which goes into judgement and decision-making and is congruent with the notion of ethics work referred to elsewhere in the thesis (in concluding comments in 10.1 which interprets the engagement of reviewers with research as 'ethics work') and specifically:

> *'the effort people put into seeing ethical aspects of situations, developing themselves as good practitioners, working out the right course of action and justifying who they are and what they have done.'* (Banks, 2013: 600).

Although relating to health and social care practitioners, this seems to me to be highly relevant to reviewers' activity and the development of their own skills in reviewing.

Finally, the reviewers I interviewed stressed that procedures and regulations played a part (and I have argued that procedurally, research ethics review is informed by over-arching principles) but that did not tell the whole story of how decisions were made in the REC.

Note this seemingly contradictory response:

> JM How do you go about making a decision?
> PM: I confess that the regulations are irrelevant – it's the underlying ethics that are important.
> However, in the same interview said*:*
> (Regulations) I have no problem with them. I'm going with the flow.
> **Interview: REC B**

Holding both of these attitudes towards regulations might at first seem untenable but in the practical working out of problems in the REC, both of these seem to be the case. Drawing on regulations when relevant and at other times wanting to be personally sure that something is morally comfortable or acceptable regardless of regulations.

9.5 Making decisions

Moving from judgement to decision-making, this part of the analysis was primarily concerned with the requirements for the inclusion of research participants deemed to

lack capacity. I used Dorothy Smith's ideas on incorporating texts into institutional ethnography (2006) as a starting point for this section. Much of the deliberation and discussion in the REC is an expression of the ethical requirements**.** The processes of the REC (discussion of the application, interview with researcher, more discussion and deliberation leading to judgement) are also the means by which ethical requirements are expressed or upheld. It is the doing of this work which achieves ethical regulation. The REC spent a great deal of time looking for evidence in the applications they reviewed of the concepts required by the regulatory text. I describe this work undertaken by the REC members as '**recognition work'**. Reviewers had considerable skill in understanding requirements and in how they must adjust their judgements to correspond with them. Nevertheless, RECs resist confining their judgement to prescribed texts engaging in 'ethics work' to connect with moral and ethical elements in research applications.

Ultimately, decisions are legitimised by the texts of ethical regulation. I have argued that *judgements* are made in myriad ways but final *decisions* are made by reference to the requirements. Following on from Boden above, often decisions as definable only become clear after they have been made (p183). In other words, people tend to work backwards to show evidence of their decision-making in a retrospective fashion. Reviewers themselves are influenced by the requirements and have a 'persuasive sense of idealised bureaucratic rationality'. This shapes and influences their work and how they account for what they do. I noted that when asked about the capacity checklist, reviewers said that they found it helpful. My argument is that they found it helpful in the justification of the judgement they had already made about the research application. Nonetheless, texts are extremely powerful in ethical regulation and the particular focus on requirements for consent (in 'capacity' studies) revealed that these can lead to potential difficulties.

Researchers also play an important part in the process of review and their perceptions of the experience of ethical regulation and the requirements, particularly relating to the 'consultee' requirement for research participants who lack capacity have been taken into account. There was some evidence that researches did what they needed to do in order to get through review to approval. Juritzen et al (2011) argue, in the context of the regulation of consent in research ethics, that this

bureaucracy transforms researchers themselves into compliant self-regulating actors. Boden et al (2009) in an analysis of power in ethical bureaucracies, assert:

> *'The regimes of control……. institute technologies of the self that require researchers to become 'docile bodies' within the research process, self-regulating and self-disciplining their own actions against particular ideas of what is standard and good.'*
> (Boden et al, 2009: 743)

The evidence for this was in the expressions of concern by researchers about ethical requirements and consent, particularly the use of consultees and aspects of confidentiality. Researchers expressed contrasting views. Some found the REC helpful while most saw it as a hurdle to be negotiated. Though unknowable, as far as this research extends, researchers may regulate their research, set parameters upon it, or even avoid areas of work which interface with 'vulnerable groups'.

Sheehan (2013) has responded to criticisms of the functioning of RECs as over-generalised and therefore inaccurate. He is dismissive of the claim that there is a 'one size fits all' approach in committees as this critique requires evidence which is not always apparent in the arguments for change. Rather than the question being whether we need RECs, he argues that attention would first need to be paid to whether the system can evolve and develop in response to problems. The research I have conducted provides some insights into the workings of committees and evidence (albeit limited) of how they work. This chapter has summarised the key arguments of the thesis and distilled the analysis of findings into a process mapping of ethical regulation as it happens in the REC. In the final chapter I complete the institutional ethnographic approach by making connections to wider overarching concepts which govern the work of regulation but which are not obvious in the everyday 'doing' of the work. I then go on to address the rigour and quality of the research putting forward my unique contributions to knowledge and understanding of ethical regulation. I address limitations in the study, before identifying areas for further development and potential benefits of the findings.

Chapter 10: Conclusions

10.1. Summary

This research set out to understand better the day-to-day work of RECs in the particular context of committees reviewing applications where potential participants were deemed to lack capacity. In the first part of the thesis, I demonstrated through the literature review how critiques of bureaucracy in ethical regulation have largely ignored how RECs do their work (with notable exceptions being Hedgecoe and Stark). I maintained a reflexive stance in the methodology, making explicit how and why I made the choices and described the processes I went through in the design of the research. I maintained this reflexive position in the description of my approach to analysis and interpretation of the data. The second part of the thesis has provided a rich description of the everyday world of the REC and how its work is ordered. It has interpreted the engagement with research as 'ethics work' showing how judgements are made. It has then explicated, explained in detail, how 'texts' are used in decision-making emphasising those texts with the legal mandate of the Mental Capacity Act 2005 (MCA 2005). The interpretation of findings has distinguished judgement and decision-making in review showing demonstrating how reviewers engage with research and researchers in subjective ways and make 'judgements'. They also work simultaneously in another complex field of activity which is concerned with the identification of components which satisfy the textual requirements ('recognition work') and this is part of the overall 'ethics work' which transforms judgements into decisions.

The technical meaning of mapping in ethnography is not a diagram of structures or job descriptions, but an analytic procedure that results in an account of day-to-day work, describing practices which give shape and form to an organisation's activities. It is developed from the accounts and observable actions of people engaged in the work who may not be aware of how the routine and ongoing activity fits with the large-scale institution and its outcomes (Turner, 2006). I have mapped in an ethnographic sense, three important features as being significant in illuminating our understanding of how ethics review is achieved.

- The ordering of work in the REC
- Judgement and engagement with research

- Making decisions and use of texts

I do not mean 'mapping' in the sense of showing institutional structures within organisations. I am using mapping here to describe both the process I have undertaken and the account of the day-to-day work of the REC which has been produced. The mapping presented is constructed from my findings and the layered descriptions of the fields of activity I discovered.

I now connect this mapping, in keeping with an institutional ethnography, to wider concepts of trust and accountability. I then conclude by highlighting the methodological limitations of the study, provide a note on validity and indicate potential ways that the research may be of benefit. To begin with, I outline the distinctiveness of the methodology employed in the study.

10.2 The distinctive ethnographic method in the study

Ethnographies of work have the advantage of showing how the everyday is complex, how complex tasks become routine and how power and control are maintained (Smith, 2002:221). This has enabled a rich description of the work of ethical regulation in the settings where decisions are made. I have drawn on institutional ethnography as an approach to illuminate the role and importance of texts in ethics review. This has enabled a critical examination of texts in context, in the exact locations (RECs) where they are actualised. Texts in their different forms dominate ethical regulation and yet they have no authority unless they are used and activated. This research has been able to show in detail how texts support and lend legitimacy to judgements made in the REC. It has also shown how committee members use the texts and their terminology proficiently. This is an incredibly complex activity and a significant contribution of this study has been to unearth or make apparent the tacit skill and knowledge of regulation. This is what Smith refers to as 'tacit knowing' (1997: 395) which here is the knowledge of 'doing ethics review' by committees in the everyday, without thinking about what they do. This is connected also to my arguments in the second chapter which show how reviewers use all kinds of tacit understandings when making judgements. In fact, the thesis shows the distinction and connections between judgement and decision-making. The focus has been maintained on how RECs carry out their work and making connections between the everyday doing of review and the wider institutional and societal structures which

determine how research is regulated. This last point is crucial. The thesis has offered detailed description and analysis of the work of the RECs. The significance of this is that members of the committee talk about and shape their work through the language of ethical regulation. Institutional discourses permeated their work and also to some extent constrained how they talked to me about their work. The challenge of the project has been to highlight how this familiar language does not accurately describe the work undertaken, it simply references the dominant discourses of ethical principles and regulation. My task has been to access what 'actually happens', how work is achieved. The resulting descriptions and analysis presented in this thesis constitute my unique contribution to knowledge, extending what is already known about the work of RECs. My discussion of the deliberations, talk and debate of the committees has some similarities with Laura Stark's 2012 study of Institutional Review Boards in the United States. However, the analysis of the use of texts is novel as is the orientation of the study to capacity and consent with a section of the analysis dedicated to the operation of consent in ethics review.

10.3 Contribution to knowledge and the wider significance of the research

This project has not aimed to evaluate the skill and expertise of reviewers. Instead, the institutional ethnographic approach has intended to look at where 'work happens' and to discover that world of work as far as possible from the standpoint of those within it. It has given attention to the actualities in context rather than subduing the particular local positions, perspectives and experiences (Smith, 1999: 54). In other words, theoretically focus is orientated to what is happening, exploring the social relations and organisation that co-ordinates people's activities. However, Smith also emphasises connecting what is learnt in the process of inquiry with wider relations of ruling. Smith explains,

> *'The project is to extend people's ordinary good knowledge of how things are put together in our everyday lives to dimensions of the social that transcend the local and are all the more powerful and significant in it for that reason.'* (Smith, 2006:3)

Furthermore,

> *'The aim is to create a sociology for rather than of people that can expand the scope of our knowledge of what we are part of but cannot apprehend directly. Investigating develops from within the local worlds of people's everyday experience, exploring the social relations and organization that co-ordinate*

*people's activities across local sites, and explicating the workings of powers
that are deeply implicated in our everyday lives'.*
(Smith, 2001:161)

The challenge of unearthing the wider social dimensions, which govern people's day-to-day work, is that the people being observed or interviewed have been trained or accustomed to using the concepts and categories that the institutional ethnographer wants to unpack (DeVault and McCoy, 2006). I refer here to the epistemological discussion at the beginning of this thesis which referred to the postmodern dominant discourses, discourses which are so embedded that they are difficult to recognise in our everyday use of them. This presented a difficulty for me because as I was asking about and observing processes, decision-making and attempting to get a sense of how capacity and vulnerability were conceptualised in review, the people I interviewed and observed were saturated in the institutional, orthodox version of these matters. However, partly what I demonstrate is that reviewers were not simply confined and constrained when making judgements about applications. Nevertheless, the overarching ruling concepts I connected to were concerning discourses of trust and accountability. Trust and accountability become even more important when research is being considered with people who are deemed to lack the capacity to consent. Consent goes to the core of what it means to be an autonomous subject and this autonomy needs to be protected and be seen to be protected when decisions are made to override it. To reiterate, what happens at the REC is connected to these 'ruling' powerful concepts which underpin the Health Research Authority as a public body.

10.4 Texts and trust
The moral philosopher Onora O'Neill has written and spoken extensively about trust and accountability in bioethics (2004) in education (2013) and in public life more generally (Reith lectures, Gifford lectures). Trust and accountability are themes which are echoed by other writers who express concern and question the purpose of the high (researchers would say, overwhelming) volume of both on-line direction, advice and application documents required for submission for review (Hammersley, 2010, Stanley and Wise, 2010).

In this extract from the Reith lectures, O'Neill refers to the hazards of the published form and the illusion that these different forms might give of accountability and trust.

> *'Socrates did not want his words to go fatherless into the world, transcribed onto tablets or into books that could circulate without their author, to travel beyond the reach of discussion and questions, revision and authentication. So, he talked and chatted and argued with others on the streets of Athens, but he wrote and published nothing. .... The problems to which Socrates pointed are acute in an age of recirculated 'news', public relations, global gossip and Internet publication. How can we tell which claims and counterclaims, reports and supposed facts are trustworthy when so much information swirls around us? It is hard to distinguish rumour from report, fact from fiction, reliable source from disinformant, truth-teller from deceiver?'*
> Onora O'Neill 2002 Reith Lectures

Although, O'Neill is not directly referring to texts as I refer to them in this study, she nevertheless is conveying something which is highly relevant. I feel this extract conveys much about the illusory nature of texts. Referring to Socrates's mistrust of writing things down, O'Neill is prompting the question of what is achieved by bureaucratization and technical approaches. These are meant to reassure and promote trust but in fact she suggests that they are meaningless unless constantly authenticated in the here and now. O'Neill seems to me to be mirroring sociological arguments which stress context. The meaning of texts can only ever be actualized, achieved in situated ways. From my reading, O'Neill's position offers a perspective which evaluates and critiques the motivations for contemporary accountability regimes while wishing to 'rethink' principles. These arguments are relevant to ethical regulation because of the level of bureaucracy inherent within it. However, in contrast to this perspective which would see texts as fixed and immutable, I have explored the texts not as fixed sources of information but as 'at work' (Smith, 2001:169). The way texts are put to work is of foundational significance to ethical regulation. A further contribution this study has made is that it has not limited the exploration of texts as static. Texts are important for 'More than simply words on paper, rules guide research practices and the possibilities for what can be known and how we know' (Stark, 2010:340). My research has illuminated how texts work in practice, how they guide and whether they limit. I have shown that judgements made about the ethicality of research are complex and that texts are one important part of the decision-making process but not the whole.

10.5 Accountability

Currently, ethical regulation could be said to be driven by the public demands for transparency and accountability in institutions. Over the last two decades, documents and other reproducible texts (on websites for example) have come to represent these two demands – if they exist in documented form then the public institutions (here, I NRES and the HRA) can demonstrate that they are trustworthy. This in part explains the increasing bureaucracy of ethical regulation. 0'Neill has offered a critical commentary on questions of transparency and trust. Part of her argument has been to show how increased information and transparency in public life was intended to reassure us that institutions were worthy of our trust. O'Neill articulates powerful arguments including the idea that knowing everything about something or a person does not necessarily mean that we trust them more. In family life, the 'typical' site of trust, we exercise trust without fully knowing everything about each other as individuals. Transparency does not necessarily mean more trustworthy. She then argues that the provision of information in itself does not make an institution transparent. Much of the information provided by organizations is not understandable or accessible to people. Transparency often means simply the provision of information. Lastly, she argues (in the lectures and elsewhere) that the lack of trust in public bodies has corresponded with a lack of trust in professionals' knowledge and expertise and this has diminished professional autonomy.

This last point about a lack of trust in professionals with an over-reliance on technical-rational knowledge can be seen in many professions, not least social work (Schon, 1991). Whilst this may be the case in institutional review structures with requirements and procedures which appear to leave little room for professional discretion, as I have shown, RECs were concerned with professional expertise and integrity and this was a crucial part of making individual judgements about research applications.

There remains a need to demonstrate accountability by RECs. This research did not look at decision letters but it is clear that decision letters are composed from the minutes of the meeting.

> *'Following the meeting, the REC Manager will produce a set of minutes, which are agreed by the Chair, after which the decision letters will be produced and*

sent to the applicant. Letters are sent to the applicant within 10 working days of the meeting. Any further information or changes to the documentation etc. from the applicant which may have been requested by the Committee will be managed by the REC Manager who will liaise with nominated members of the Committee as appropriate'.
(HRA, 2016)

This is why the texts were so crucial in the REC meetings. The outcome letters detail what the researcher needs to do in the application to address the concerns of the reviewers. O'Reilly et al (2008) point out that about two thirds of opinions made by RECs are 'favourable with conditions'. What I highlighted in chapter 7 on texts was the process of making decisions credible. I argued that RECs engaged in recognition work itself established the familiar concepts and categories – the principles of ethical research. The recognition work continued in seeking out expressions of the requirements in the applications, looking for the recognisable concepts in the form of expression required. The recognition work is taken up with the researcher. Further expressions of requirements are explored with the researcher. Finally, the 'gaps' are detailed in a letter sent from the REC and the researcher closes the gap by responding to the details of the letter by amending her/his application. These gaps are those procedures which have been recognized as not being present in the review. This engagement with texts in the various forms of requirements, applications, paper, and electronic, web-based information is needed to demonstrate RECs as accountable bodies. This is the external and public face of RECs. In contrast to this, what I have presented is from 'inside' the committee meetings, revealing what goes on behind closed doors and showing how reviewers judgements and decisions are rooted in real life, engaged with research and with each other. Discussions which lead to decisions are sometimes convoluted, messy and pragmatic. In this way, I have contrasted how decisions are accomplished in the REC and how they then become accountable and related to requirements.

10.6 Official and unofficial - the rational and the local

To return to the methodology chapter, Miller, Dingwall and Murphy (2004) reflected that qualitative research was useful because organisations and institutions adopt all kinds of ways of achieving their work which are largely unacknowledged. The increasing public demands for organizations to be transparent in their governance and processes and assure quality in their work sometimes leads to failures.

Organizations can focus on outcomes as tests of their efficiency for example but the processes at local level which lead to these outcomes is not scrutinized. Organisation members often use unofficial means to achieve official outcomes. This is not to say that unofficial means unethical. In the context of RECs, the outcome arrived at may be couched in the required language but the debate and process of how the decision was arrived at might be termed 'unofficial' in so far as the means by which a judgement is made is contingent upon factors which occur in the course of the meeting.

Boden (1994) discusses this paradox. In most organisations, substantial material is made available intended to assist with decision-making (academic institutions spring to mind here). The information must be relevant and *interactionally* available. I have shown that the specific text on capacity which I analysed and the general use of official texts in the meetings became realised through use with reviewers and co-ordinators using information in particular ways. As Smith (2006) comments, texts do not come into being merely by their existence but are used and interacted with. Boden's second point is that in fact decisions are in fact part of a sequence of tinkering with the problem to be resolved. She argues, 'The structures of everyday life underpin and at times undermine 'formal' and 'institutional' frameworks just because they are the bedrock of social existence.'(p183). RECs did not undermine frameworks, as I noted earlier, they often talked to me in the language of the frameworks as they are so immersed in them, or 'ruled' by them as Smith would say. My argument here is that the wider need for institutions to appear rational, objective, trustworthy and accountable is actually achieved at local level in the midst of idiosyncratic (at times) and busy RECs which are essentially human and social affairs.

The tension between procedural ethics and ethics in practice has often been taken up by qualitative researchers and was borne out in this research by researchers who talked about how everything changes when 'you're out there' and the difficulties of putting requirements (consultee arrangements for example) in place. Procedural ethics has limitations. Hammersley (2015) has problematized the principlist approach to ethical regulation and argued that commands and rules set up a pretence that ethical judgements can and ought to be governed. This, he argues,

distorts researchers' attitudes to research and their practical engagement in the field and can encourage compliance with regulations rather than actively exercising discretion in ethical judgements. As a counter narrative to this, all the reviewers and researchers I spoke to were sensitive to the ethical issues in their research. Guillemin and Gillam (2004) have proposed that the gap between procedure and practice is not so great, even in qualitative research, and see some value in the process of seeking approval as it helps to potentially provide a framework for researchers to think about the critical ethical issues in their projects, address fundamental principles and this in turn gives credibility to what they are doing. There is perhaps a more significant gap that was highlighted by some reviewers, which is that the REC has no overview of whether research is conducted ethically following review and approval. Ethical conduct then depends on ethically reflexive and responsible researchers in both qualitative and quantitative research domains.

10.7 Quality in qualitative research: the credibility of this study

The use of epistemological concepts such as 'reliability' and 'validity' as claims are inappropriate in qualitative ethnography when the aim of such projects is for understanding and interpretation of a particular culture. I would argue that the rigour of this research relies on the familiarity and immersion I had in the subject and the interpretation found in the writing in this thesis. Campbell and Lassiter (2015) refer to the interpreting process as being 'tentative' and 'tenuous'. They suggest that the process of looking at what has been amassed can be disconcerting but it is 'both the very nature of emergence….and the place from which ethnography's unanticipated outcomes often arise.' (p120). I would agree with this. I have used initial experiences, interview transcripts, observations and field-notes as well as texts in my interpretation and attempted a truthful account of how I 'assembled' or put together the ethnography. This endeavour has therefore combined both sufficient familiarity of the field with transparency in the analysis and reflexivity in the interpretive process. In terms of quality, transparency was evidenced in this thesis in clearly showing the steps taken and decisions made when coding and analysing data. I provided a coherent explanation of my approach, how I identified and determined what was significant. This means that though there may be alternative plausible accounts constructed from the data, I have shown how my account was constructed.

I have maintained a reflexive approach throughout explaining my thinking about ethnography of organisations through to the adoption of institutional ethnography as a methodology. I have been transparent and clear about the origins of the study in my own negative experience of attending a NHSREC with a capacity study and my interest in mental health. However, I have also explained how the research evolved and changed emphasis. The first shift came soon after fieldwork began, it became clear that I could only look at capacity and consent in the context of how work happened and decisions achieved in the REC meetings. The second shift was that I had to bracket my initial assumptions about authority in the REC to simply discover how they worked. This was important ethically as though RECs are viewed as powerful and authoritative, they were my research participants and needed to protect their interests as such. The research has aimed to illuminate 'the subjective meaning, actions and context of those researched' (Popay *et al.*, 1998). The process of research was not straightforward and I have not claimed that it was. A thesis is sometimes a retrospective shaping of what happened throughout the process to make it appear logical. As research unfolds however, the process may not be linear, but as Swanson (2001) has highlighted, questions may have to be changed or methods modified to meet the analytic goals. I have attempted to demonstrate reflexivity in relation to the development of the research in order to provide coherence, transparency and rigour. I have described how my interpretation of data was built incrementally from initial familiarity with the committees to immersion which enabled me to see what was important in mapping the processes of regulatory ethics.

Hammersley's claim that 'reasonable confidence' in validity rather than certainty are important as well as claims made about knowledge being assessed as plausible and credible (1992). In general, I can demonstrate reasonable confidence that the knowledge created is plausible in a number of ways. I generally drew on phenomena which occurred frequently, so for example references to the written application happened during observations and in interviews. However, it may be more productive to consider that different measures of quality are applicable to qualitative research than those borrowed from quantitative research such as 'validity' even using Hammersley's version of what that means. Tracy (2010) proposed eight criteria for judging quality in qualitative research. One of these is conceptualised as

'meaningful coherence', which seems to me to encapsulate a number of converging criteria.

> *'Meaningfully coherent studies (a) achieve their stated purpose; (b) accomplish what they espouse to be about; (c) use methods and representation practices that partner well with espoused theories and paradigms; and (d) attentively interconnect literature reviewed with research foci, methods, and findings'.* (p848)

Tracy stresses that coherence does not exclude 'messy' or 'unexpected' research, nor does she mean that concepts might not be drawn from multiple paradigms. Rather, that there is a coherence in the design, data collection and analysis. That these are connected to the theoretical framework and goals of the research and that findings are situated in literature. I would claim that the work I have undertaken demonstrates meaningful coherence. As an example, in part the epistemological stance taken in this research is subjectivist. A subjectivist epistemology emphasises that knowledge is generated from and exists within a particular perspective (Ravenek and Rudman, 2013:449) as well as accepting that people act in the world on the basis of their subjective knowledge. In relation to quality, this stance provides a coherence which is traceable in my research through the auto-ethnographic origins of the study to the methodological choice of institutional ethnography (which acknowledges 'standpoint') and extends to the resulting analysis. Another claim to coherence is in the study's methodology. Attention has been maintained on what we can learn from everyday work contexts and what people say about their work. This has been strengthened by an analysis of the use of texts at work. The study has been contextualised in literature in relevant fields and though I utilised a diverse range of disciplines to illuminate research focus, methods and findings, I have attempted to show the interconnections between these throughout the thesis.

To conclude, although it could be seen as a limitation of the research, I do not claim to draw specific conclusions, instead I provide depth of description and insights into how the work of ethical regulation is achieved. The reflexivity demonstrated in the accounts of methods, collection of data and analysis provides transparency in the processes undertaken at each stage of the research and these processes including exploratory processes are an important part of 'the transformation from personal experience and intuition to public and accountable knowledge' (Atkinson and

Coffey,1996: 191). Given the time and thought afforded me by reviewers and researchers, I feel it is ethically important to share the findings with research participants.

10.8 Methodological challenges in the research

Ethnography can contribute to an understanding of cultures. It can raise questions and make connections which may not be made by the people being observed (Rock, 2001). In this study, institutional ethnography as a method has helped to see through professional language and accounts of ethical regulation and instead provide an account of the actualities of work carried out by ethics committees. There are however limits to that account as my account has been contingent upon the particular RECs I observed and the people I encountered. The knowledge I have produced has been somewhat dependent on the knowledge of those reviewers and researchers in the field, my interpretations are the interpretations of what they said, how they understood the world of ethics review. Rock puts it like this: '…knowledge may be useful, public, accessible and illuminating, but it is also necessarily dependent and derivative' (Rock:31). In addition, the challenge of institutional ethnography is to translate what one sees and hears into not solely a descriptive account but an analytic account. Analytic strategies vary greatly and the particular meanings I have constructed will be distinctive to me and will have emanated from the theoretical understandings I have used in the analysis. The distinctiveness and of an institutional ethnographic approach is that it moves beyond an understanding from the emic (insiders) perspective to explicate everyday experiences and people's accounts of their work. By explicate, I mean that I have attempted to analyse what was happening, explain it in detail and look at how texts work in the processes. What I have not produced (or aimed for) is an objective account which can be generalised or provide a meta-account of ethical regulation. I have reiterated throughout that I was not evaluating how RECs performed or the quality of their decisions. I therefore do not have recommendations for concrete changes to RECs or review of research ethics overall.

10.8.1 Critiques of the methodology and some limitations

A familiar critique of ethnography is that it provides a limited representation of reality and that the writing of ethnographies shapes reality. Atkinson (1990) exposes the rhetorical power of writing and argues that both 'writing down' (the process of capturing what the researcher observes and hears) and 'writing up' (the construction of a commentary from field-notes and other transcripts) are both matters of textual construction. The researcher has to chronicle the social world which is subject to inquiry but also persuade the reader that the representation put forward is reasonable. The writing of this account is my interpretation, one version of events. To the extent that it does represent a contemporary account of what happens at RECs, a further limitation of ethnographies of work is that commentaries are historically specific and may therefore have short-term relevance (Smith, 2001). In the context of current discourses about transparency and trust, regulations and requirements change constantly and have done so even during the course of this research.

It may be viewed as a limitation that the researcher participants' perspectives are not included in this study. Indeed, specifics of research applications are only included so far as they illuminate and assist the discussion. The elements which were relevant to discussions and deliberations in the REC are included with some details changed so that they would not be easily identifiable. However, this was a methodological choice. The aim of the study was to look at the social world of ethics review in the context of the REC. Concern with research participants is viewed as paramount in but they are not directly part of the process. Researcher perspectives in this study were confined to a single experience at the REC which I observed. It would be useful to extend the analysis in order to explore if and how researchers shape applications for the purposes of negotiating the REC.   In future research, it would also be helpful for attention to be paid to the participation of people in research who are deemed to lack capacity and in particular the role of consultees. This was the subject of much discussion in the RECs and was certainly not viewed as straightforward by researchers.

Finally, I dealt extensively with access issues in the first part of the thesis. Some researchers and reviewers I pursued for interviews did not get back to me and I had to accept that reviewers are busy and that what they do is voluntary. Researchers

may also have preferred to forget their experience of attending the REC and not all of them were forthcoming in wanting to arrange interviews despite my best efforts. In the main, the researchers and reviewers I made personal contact with on the day of the meeting were more likely to allow a follow-up interview. A greater number of interviews would have provided more data but the depth of the interviews conducted yielded sufficient data to provide evidence of recurring themes.

10.9 Original contribution to knowledge

The efficacy of qualitative research is important. MacDonald and Carnevale (2008) argue that qualitative research is increasingly being used to foster change in policy and practice in health but argue that during ethics review (in the United States) its outcomes or potential are judged through the prism of quantitative research. 'Quantitative research is retained as the definitive way to advance knowledge' (p3). Quantitative or scientific research in the positivist tradition uses realist standards, has a 'means to an end' approach which more obviously or straightforwardly can deal with 'so what?' questions (MacDonald and Carnevale,2008). However, MacDonald and Carnevale point out that qualitative research has the potential to contribute to knowledge by its understanding and illumination of complexity, and it can do this in two significant ways. Firstly, in its rich, conceptual analysis which advances knowledge about the phenomena examined; and secondly, as well as an 'end in itself', it can generate knowledge to foster change. Even if not specifying particular changes, it can contribute to change by offering a framework for rethinking conventional wisdom or views (p2). The interpretive framework used in the analysis of findings in this study provides a conceptually rich description of the work of NHSRECs. I have used a range of ideas to illuminate my findings. Instead of focusing on outcomes or performance indicators, my research provides a unique representation of the everyday work of ethics review in the form of an ethnographic mapping. It is distinct in the methodology employed including the use of texts in review and in its context of NHSRECs flagged to review studies involving research subjects who lack capacity. The interpretation of findings which I offer is multi-layered layered and complex. It emerges from a subjective position which seeks puzzles and complexity. This is not the same as 'looking for trouble'. It simply means that I do not view the review of the ethics of research as a straightforward or obvious activity and in fact an important part of the research is about 'troubling' the view that

it is. This is why the discussion in this final chapter drawing out the significance of the research and linking it to wider social discourses of trust and transparency is important. I propose that there is potential for practical application of this research to inform, shape and develop practice. However, this is contingent upon contextual factors. RECs work is located in a wider institutional context of ethical procedure and formal regulation. Environments where work 'happens' are shaped by political, personal, social, educational and organizational factors all of which play a role in determining the use of research in practice.

Of course, the nature of qualitative research means that there may be multiple 'truths' to be gleaned from findings. Nonetheless, the substantive and unique contribution of this thesis has been in the explication of the following:

- How committees (in this study and specifically those 'flagged' for capacity) 'do' regulation in meetings, how meetings work to produce a decision, how the collective work of members and the sequence of meetings supports common agreement on decisions.
- The significance of the researcher attendance for reviewers.
- How committees make judgements and the subjective ways in which they make sense of applications.
- The ways in which reviewers care for the work they do, for colleagues, researchers and research.
- How texts are used to support and justify decisions (particularly in the context of capacity and consent requirements).

These insights may illuminate the work engaged in by reviewers in ways which are potentially practical, affirmative and generally helpful.

10.9.2 Original contribution: mapping ethics review

This ethnography has endeavoured to look at how ethics review is socially organised and the analysis has attempted to 'map', weaving a way through what happens and how things happen at these important meetings. I have given attention to both the work and the use of texts through observations and through discussions with the reviewers and researchers involved. This has resulted in a particular account of the work of the REC. It is my version but importantly, the mapping was developed through the observable actions and accounts of people who are engaged in that work starting as Smith says from 'where it happens'. I have also explained how much

of the criticism of RECs does not use their everyday work as a starting point but look at the endpoint, the outcome rather than the means by which this is achieved. This approach can offer more potential for adapting the current system of review. This is congruent with Sheehan's (2013) response to criticisms of the functioning of RECs as over-generalised. The evidence has shown that there is not a 'one size fits all' approach in committees and judgement is often subjective and nuanced. The use of texts in the form of regulations indicates that RECs are working within these potentially limiting procedural requirements as much as researchers are. Sheehan's view that attention would first need to be paid to whether the system can evolve and develop in response to problems is important. The research I have conducted provides original insights into the workings of committees and evidence of how they work. This has the potential to influence the evolution and development of RECs.

10.9.3 Ethical responsibilities in reporting

There is an ethical responsibility to provide feedback on the research to participants. Careful thought needs to be given to this and this may be helpfully done through presentation providing the opportunity for reviewers to evaluate and develop meaning on the findings for them and how they might be useful. This will need to be negotiated with the HRA. Tracy (2013) cautions that we need to be mindful of the audience and to take care in reporting in order to prevent the possibility of appropriation of findings which might have unjust consequences (p301). As my most meaningful discussions were directly with reviewers, it would be desirable for me to have direct dialogue with them regarding findings and my interpretations of their work.

10.10 'Pragmatic utility' and implications of the research

10.10.1 Implications for Research Ethics Committees
  • Insights revealed through the research and relevance to REC training

Reviewers are so immersed in the *doing* of the work and in the texts of ethical regulation that it is difficult to examine processes. Much becomes taken for granted or obvious. The consequence of this is that work become familiar and routine. If practices in any area of work become mundane then it is difficult to conceptualise alternative ways of working. Even the straightforward analysis I offer of who talks and the sequencing of meetings could potentially inform committees and prompt thinking about participation from a wider range of members.

The insights I provide also reveal positive practice. A substantial part of the discussion and deliberation at meetings was with the researcher. This demonstrated a genuine interest and support for research and willingness to engage with researchers' challenges in practice. The most frequent response to my question of who is vulnerable in research, was 'researchers'. Members are keen to protect researchers and ensure they have support in conducting research.

The HRA is committed to training of members and offers training days and makes suggestions for self-directed learning. Space on training days for a reflexive consideration of processes in committees could be beneficial for reviewers. Training focussed solely on bureaucratic process is limited in its potential to improve practice in a meaningful way as it focuses primarily on efficiency. Similarly, The HRA has been committed to 'Shared Ethical Debate' since 2007. This is part of the quality assurance process and its intention is to improve consistency in review of applications. Applications are sent out to a sub-group of RECs and reviews analysed. This is integral to governance and quality assurance (HRA, 2007). This initiative has the potential for wider discussion of processes which could include an analysis of *how* decisions are arrived at rather than the outcome.

Furthermore, an acknowledgement of the use of subjective judgement in decision-making would be positive as would allow members to consider what influences their decision-making. An important part of this would be developing a critically reflective approach which acknowledges the factors shaping of review for examples, the role of bias, individual morality and overarching discourses of trust and accountability. All of these inevitably impact on the work undertaken in review.

10.10.2 Implications for research ethics education
- Inclusion of alternative perspectives of ethics review and enabling students to have meaningful dialogue about ethical issues in research.

The literature review in this thesis highlights how researchers from qualitative and quantitative orientations have criticised the REC processes generally and the NHS review process in particular. The critiques centre on the overly bureaucratic nature of review and the bias in review against qualitative research. The review also raised the concern that researchers moderate their proposals, particularly with 'incapacitate' people in order to achieve ethical approval (Juritzen et al,2011). The reach of this

dominant way of seeing ethical regulation extends to and influences some curricula content of research ethics teaching in Universities in the United Kingdom. Curricula frequently take a procedural perspective in teaching. Unsurprisingly this is because student researchers need to have approval from (potentially) a range of RECs, including the University REC.   However, this research has shown that committees are open to dialogue and interested in research. Reviewers acknowledged that they did not always 'get' qualitative research (concurring with Hedgecoe's 2008 findings) but this did not necessarily mean that they were against it. Another positive was that committees were often concerned with inexperienced researchers and their protection within research teams or by supervisors. Researchers are part of a community responsible for ethical research and therefore have some responsibility for raising the level of debate in review beyond the procedural. This research has shown how researchers themselves can assist by open dialogue and seeking advice at RECs rather than perceiving review as a potential barrier. Trust played a significant role in judgements made about research and researchers. Researchers are not expected to have anticipated all the potential challenges of design or ethics. One reviewer put it like this:

They (researchers) don't know the answers but the project will help find some of them. Because we trust them (even if we don't fully understand the methodology) we will approve…….
So, (we're) not bogged down with minutiae – (we are) willing to trust.   It (the minutiae) becomes important if we're not able to trust.

In this interview, 'minutiae' referred to the 'principles-informed' regulations and requirements. This perspective seems to contradict Hammersley's (2015) critique of the nature and role of principles in ethical regulation arguing that the principles informing frameworks are turned into specific judgements about research in RECs and become 'prescriptions' and 'proscriptions' required of researchers (p444).

It is important then for teaching content in curricula to reflect these findings which may empower student researchers to be bold in their ideas and be accountable for them in review of ethics. Rather than teaching reflecting a procedural view of ethics, it may be more valuable to acknowledge the complexity of issues, of consent for example, as this may better equip students to respond to reviewers' questions. Similarly, whilst holding in mind the protection of research participants, teaching needs to enable researchers to articulate the balance of risks and benefits in their research and argue persuasively in ethics applications.

This point echoes Wiles (2013) view that review can potentially assist researchers with ethics questions at the anticipatory stage of research.

10.11 Potential for future research

10.11.1 Primary focus
The potential for a pilot training project would be dependent on the HRA and willingness of members to engage when their commitment is substantial anyway. However, there would be potential benefits to such an initiative and research might evaluate advantages to members and lead to action in the form of change in processes or the organisation.

This kind of reflexive analysis requires of committee members, a different way of thinking about review. The benefits of this are that committee members themselves can potentially have influence on the organisation rather than the organisation setting priorities. Although some legal and regulatory requirements are non-negotiable, recognition of the ways in which RECs achieve their work by members themselves is an important step in achieving what Gorli et al (2015) have termed 'organisational authorship'. Organisational authorship means increasing professionals' influence on the development of an organisation's work. Using a straightforward conceptual tool, comprising exploration of work practices, analysis and action, Gorli et al show how this process can assist people to have more influence in institutions.

- Exploration of work practices – the first task would be for members to investigate and describe their own work in its complexity. My research findings could illuminate this as what has been highlighted in this research and thesis is that the description of what people do is difficult as they are so immersed in the doing and much is seen as 'obvious'.
- Critical examination of activity/practices – again, my presentation of the 'mapping' of work in the REC and 'recognition work' in the use of texts would assist in an analysis of how review is achieved.
- Action and evaluation - suggestions for change and improvements would hopefully emerge, for example, relating to process, debate, deliberation and roles in the REC meetings. Evaluation of the pilot would be required.

10.11.2 Use of methodology

The use of methodology in this research gives rise to the possibility of transferability to other institutional contexts. The methodology is well established taking as a starting point 'work where it happens' and beginning theoretically in people's experience (Smith, 2006:2) in line with the first principle of institutional ethnography. However, the mapping I have developed could potentially provide a framework for further research into small or larger scale organisations. In my selection of NHSRECs as a research site I have limited the research to a particular group of participants, however, the use of texts in organisations is a highly relevant focus of inquiry in contemporary organised societies and the techniques I have developed expertise in are transferable to other sites. Making connections to the larger influences which shape work practices, what Smith calls the 'ruling relations' (Smith, 2005) described in this thesis in relation to review, is an important part of enabling professionals in work settings to have a deeper understanding of the work they do and potentially their ability to influence and change practice. The methodology could be used in studies of other forms of REC (for example University RECs) and to make international comparisons between systems of review.

10.12 Concluding comments

What happens in RECs is of foundational significance to the ethical regulation of research and this thesis has aimed to provide insights into the everyday work of committees, the significance of which stretches beyond the confines of meeting rooms. My methodological choice, institutional ethnography, aims to produce a sociology for people which can expand knowledge of what people are part of but cannot apprehend (Smith, 2001:161). Occupied with doing the work and with the texts of ethical regulation, it is difficult for reviewers to look at *how* they go about their work. So much becomes taken for granted or obvious.

The concluding chapter has connected the practices of ethical regulation to wider social discourses of trust and accountability showing how these two factors influence and shape the work of committees. I have presented an analysis of ethics review which is situated in the everyday world of committees, revealing the subjectivities involved in making judgements and the use of texts in decision-making. I question how helpful evaluations of ethics committees are if they are confined to looking at outcome decisions. I propose that extending our understanding, knowledge and

potential for development of RECs is dependent upon a more detailed analysis of their everyday work. This thesis contributes to that knowledge offering novel insights into the work of RECs whose members may benefit from a reflexive analysis of individual and group participation of the work undertaken.

Appendix 1: University Ethical Approval Letter

**Research, Innovation and Academic
Engagement Ethical Approval Panel**

College of Health & Social Care
AD 101 Allerton Building
University of Salford
M6 6PU

T +44(0)161 295 7016

██████████████████

www.salford.ac.uk/

10 January 2012

Dear Julie,

**RE: ETHICS APPLICATION HSCR11/17 - AN OBSERVATIONAL STUDY OF RESEARCH ETHICS
COMMITTEES (RECS) IN ENGLAND AND WALES WHICH MAKE DECISIONS ABOUT RESEARCH WITH
ADULTS WHO ARE DEEMED TO LACK CAPACITY**

Following your responses to the Panel's queries, based on the information you provided, I am
pleased to inform you that application HSCR11/17 has now been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon
as possible.

Yours sincerely,

College Support Officer (R&I)

Appendix 2: Correspondence with NRES

Sent: Ethical Adviser to NRES Thu 27/10/2011

To: Morton Julie

Cc: PhD supervisor

Subject: RE: Draft letters/info sheets

Dear Julie

your information looks okay to me. A couple of minor points, use PI instead of LI, I think you should say that you have permission of NRES Director as well as your own REC approval and I also suggest the following minor change:

'I intend to carry out the first part of this research by doing an observational study. What I mean by this is sitting in on Mental Capacity Act 'flagged' Research Ethics Committees (RECs) in order to observe committees "at work". The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred and because committee members have undergone some additional training in consent, capacity in the context of the Mental Capacity Act 2005.

Best wishes

To: Morton Julie

Cc: Ethical Adviser to NRES

Subject: FW: Draft letters/info sheets

Dear Julie,

Thank you for sending these, I know you already have ******* comments.

Only one thing to add from me is that taping of the REC meetings is not permitted within NRES Guidelines for Operational Purposes and so wouldn't be approved for this purpose (sorry, you will have to rely on your written notes).

Please let me know when you require our assistance to find appropriate meetings/studies.

Regards

Deputy Head of Operations, England

National Research Ethics Service (NRES)

National Patient Safety Agency

Appendix 3: Literature search strategy

Literature searches were adapted to reflect themes which emerged from scoping searches and reading.

Searches were conducted of academic databases, journals and national archives of theses.

Searches were initially confined to the United Kingdom but literature included later in the thesis originates in the United States.

Database searches

Web of Knowledge

Web of Science

Medline

Academic Search Premier

Terms

Where possible SmartText (available on Academic Search Premier) has been used as this allows for phrases, sentences or even paragraphs to be used in the search.

Subject

'research ethics committees'

'research ethics committees' and 'capacity'

'ethical regulation and bioethics

'ethical regulation and qualitative research'

'capacity and consent'

Methodology

'ethnography'

'institutional ethnography'

'work'

'organisations'

These terms have allowed searches to be conducted for literature on the functioning of ethical and ethics committees, committees and capacity, committees and capacity and consent more broadly

Restrictions

(Available in) Great Britain

1990- 2012

In Abstract or Author supplied key words

Later stage

2013-15

Theses search

Searches have also been conducted of dissertations and theses in University of Salford, University of Manchester and via Scholaris.

Academic Journals

Regular searches of particular journals which relate to ethics and/or research methodology, which include:

Journal of Medical Ethics

Sociology

Sociological Review

International Journal of Social Research Methodology

Social Science and Medicine

Sociological Research Online

Research Ethics (the journal of the Association of Research Ethics Review)

Cambridge Quarterly Review

Sociology of Health and Illness

Qualitative Inquiry

Journal of Contemporary Ethnography

Journal of Social Research Methodology

Ethics and Social Welfare

In addition, the NRES website has a useful repository of articles which relate to ethical regulation in general.

Appendix 4: Letters, Participant Information Sheets and Consent Form

    1.   <u>Letter to Reviewers</u>

Dear Madam/Sir,

I am a Senior Lecturer in Social Work at Salford University. I have previously undertaken some research in mental health services and I have developed an interest in the ethics of research with adults who are deemed to lack capacity. I am interested in the processes of gaining ethical approval for research with this group of people.

<u>What the study involves</u>

I intend to carry out the first part of this research by doing an observational study. What I mean by this is sitting in on 'flagged' (adults who lack capacity) Research Ethics Committees (RECs) in order to observe panels "at work". The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred and because panel members have undergone some additional training in consent, capacity in the context of the Mental Capacity Act 2005.

I will use written notes to record how panel members debate and think about the studies they are asked to consider and how they arrive at decisions about ethical research with people who are considered to be vulnerable.

<u>Confidentiality and anonymity</u>

For the purposes of observation, I will make notes of the meeting. All notes will be coded so that the details (location, date of sitting, names of panel members etc) of a committee could not be identified.

<u>Ethical Approval</u>

I have gained ethical approval for this study from the University of Salford Research and Ethics Committee (Reference HSCR11/17). Any concerns about the conduct of this research can be directed to them at University of Salford █████████

<u>Participation</u>

I understand that some members of panels may feel uncomfortable about my attendance. If this is the case then you can notify me and I would not attend. My contact details are at top of this letter.

<u>Interviews</u>

Some applications may throw up interesting questions which I would like to pursue further. In this event, I would like to make an appointment to interview the Lead Reviewer(s) or Chair outside of the committee to discuss in more detail. I will provide a more detailed Information Sheet at the end of the meeting and request that I contact you in the near future to make an appointment for an interview.

2. **Information Sheet for REC panel members**

I am a Senior Lecturer in Social Work at Salford University. I have previously undertaken some research in mental health services and I have developed an interest in the ethics of research with adults who are deemed to lack capacity. I am interested in the processes of gaining ethical approval for research with this group of people.

What the study involves
I intend to carry out the first part of this research by doing an observational study. What I mean by this is sitting in on Mental Capacity Act 'flagged' Research Ethics Committees (RECs) in order to observe panels "at work". The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred and because panel members have undergone additional training in the Mental Capacity Act 2005 with particular reference to conducting research.
 I will use notes to record how panel members debate and think about the studies they are asked to consider and how they arrive at decisions about ethical research with people who are considered to be vulnerable.

Confidentiality and anonymity
For the purposes of observation, I will make notes. All notes will be coded so that the details (location, date of sitting, names of panel members etc.) of a committee could not be identified.

Ethical Approval
I have gained ethical approval for this study from the University of Salford Research and Ethics Committee (Reference HSCR11/17). Any concerns about the conduct of this research can be directed initially to the College Support Officer, Research Governance and Innovation Unit, The School of Nursing, Midwifery and Social Work at the University of Salford on telephone number ▮▮▮▮▮ ▮▮▮▮

In addition, I have the permission of NRES Director ▮▮▮▮▮▮▮ to carry out this research.

Participation
It is important that you as a panel member consent and are a voluntary participant in this research. I understand that some members of panels may feel uncomfortable about my attendance. If this is the case, then you can speak directly to your local REC co-ordinator or Chair prior to the meeting taking place. In this event, the co-ordinator will notify me and I would not attend the meeting. Alternatively, you can contact me directly. My contact details are ▮▮▮▮▮▮▮▮▮▮▮▮▮

The second part of the study - interviews
Some applications may throw up interesting questions which I would like to pursue further. In this event, I would like to make an appointment to interview the Lead Reviewer(s) and/or Chair outside of the committee **on the day of the meeting** if possible or at a later date to discuss in more detail. I will provide a more detailed Information Sheet about interviews at the REC meeting.

3. **Letter to Researchers**

Dear Madam/Sir,

I am a Senior Lecturer in Social Work at Salford University. I have previously undertaken some research in mental health services and I have developed an interest in the ethics of research with adults who are deemed to lack capacity. I am interested in the processes of gaining ethical approval for research with this group of people.

What my study involves

I intend to carry out the first part of this research by doing an observational study. What I mean by this is sitting in on Mental Capacity Act 'flagged' Research Ethics Committees (RECs) in order to observe panels "at work". The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred and because panel members have undergone some additional training on the Mental Capacity Act 2005 with particular reference to conducting research.

I will use notes to record how panel members debate and think about the studies they are asked to consider and how they arrive at decisions about ethical research with people who may be considered to be vulnerable.

As the PI whose research study is under consideration, you will be a participant in the committee meeting. However, it is important to state that as an observer of the meeting, I have no influence on the decision outcome of the panel.

Confidentiality and anonymity

For the purposes of observation, I will make notes at the meeting. All notes will be coded so that the details (location, date of sitting, names of panel members etc.) of a committee could not be identified. The particular studies under consideration will not be identifiable as identifying features will be removed from my own notes.

Ethical Approval

I have gained ethical approval for this study from the University of Salford Research and Ethics Committee (Reference HSCR11/17). Any concerns about the conduct of this research can be directed initially to the College Support Officer, Research Governance and Innovation Unit, The School of Nursing, Midwifery and Social Work at the University of Salford on telephone number ▮▮▮▮▮ ▮▮▮.

In addition, I have the permission of NRES Director ▮▮▮▮▮▮▮ to carry out this research.

Participation

It is important that you consent and are a voluntary participant in this research. If you do not wish me to observe when you attend for your appointment with the REC then please contact your REC co-ordinator ahead of the meeting. Alternatively, let the Chair know on the day and I will not sit in. Your decision about whether I sit in or not will have no influence on the outcome decision. I am independent from the ethical application process.

The second part of the study - interviews

Some applications may throw up interesting questions which I would like to pursue further and I would want to interview the Lead Reviewer(s) or Chair outside of the committee to discuss in more detail. I would also want to interview you as PI about how you approached the ethics of your study, in particular, how you thought the ethical issues through in relation to capacity and consent. In this event, I would provide a more detailed Information Sheet to you at the committee meeting. I would then contact you in the near future to request an appointment for an interview.

4. Letter to Chairs of RECs

Dear Madam/Sir,

I am a Senior Lecturer in Social Work at Salford University. I have previously undertaken some research in mental health services and I have developed an interest in the ethics of research with adults who are deemed to lack capacity. I am interested in the processes of gaining ethical approval for research with this group of people. I have permission from NRES to undertake an observational study of panels but would like as a matter of courtesy to request your agreement to me attending the panel which you chair.

What the study involves

I intend to carry out the first part of this research by doing an observational study. What I mean by this is sitting in on Mental Capacity Act 'flagged' Research Ethics Committees (RECs) in order to observe panels "at work". The 'flagged' committees have been selected for this study because studies where capacity is an issue are likely to be referred and because panel members have undergone training on the Mental Capacity Act 2005 with particular reference to conducting research.

I will use notes to record how panel members debate and think about the studies they are asked to consider and how they arrive at decisions about ethical research with people who are considered to be vulnerable.

Confidentiality and anonymity

For the purposes of observation, I will make notes. All notes will be coded so that the details (location, date of sitting, names of panel members etc.) of a committee could not be identified.

Ethical Approval

I have gained ethical approval for this study from the University of Salford Research and Ethics Committee (Reference HSCR11/17). Any concerns about the conduct of this research can be directed initially to the College Support Officer, Research Governance and Innovation Unit, The School of Nursing, Midwifery and Social Work at the University of Salford on telephone ████████████

In addition, I have the permission of NRES Director ██████████ to carry out this research.

Participation

It is important that you and panel members consent and are voluntary participants in this research. Members of panels will receive this information separately in the paperwork they receive from NRES.

I understand that some Chairs or members of panels may feel uncomfortable about my attendance. If this is the case, then you as Chair or individual panel members can speak directly to your local REC co-ordinator. In this event, the co-ordinator will notify me and I would not attend the meeting. Alternatively, you can contact me directly. My contact details are j.w.morton@salford.ac.uk.

The second part of the study - interviews

Some applications may throw up interesting questions which I would like to pursue further. In this event, I would like to make an appointment to interview the Lead Reviewer(s) and/or Chair outside of the committee either if possible **on the day of the meeting** or at a later date to discuss in more detail. I will provide a more detailed Information Sheet at the REC meeting.

5. **Information Sheet for Researchers**

<u>Request to interview</u>

Thank you for letting me observe the REC meeting which you attended when your study was considered for ethical approval. I would now like to contact you again in order to interview you in more detail about your study.
The reason your study is suitable for my research is that you have considered issues of capacity in your application for ethical approval.

<u>The interview</u>
The interview is likely to last about an hour.   I would anticipate our discussions to explore the following:
- How and what you considered in relation to consent and capacity in preparing your application.
- Your experience of attending the Ethics Committee.
- Description of your study.

<u>Confidentiality</u>

<u>1.You as Principal Investigator</u>
Any information which is collected about you during the course of the research will be kept strictly confidential. The exception to this would be if I heard or saw something during the interview that appeared to be a breach of the conditions which had been detailed in the ethical approval of your study. Any information in the form of notes or recordings and transcripts of recordings will have any identifying features removed so that you cannot be identified.

<u>2.Details about your research</u>
Clearly, in order for me to understand the ethical concerns in your study it will be helpful for you to outline the nature and purpose of your research. Again, all written field notes, audio recordings and transcriptions will be coded and anonymised. In the future, should any research findings be published, brief descriptions of your research may be necessary. In this case, identifying information such as time, place of study will be removed.

<u>Data</u>
 Any details of project kept on a laptop will be encrypted and transferred to a University of Salford computer as soon as possible after the interview.
Recordings of interviews will be downloaded from a digital recorder to my institution's computer for transcribing purposes. Salford University is a secure server system.
Al other material relating to interviews or material from observations will be kept in a locked filing cabinet at the University.
<u>Dissemination of findings</u>
I will provide a summary of findings to the National Research Ethics Committee. However, if you as Principle Investigator and/or your team would like a copy of the summary then this would be provided.
<u>Participation in this study</u>
Of course, your participation in this research is entirely voluntary. Please do not hesitate to email me with any questions which have not been addressed by this Information Sheet or to inform me that you do not wish to be contacted. If you agree to being interviewed, I would ask **you to sign this Information Sheet when we meet as evidence that I have talked through this information with you and** that you consent to the interview.
My contact details are <u>j.w.morton@salford.ac.uk</u>.

Alternatively, you can contact the REC co-ordinator who will notify me directly.

6. **Information Sheet for Lead Reviewers/Chairs**

Request to interview

Thank you for letting me observe the REC meeting. I would now like to meet with you again in order to interview you in more detail.

The reason I want to interview you is that at the Committee meeting I observed you had given consideration to issues of capacity, consent and vulnerability in the context of the applications which were considered for approval. If at all possible I would like to interview you on the day of the meeting, however, if this is not possible I would like to contact you again to arrange an alternative date.

The interview

The interview is likely to last about an hour. I would anticipate our discussions will explore the following:

- What factors you considered in relation to consent and capacity in your discussions.
- How the REC arrives at decisions.
- The kind of questions which you and your colleagues at the REC considered important to raise with the Principal Investigator (if s/he attended).
- How the process of approval works in the context of the meeting. For example, the roles of individual members of the REC, scope of discussions before seeing the applicant etc.

Confidentiality

Any information which is collected about you during the course of the research will be kept strictly confidential. Any information in the form of notes or audio recordings and transcripts of recordings will have any identifying features removed so that you cannot be identified.

Data

Any details kept on a laptop will be encrypted and transferred to a University of Salford computer as soon as possible after the interview.

Recordings of interviews will be downloaded from a digital recorder to my institution's computer for transcribing purposes. The University is a secure server system.

Al other material relating to interviews or material from observations will be kept in a locked filing cabinet at the University.

Dissemination of findings

I will provide a summary of findings to the National Research Ethics Committee.

Participation in this study

Of course, your participation in this research is entirely voluntary. Please do not hesitate to email me with any questions which have not been addressed by this Information Sheet or to inform me that you do not wish to be contacted. My contact details are j.w.morton@salford.ac.uk.

Alternatively, you can contact the REC co-ordinator who will notify me directly.

If you agree to being interviewed, I would ask **you to sign this Information Sheet when we meet as evidence that I have talked through this information with you and** that you consent to the interview.

Approval for this study

I have the permission of NRES Director ████████ to carry out this research.

Scientific review of this study has been undertaken by my Lead Supervisor and reviewed internally by the Executive Committee of the School of Nursing, Midwifery and Social Work. The study has also been reviewed and given favourable opinion by the University of Salford's Research Ethics Committee. Any concerns about the conduct of this research can be directed initially to the College Support Officer, Research Governance and Innovation Unit, The School of Nursing, Midwifery and Social Work at the University of Salford on telephone number xxxxxx.

Consent Form

Title of Project: A study of Research Ethics Committees (RECs) in England and Wales which make decisions about research with adults who are deemed to lack capacity.

Name of Researcher: Julie Morton University of Salford

I have had an Information Sheet about this project and have been consulted about participation in this research project.

The Information Sheet outlined anonymity and confidentiality relating to data/material collected.

 I have had the opportunity to ask questions
about the study and I understand what is involved.

I have no objection to being interviewed as part of the above study.

I understand that I can withdraw from this study at any time even after the interview has been conducted.

Principal Investigator/Lead Reviewer (delete as appropriate)

Name …………………………………………………

Signature………………………………………….

Date………………………………………………..

Researcher

Julie Morton, University of Salford

Signature …………………………………….

Date………………………………………….

Appendix 5: Sample consent emails (observations and interviews)

Sample 1: email correspondence re administrative support arrangements and contact with RECs/administration of consent matters etc

From: xxxxxxx @nres.nhs.uk]

To: Morton Julie; xxxxxx (NHSNW)

Subject: RE: PhD Ethics Study

Dear Julie,

Nice to hear from you, and pleased to her that things are progressing. By way of this email I am introducing you to xxxxxxx who is the Centre Manager for the Manchester office and she should be able to assist locally and also advise how the staff from her office can help.

It would be useful if in the first instance you could send Catherine your protocol so that she can see what it is you are going to do.

Dear xxxxxxx,

These has been an agreement from xxxxxxx and xxxxxx that we should support Julie's project, when you have seen the protocol we should discuss to iron out any practicalities.

Best Regards, xxxxxx

Deputy Head of Operations, England. Health Research Authority

Sample 2: email correspondence: consenting to reviewer interview

From Morton Julie
To: xxxxxxxxx
Subject: RE: mca nres research

Dear xxxxxxxx,

Thanks so much for getting in touch. Tomorrow morning at 10.00 would be best.

Thanks, Julie

From: xxxxxxxxxx

Sample 3: Reviewer arranging for telephone interview

To: Morton Julie
Subject: mca nres research

Dear Julie
We met on friday when you came to observe our rec in action, hope you found it of interest.
just to let you know when i'm free to have our phone chat are any of these times suitable:
sorry to only give 2 but it needs to be soon otherwise i'll forget the meeting and eves are best for me
so if that's ok with you that would suit me better
let me know if you can do any of the above
best wishes, xxxxxx ps. here's my number

Sample 4: Correspondence with co-ordinator to arrange interviews via email

From: Morton Julie
To: xxxxxxxxxNRESCommittee._____- (HEALTH RESEARCH AUTHORITY)
Subject: RE: Bookings xxxxx and xxxxxx

Dear xxxxxxx
Thank you for all your help with the Committee meeting last week.
I have already interviewed xxxxxxx
Contacted xxxxxx via mobile as he suggested but not had a response.
I would also like to interview xxxxxx and xxxxx who I spoke to briefly after the meeting and were happy for me to interview.The researchers I'd like to interview are
xxxxxx dementia study and xxxxxx substance misuse qualitative study.

I know you are incredibly busy xxxxxx - I really do appreciate your expertise and assistance.

Kind regards, Julie

Sample 5: email seeking consent to interview researcher

Subject: Interview with researcher/Salford University

Dear xxxxxx,We met at the REC meeting which took place on Thursday 5th April. I have attached the Information Sheet and hope this explains more fully what I am doing.As well as observation of the REC I also want to interview the lead reviewers in each case. I have attached the questions framework I intend to use. I envisage that the interview (on the telephone) would take about 30 minutes.

If you are prepared to let me interview you then I would be grateful if you could let me have contact details and a convenient time-slot when I could ring. Am happy to ring in the evenings if that is easier. Many thanks, Julie

Sample 6: email correspondence arranging reviewer interview

To: Morton Julie
Subject: RE: Research interview REC meeting xxxxx

Dear Julie,

Sorry for the delay in responding to your email . but we been having problems with our telephone in our meeting rooms. I wanted to get this problem resolved before confirming the telephone number that you will be needing. On xxxxxx please ring xxxxxxxx at 1pm on the following number xxxxxxx. However, this number is a direct line to one off our meeting room and not the switchboard. xxxxxx will be in the room waiting for your call. If you have any problems with the above, please let me know. Many thanks, xxxxxx

Sample 7: email from reviewer's secretary confirming consent to interview

To: Morton Julie
Subject: RE: Research interview REC meeting xxxxx

Dear Julie, Hi, I am in colleague of xxxxxxxx. He had asked me to arrange a time and date for a telephone interview regarding your study on capacity and consent in research ethics. The convenient dates are: ….…..Please let me know which one of these dates are most convenient, and I will add it to xxxxxx dairy. I look forward to hearing from you shortly

Kind Regards, xxxxxx

Sample 8: email from co-ordinator confirming consent to interview Chair

From: (HEALTH RESEARCH AUTHORITY) [nrescommittee.xxxxxxxxxxxxx@nhs.net]
To: Morton Julie
Subject: RE: Bookings xxxxxx and xxxx

Good morning Julie,

My colleague said you are unable to get through to xxxxxxxx on the number provided below. Could you please try the number ▮▮▮▮▮▮▮▮ as this is the one I have on my system.Please do let me know if you are still not able to get through to him. He confirmed he is happy for you to contact him this morning. Kind regards, xxxx

Sample 9: Email (direct) consent to interview researcher

To: Morton Julie
Subject: RE: researcher interview

Dear Julie

Yes, I am happy to be interviewed. Please remind me how long it is likely to take? After you get back from leave I have two weeks before being out of the office until ▮▮▮▮▮ and those two weeks are virtually full up already, definitely can't do anything until the week beg 9th. I am awaiting confirmation of a couple of other things that week but could provisionally do Monday 9th or Thursday 12th – I should know for definite by the time you get back on the 2nd so we can firm up a date then, OK? Best wishes, xxxxxxx

Appendix 6: Coding and initial analysis of data

Process of analysis

- Field-notes, observations, interviews and perception type field-notes were transcribed into Word.
- Nodes in NVivo were generated as I went through the transcripts.
- NVivo generated information on frequencies and occurrences across data types.

Name	Sources	References
Assertions of medical authority	8	9
Committee dynamics	15	29
Concern with design	11	21
Concern with 'good' research	13	31
Concerns with language	2	7
Confidentiality or anonymity concerns	8	8
Consent concerns in study	12	20
Considerations of capacity-researcher	4	4
Design –researcher	3	3
Engagement with the study	3	3
Judgement about researcher	4	7
Key points about capacity	6	8
Moral and ethical dimensions	15	32
Notions of harm	6	6
Committee expertise or knowledge	5	5
Perception of committee- researcher	8	12
Qualitative and quantitative comments	6	6
Reference to me as observer	6	7
Reference to previous studies	5	7
Reference to professional status	8	11
References to paperwork	11	24
Remit of the committee	4	5
Requirements	7	9
Seeking clarity on requirements	10	19
Vulnerability	17	19

- Read over extracts under each node.
- Refer back to full transcript for context.
- Go back and forth to check nodes appear across whole data set.
- Check significance of high frequency and low frequency nodes.
- Develop emerging questions/problematics which integrate data across sets. Data produced from range of methods (observation, interview, field notes) labelled as 'sources' in NVivo.
- Nodes overlap. Classify nodes into overarching categories.
- Analytical focus on the 'work' of the committees - this groups around three domains:

  The 'doing' of ethics review – the work of committees (rich description of the doing of ethics review)

  The practical strategies employed by committees to make sense of applications – making judgements.

  The use of texts in RECs – making decisions.

References

Altheide, D.L., & Johnson, J.M. (1994). Criteria for assessing interpretive validity in qualitative research. In N. K. Denzin & Y. S. Lincoln (Eds.), *Handbook of Qualitative Research* (2nd ed.). (pp. 485-499). London: Sage.

Anderson, L. (2006) Analytic Auto-ethnography. *Journal of Contemporary Ethnography.* Vol 35, 4, 373-395.

Angrosino, M (2008) *Doing Ethnographic and Observational Research*. London. Sage. Retrieved from EBSCO*host*

Ashencaen Crabtree, S. (2013) Research Ethics and the Moral Enterprise of Ethnography: Conjunctions and Contradictions. *Ethics and Social Welfare*, **7**(4), pp. 359-378.

Atkinson P. (1990) *The Ethnographic Imagination: Textual Constructions of Reality*. London. Routledge.

Atkinson, P. (1995) *Medical talk and medical work: the liturgy of the clinic*, London, London: Sage.

Atkinson, P. A. Coffey, S. Delamont, J. Lofland and L. Lofland (eds.) (2001) *Handbook of ethnography*, London, London: SAGE.

Aveyard, H.A. (2014) *Doing a literature review in health and social care: A practical guide* (3rd ed.) Maidenhead: Open University Press, McGraw Hill Education.

Banks, S. & Williams, R. (2005) Accounting for Ethical Difficulties in Social Welfare Work: Issues, Problems and Dilemmas. *Journal of Social Work,* 35 (7), 1005 – 1022.

Banks, S. (2008) Critical commentary: Social work ethics, *British Journal of Social Work*, 38(6), 1238-1249.

Banks, S. & Gallagher A. (2009) *Ethics in Professional Life: Virtues for Health and Social Care*. Basingstoke: Palgrave Macmillan.

Banks, S. (2010) 'Integrity in Professional Life: Issues of Conduct, Commitment and Capacity', *British Journal of Social Work*, 40 (7), 2168-2184.

Banks, S. (2013) 'Negotiating personal engagement and professional accountability: professional wisdom and ethics work', *European Journal of Social Work*, 16(5), 587-604.

Banks, S. (2016) 'Everyday ethics in professional life: social work as ethics work', *Ethics and Social Welfare*, 10(1), 35-52.

Barksy, A.E. (2010) 'The Virtuous Social Work Researcher', *Journal of Social Work Values and Ethics,* 7 (1)

Bauman, Z. (1992) *Intimations of Postmodernity*. London, New York: Routledge

Bauman, Z. and May, T. (2001) *Thinking Sociologically (*2nd ed.). Oxford. Wiley-Blackwell.

Beauchamp, T.L. & Childress, J.F. (1994) *Principles of biomedical ethics.* Oxford: Oxford University Press.

Beauchamp, T.L. & Childress, J.F. (2013) *Principles of biomedical ethics. (*7th ed.) Oxford: Oxford University Press.

Beauchamp T. (2010) *Standing On Principles: Collected Essays* [e-book]. New York: Oxford University Press. Retrieved from http://EBSCO e-books

Bentall, Richard. (2010) *Doctoring the Mind: Why psychiatric treatments fail.* Penguin. London

Bloor, D (1976) *Knowledge and Social Imagery*. Chicago. University Press

Boden, D. (1994) *The Business of Talk: Organizations in Action*. Cambridge: Polity Press.

Boden, R., Epstein, D. and Latimer, J. (2009) 'Accounting for ethos or programmes for conduct? The brave new world of research ethics committees', *Sociological Review*, 57(4), 727-749.

Boulton, M. and Parker, M. (2007) Informed consent in a changing environment - Introduction, *Social Science & Medicine*, 65(11), 2187-2198.

Bourdieu, P. & Waquant, L. (1992) *An invitation to reflexive sociology*. Chicago, University of Chicago Press.

Bourdieu, P. (2000) *Pascalian meditations*. Cambridge. Polity Press

.Bourgeault, I.L., Dingwall, R. and De Vries, R.G. (2010) *The Sage handbook of qualitative methods in health research*. London: Sage.

Brenneis, D. (1994a) 'Discourse and Discipline at the National Research Council: A Bureaucratic Bildungsroman', *Cultural Anthropology*, 9(1), 23-36.

Brewer, J.D (2000) *Ethnography*. Buckingham. Open University Press.

British Sociological Society (2002) Statement of Ethical Practice. Retrieved from www.britsoc.co.uk/media/27107 August 2016

Bryman,A & Burgess,R.G.(eds.) (1994) *Analysing Qualitative Data*. London. Routledge.

Burr, J. and Reynolds, P. (2010) 'The Wrong Paradigm? Social Research and the Predicates of Ethical Scrutiny', *Research Ethics*, **6**(4), pp. 128-133.

Campbell, M and F. Gregor (2008) *Mapping Social Relations: A Primer in Doing Institutional Ethnography. Toronto*. Higher Education University of Toronto Press.

Campbell, E & Lassiter, L.E (2015) *Doing ethnography today: theory, methods, exercises.* Chichester. Wiley Blackwell. Retrieved from http://salford.elib.com.salford.idm.oclc.org

Chambliss, D. (1996) *Beyond Caring: Hospitals, Nurses, and the Social Organization of Ethics.* Chicago. University of Chicago Press.

Charmaz, K. and Mitchell, R. (2007) *Grounded theory in ethnography.* London. Sage.

CIOMS (The Council for the International Organisation of Science) (2002) Ethical Principles and Guidelines for the Protection of Human Subjects for Research http://www.cioms.ch/index.php/publications/printablev3/541/view_bl/65/bioethics-and-health-policy-guidelines-and-other-normative-documents/downloaded August 2016

Clarke, A. E.& Star S.L. (2007) The social worlds framework as a theory-methods package in Hackett, E.J., Amsterdamska, O., Lynch, M., Wajcman, J. (Eds.), *The handbook of science and technology studies.* Cambridge MA: MIT Press. pp. 113–137.

Coffey, A. (1999) *The Ethnographic Self: Fieldwork and the Representation of Identity.* London: Sage.

Coffey, A. & Atkinson, P. (1996) *Making Sense of Qualitative Data Analysis: Complementary Strategies.* Thousand Oaks, Ca. Sage.

Collins, S. (2015). *The core of care ethics.* New York. Palgrave Macmillan

Corrigan, O. (2003) Empty ethics: the problem with informed consent. *Sociology of Health & Illness*, 25(7) 768-792.

Coulter, J (1973) *Approaches to insanity: A philosophical and sociological study.* London: Robertson

Crotty, M. (1998) *The foundations of social research: meaning and perspective in the research process.* London: SAGE.

Crowe, G**.,** Wiles, R., Health, S., and Charles, V. (2006) 'Research Ethics and Data Quality: The Implications of Informed Consent', *International Journal of Social Research Methodology* 9 (2) 83-95.

Dawson, C. (2005). The Association of Research Ethics Committees -- A Brief History. *Research Ethics, 1*(1), 33-35

Delamont, S. (2004) Participant Observation. In C. Seale, G. Gobo, J.F. Gubrium and D. Silverman (eds.) *Qualitative Research Practice.* (pp 205-218). Retrieved from http://www.dawsonera.com/

DeVault, M.L. & McCoy, L. (2006) Institutional Ethnography: Using Interviews to Investigate Ruling Relations in Smith, D. E. (2006) *Institutional Ethnography as Practice* (pp 15-44). Oxford. Rowman and Littlefield.

Denzin, N. (1997) *Interpretive Ethnography: Ethnographic Practices for the 21st Century.* London: Sage.

Denzin, N & Lincoln, Y. (2011) *The Sage Handbook of Qualitative Research.* (4th ed.) Thousand Oaks. Sage.

Department of Health (1991) The 'Red Book' HSG (91) 5. Retrieved 2 May 2016 from http://www.doh.gov.uk/research/rd1/researchgovernance/corec.htm (Archived at: 2003-12-21 01:04:05)

Department of Health (2011) 'Governance Arrangements for Research Ethics Committees' (GAfREC). Retrieved 2 May 2016 from http://www.doh.gov.uk/research

Department of Health (1989) The Children Act. HMSO. London.

Department of Health (1998) The Data Protection Act. HMSO. London

Department of Health (2004) The Human Tissue Act. HMSO. London.

Department of Health (2005) Mental Capacity Act. HMSO, London

Department of Health (2007) Mental Health Act. HMSO, London

Dingwall, R. (2006) An exercise in fatuity: research governance and the emasculation of HSR, *Journal of Health Services Research and Policy*, 11,4, 193-194.

Dixon-Woods, M. and Angell, E.L. (2009) 'Research involving adults who lack capacity: how have research ethics committees interpreted the requirements?', *Journal of Medical Ethics*, 35(6),377-381.

Dyck, M., & Allen, G. (2013). Is mandatory research ethics reviewing ethical? *Journal of Medical Ethics, 39*(8), 517.

Eberle, T and Maeder, C. (2011) Organisational ethnography in D. Silverman (ed) *Qualitative Research* (3rd ed.) (pp. 53-74). London. Sage.

Edwards, R and Mauthner,M. Ethics and Feminist Research; Theory and Practice in Mauthner, M, Birch, M., Jessop, J. and Miller, T. (eds) (2002) Ethics in Qualitative Research. London. Sage

Economic Social Research Council (2010) Framework for Research Ethics; Swindon: ESRC

Edwards, S. (2011). The Role, Remit and Function of the Research Ethics Committee — 5. Collective Decision-Making and Research Ethics Committees. *Research Ethics, 7*(1), 19-2

Foucault, M. (1980) *Power/Knowledge: Selected Interviews and Other Writings 1972-1977*. Harlow. The Harvester Press Ltd.

Fox, R., & Swazey, J. (2010). Guest Editorial: Ignoring the Social and Cultural Context of Bioethics Is Unacceptable. *Cambridge Quarterly of Healthcare Ethics, 19*(3), 278-281.

Gallagher, A. (2011) 'Keeping research ethics under review'. *Nursing Ethics*, 18, 6, 751-752.

Gallagher, A.R.G.N. and Hodge, S. (2012) *Ethics, law and professional issues: a practice-based approach for health professionals*, Basingstoke: Palgrave Macmillan.

Garfinkel, H (1967) *Studies in ethnomethodology.* New Jersey: Prentice-Hall.

Garfinkel, H. & Rawls, A. (2005) *Seeing sociologically: the routine grounds of social action.* Boulder, Colo.: Paradigm Publishers.

Garfinkel, H and Sacks, H. (1986). On formal structures of practical actions. In Garfinkel, H (Ed.), *Ethnomethodological Studies of Work* (pp160-193) London: Routledge and Kegan Paul Inc.

Geertz, C (1973) *The Interpretation of Cultures.* New York. Basic Books.

Gelling, L. (2004) Researching patients in the vegetative state: difficulties of studying this patient group. *NT Research*, 9,1, 7-17.

Gelling, L. (2010) Gaining Access to the Research Site. In Gerrish, K. and Lacey, A. In *The research process in nursing* (pp114-125*).* Chichester: Wiley-Blackwell.

Gelling, L. and Munn-Giddings, C. (2011) 'Ethical Review of Action Research: The Challenges for Researchers and Research Ethics Committees', *Research Ethics*, **7**, 3, 100-106.

Gelling L. & Rodriguez Borrego M.A. (2014) Originality in doctoral research. *Nurse Researcher.* 21, 6, 6-7.

Gelling, L. (2016). Applying for ethical approval for research: The main issues. *Nursing Standard (Royal College of Nursing (Great Britain). 30*(20), 40-4.

Gilligan, C. (1982). *In a different voice: psychological theory and women's development.* Cambridge, Mass.: London: Harvard University Press.

Goffman, E. (1990). *The Presentation of the Self in Everyday Life.* London. Penguin

Gold, R.L. (1958) Roles in sociological field observations. *Social Forces.* 36,217-83. Retrieved from http;//heionline.org

Gorli, M., Nicolini, D. and Scaratti, G. (2015) 'Reflexivity in practice: Tools and conditions for developing organizational authorship', **68**(8), pp. 1347-1375.

Gray, M and Webb, S. A. (2013) *Social Work Theories and Methods.* (2nd ed) London. Sage.

Greenhough, B. (2007) Situated knowledges and the spaces of consent. *Geoforum,* 36(6), 1140-1151.

Guillemin, M. and Gillam, L. (2004) Ethics, Reflexivity, and "Ethically Important Moments" in Research. *Qualitative Inquiry*, 10(2), 261-280.

Halvorsen, K. and Sarangi, S. (2015) Team decision-making in workplace meetings: The interplay of activity roles and discourse roles, *Journal of Pragmatics*, 76,1-14.

Hammersley, M. (1992) *What's wrong with ethnography?: Methodological explorations.* London. Routledge

Hammersley, M and Atkinson, P. (2007) Ethnography: Principles in Practice. (3rd ed) London. Taylor and Francis

Hammersley, M. (2009) 'Against the ethicists: on the evils of ethical regulation', *International Journal of Social Research Methodology*, 12(3), 211-225.

Hammersley, M. (2010) Creeping Ethical Regulation and the Strangling of Research, *Sociological Research Online*, 15(4). Retrieved from http://www.socresonline.org.uk July 2013

Hammersley, M. and Traianou, A. (2014) An Alternative Ethics? Justice and Care as Guiding Principles for Qualitative Research, Sociological Research Online, 19 (3). Retrieved from http://www.socresonline.org.uk September 2015

Hammersley, M. (2015) On ethical principles for social research, *International Journal of Social Research Methodology*, 18(4), 433-449. doi:10.1080/13645579.2014.924169

Humphreys, L. (1975). *Tearoom Trade: Impersonal Sex in Public Places*. New Jersey. Piscataway.

Iphofen, R. (2009). *Ethical Decision Making in Social Research: A Practical Guide*. Basingstoke. Palgrave Macmillan

Israel, M.A. and Hay I.M.(2006). *Research Ethics for Social Scientists: between ethical conduct and regulatory compliance.* London, UK: Sage Publications.

Israel, M. (2013). Rolling back the bureaucracies of ethics review. *Journal of Medical Ethics, 39*(8), 525.

Health Research Authority (2007) 'Shared Ethical Debate'. Retrieved from http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance August 2016.

Health Research Authority 'RECs flagged to review research which uses qualitative methodologies' Retrieved from http://www.hra.nhs.uk/news/2012/11/30/recs-flagged-to-review-research-which-uses-qualitative-methodologies August 2016.

Health Research Authority 'Summary of the role, structure and functionality of Research Ethics Committees within the Health Research Authority in England. 'Retrieved 14 April 2016 from, http://www.hra.nhs.uk/about-the-hra/our-committees/

Health Research Authority 'The Review Process'. Retrieved from www.hra.nhs.uk/research-community/the-review-process/nhs-research-ethics-committee-rec-review August 2016

Health Research Authority www.hra.nhs.uk/research-community/the-review-process/nhs-research-ethics-committee-rec-reviewretrieved 20 September 2016

Health Research Authority NRES Shared Single Issue: Ethical Debate www.hra.nhs.uk/documents/2013/09/issues-and-arguments-time-to-consent.pdf retrieved September 2016

Health Research Authority 'Types of study/What is a qualitative study?'. Retrieved from www.hra.nhs.uk/patients-and-the-public-2/types-of-study/what-is-a-qualitative-study/ August 2016..

Health and Care Professions Council Standards of Conduct Performance and Ethics. Retrieved from www.hcpc-uk.org/publications/standards/index.asp?id=38 October 2016

Hedgecoe, A. (2009) A form of practical machinery: The origins of research ethics committees in the UK. *Medical History* 53(3),331 - 350.doi:10.1017/S0025727300000211

Hedgecoe, A. (2008) Research Ethics Review and the Sociological Research Relationship. *Sociology*, 42(5), 873-886.

Hedgecoe, A.M. (2012) 'Trust and regulatory organisations: The role of local knowledge and facework in research ethics review', *Social Studies of Science*, 42(5), 662-683

Hedgecoe, A. (2014) A deviation from standard design? Clinical trials, research ethics committees, and the regulatory co-construction of organizational deviance. *Social Studies of Science*, 44(1), 59-81.

Hedgecoe, A. (2015) Reputational Risk, Academic Freedom and Research Ethics Review, *Sociology*, 1-16, doi: 10.1177/0038038515590756

Heizmann, H. and Olsson, M.R. (2015) 'Power matters: The importance of Foucault's power/knowledge as a conceptual lens in km research and practice', *Journal of Knowledge Management*, 19(4), 756-769.

Hem, M.H., Heggen, K. and Ruyter, K.W. (2007) 'Questionable requirement for consent in observational research in psychiatry', *Nursing Ethics*, 14(1),41-53.

Homan, R. (1991). *The Ethics of Social Research*. London. Longman.

Israel, M. (2013). Rolling back the bureaucracies of ethics review. *Journal of Medical Ethics,* 39 pp. 525-526.

Irvine, A., Drew, P. & Sainsbury, R. (2010) Mode effects in qualitative interviews: a comparison of semi-structured face-to-face and telephone interviews using conversation analysis, *Research Works*, 2010-03, Social Policy Research Unit, York, University of York.

Johnson, M. (1997) *Nursing Power and Social Judgement*. Aldershot. Ashgate.

Johnson, M. (2004) 'Real-world ethics and nursing research' *Journal of Research in Nursing,* Vol. 9, No. 4, pp. 251-261.

Junghans, C., Feder, G., Hemingway, H., Timmis, A. & Jones, M. (2005) Recruiting patients to medical research: double blind randomised trial of "opt-in" versus "opt-out" strategies. *British Medical Journal*, 331:940.

Juritzen, T.I., Grimen, H. and Heggen, K. (2011) 'Protecting vulnerable research participants: A Foucault-inspired analysis of ethics committees', *Nursing Ethics*, 18(5),640-650.

Kelly, M (2013) 'Research questions and proposals'. In Seale, C. (2012) *Researching society and culture*, London: Sage.

Kent, G (2000) Ethical Principles, in Burton, D. (ed)Research Training for Social Scientists: A Handbook for Postgraduate Researchers. London: Sage.

Kittay, E.F. (2007) Beyond Autonomy and Paternalism: The Caring Transparent Self in Autonomy and Paternalism, in Nys,T., Denier , Y.& Vandevelde, T. (eds) *Reflections on the Theory and Practice of Health Care.* Leuven: Peeters

Long, T & Johnson, M. (2007) (Eds.) *Research Ethics in the real world: issues and solutions for health and social care.* Edinburgh. Churchill Livingstone Elsevier.

Macdonald, M. and Carnevale, F. (2008) 'Qualitative Health Research and the IRB: Answering the "So What?" with Qualitative Inquiry', *Journal of Academic Ethics*, **6**(1), pp. 1-5.

Manson, N.C. and O. O'Neill (2007) *Rethinking informed consent in bioethics*, Cambridge: Cambridge University Press.

Mason, J (1994) Linking qualitative and quantitative data analysis. In Bryman,A & Burgess,R.G.(Eds.). *Analysing Qualitative Data* (pp 89-110) London. Routledge**.**

Masson, J. (2004) The law and research with young people. In Fraser, S. (Ed) *Doing Research with Children and Young People* (pp.43-58). London: Sage.

Mason, J. (1996) *Qualitative Researching.* London. Sage.

Mantzoukas, S. (2012) Exploring ethnographic genres and developing validity appraisal tools. *Journal of Research in Nursing* 17: 420-31.

May-Chahall, C, Hicks, S. & Tomlinson, J (2004) *The relationship between child death and child maltreatment. NSPCC.*

Macfarlane, B. (2008). Researching with integrity: The ethics of academic enquiry. London: Routledge.

McLaughlin, H & Shardlow, S M 2009, Different cultures, different ethics? research governance and social care, *Ethics and Social Welfare,* 3,4-18.

Miller, G. (1997) 'Building Bridges: The Possibility of Analytic Dialogue Between Ethnography, Conversational Analysis and Foucault' in Hamm, D (ed) *Qualitative Research: Theory, Method and Practice* (pp 24-44). London: Sage.

Miller, T. and Boulton, M. (2007) Changing constructions of informed consent: Qualitative research and complex social worlds, *Social Science & Medicine*, 65(11), 2199-2211.

Miller, G., Dingwall, R. & Murphy, E. (2004) Using qualitative data and analysis: reflections on organizational research. In Silverman, D. (Ed). *Qualitative research: theory, method and practice* (pp324 -340). London: Sage.

Minghella, E., R. Ford, T. Freeman, J. Hoult, and P. McGlyn. (1998) Open all hours: 24-hour response for people with mental health emergencies. London: The Sainsbury Centre for Mental Health.

Mishler, E. (1986) *Research Interviewing: Context and Narrative*. Cambridge. Harvard University Press.

Morse, J.M., Swanson, J.M. Kuzel, A. J (2001) *The Nature of Qualitative Evidence.* London: Sage.

Morse, J (2007) Sampling in Grounded Theory. In Bryant, T., & Charmaz, Kathy. *The SAGE Handbook of Grounded Theory*. London.Sage.

Murphy, E. & Dingwall, R. (2007) Informed Consent, anticipatory regulation and ethnographic practice. *Social Science and Medicine,* 65(11) 2223-2234.

Myers, M.D. (2013) *Qualitative Research in Business and Management* (2nd ed.) London: Sage.

Nadai, E. & Maeder, C. (2005) Fuzzy Fields. Multi-Sited Ethnography in Sociological Research. *Forum: Qualitative Social Research*, 6 (3). Retrieved from http://www.qualitative-research.net/index

National Research Ethics Service (2009) PRS SOPs v1 1 - No Material Ethical Issues Tool. Retrieved from: www.nres.npsa.nhs.uk/applications/proprionate review on 11th November 2010.

Nikander P. (2003) The Absent Client: Case description and decision-making in interprofessional meetings. In Hall Chris, Juhila Kirsi, Parton Nigel and Pösö Tarja (Eds.): *Constructing Clienthood in Social Work and Human Services: Identities, interactions and practices.* Jessica Kingsley. eBook Collection (EBSCOhost) viewed 4 May 2016

Noblit, G and Hare, R (1988) *Synthesising Qualitative Studies*. London. Sage

Nolas,S-M. 2011 Grounded Theory Approaches. In Frost, N. (2011) *Qualitative Research Methods in Psychology: Combining Core Approaches.* Maidenhead. Open University Press. Retrieved from http://www.dawsonera.com/

O'Neill, O (2002) Reith Lectures See especially Lecture 4: 'Trust and Transparency'

O'Neill, O (2001) Autonomy and Trust in Bioethics www.ed.ac.uk/.../gifford-lectures/archive/archive-2000-2001/dr-oneill

O'Neill, O. (2003) Some limits of informed consent *Journal of Medical Ethics* 29, 4-7.

O'Neill, O. (2004) Accountability, trust and informed consent in medical practice and research, *Clinical medicine* 4(3), 269.

O'Neill, O. (2007) 'Experts, Practitioners, and Practical Judgement', *Journal of Moral Philosophy*, 4(2),154-166.

Oeye, C., Bjelland, A.K.& Skorpen, A. (2007) 'Doing participant observation in a psychiatric hospital - research ethics resumed', *Social Science & Medicine*, 65(11), 2296-2306.

Okai, D., Owen, G., McGuire, H., Singh, S., Churchill, R. and Hotopf, M. (2007) Mental Capacity in Psychiatric Patients: Systematic Review. *British Journal of Psychiatry,* 101, 291-297.

Olson, K (2001) 'Using qualitative research in clinical practice' in Morse, J.M., Swanson, J.M. Kuzel, A. J (2001) *The Nature of Qualitative Evidence.* London: Sage.

O'Reilly, M., Dixon-Woods, M., Angell, E., Ashcroft, R. and Bryman, A. (2009) Doing accountability: a discourse analysis of research ethics committee letters. *Sociology of Health & Illness*, 31(2), 246-261.

Popay,J., Rogers, A. and Williams, G. (1998) 'Rationale and standards for the systematic review of qualitative literature in health services research', *Qualitative Health Research*, 8(3), 341-351.doi:10.1177/104973239800800305

Potter, J. (1996) *Representing Reality: discourse, rhetoric and social construction.* London: Sage.

Ransome, P (2013) *Ethics and Values in Social Research.* London: Palgrave.

Ravenek, M.J. and Rudman, D.L. (2013) Bridging Concepts of Quality in Moments of Qualitative Research. *International Journal of Qualitative Methods (*12) 436-456.

Rawls, A. (2003) Harold Garfinkel. In Ritzer, G (ed) (2003) The Blackwell Companion to Major Contemporary Theorists. Oxford. Blackwell.

Richards, L & Morse, J.M. (2007) *User's Guide to Qualitative Methods (*2nd ed.*).* London. Sage.

Rock, P. (2001) Symbolic Interactionism and Ethnography. In Atkinson, P., Coffey, A., Delamont, S., Lofland J.and Lofland, L. (Eds.). *Handbook of Ethnography* (pp.26-39). London: SAGE.

Rosenhan, D.L. (1973) 'On being sane in insane places', *Science (New York.)*, 179 (4070), p. 250.

Saldana, J (2009) *The Coding Manual for Qualitative Researchers.* London: Sage.

Schenshul, S.L., Schenshul, J and LeCompte, M.D. (2013) *Essential Ethnographic Methods.* Oxford. Alta Mira Press.

Schön, D.A. (1999) *The reflective practitioner: how professionals think in action*.

Sheehan, M (2013) Do we need research ethics committees? Journal of Medical Ethics. 39 (8)

Sherwin, S.(1996) "Feminism and Bioethics" in Susan Wolf, ed. Feminism and Bioethics: Beyond Reproduction, New York: Oxford University Press, 1996: 47-66.

Smart, G. (1998) Mapping Conceptual Worlds: Using Interpretive Ethnography to Explore Knowledge-Making in a Professional Community, *Journal of Business Communication*, 35 (1) 111-127. Retrieved from Business Source Premier, EBSCO*host.*

Smith, D.E. (1987) *The Everyday World as Problematic: A Feminist Sociology.* Toronto: University of Toronto Press and Northeastern Press.

Smith, D.E. (1990) *Texts, facts, and femininity: exploring the relations of ruling.* London: Routledge.

Smith, D.E. (1999) *Writing the social: critique, theory, and investigations*, Toronto, Ont.: University of Toronto Press.

Smith, D.E. (2001) 'Texts and the ontology of organizations and institutions', *Studies in Cultures, Organizations and Societies*, 7(2),159-198.

Smith, D. E. (2006) *Institutional Ethnography as Practice.* Oxford. Rowman and Littlefield.

Smith, V. (2001) Ethnographies of Work and the Work of Ethnographers in Atkinson, P. A. Coffey, S. Delamont, J. Lofland and L. Lofland (eds.) (2001) *Handbook of ethnography*. London: Sage.

Sheehan, M (2013) Do we need research ethics committees? Journal of Medical Ethics. 39 (8).

Silverman, D. (2001) *Interpreting Qualitative Data. Methods for Analysing Talk, Text and Interaction.* London: Sage.

Silverman, D. (2005) *Doing Qualitative Research: A Practical Handbook* (2nd ed.). London: Sage.

Silverman, D. (2010) *Doing Qualitative Research* (3rd ed.). London: Sage.

Silverman, D (2013) *Doing Qualitative Research* (4th ed.). London: Sage. Smart, G. (1998) Mapping Conceptual Worlds: Using Interpretive Ethnography to Explore Knowledge-Making in a Professional Community, *Journal of Business Communication*, 35 (1) 111-127. Retrieved from Business Source Premier, EBSCO*host.*

Smith, D.E. (1987) *The Everyday World as Problematic: A Feminist Sociology.* Toronto: University of Toronto Press and Northeastern Press.

Smith, D.E. (1990) *Texts, facts, and femininity: exploring the relations of ruling.* Abingdon.Routledge.

Smart, G. (1998) Mapping Conceptual Worlds: Using Interpretive Ethnography to Explore Knowledge-Making in a Professional Community, *Journal of Business*

Communication, 35 (1) 111-127. Retrieved from Business Source Premier, EBSCO*host.*

Smith, D.E. (1987) *The Everyday World as Problematic: A Feminist Sociology.* Toronto: University of Toronto Press and Northeastern Press.

Smith, D.E. (1990) *Texts, facts, and femininity: exploring the relations of ruling.* London: Routledge.

Smith, D.E. (1999) *Writing the social: critique, theory, and investigations*, Toronto, Ont.: University of Toronto Press.

Smith, D.E. (2001) 'Texts and the ontology of organizations and institutions', *Studies in Cultures, Organizations and Societies*, 7(2),159-198.

Smith, D. E. (2006) *Institutional Ethnography as Practice.* Oxford. Rowman and Littlefield.

Smith, V. (2001) Ethnographies of Work and the Work of Ethnographers in Atkinson, P. A. Coffey, S. Delamont, J. Lofland and L. Lofland (eds.) (2001) *Handbook of ethnography.* London: Sage.

Smith, D.E. (1999) *Writing the social: critique, theory, and investigations*, Toronto, Ont.: University of Toronto Press.

Smith, D.E. (2001) 'Texts and the ontology of organizations and institutions', *Studies in Cultures, Organizations and Societies*, 7(2),159-198.

Smith, D. E. (2006) *Institutional Ethnography as Practice.* Oxford. Rowman and Littlefield.

Smith, V. (2001) Ethnographies of Work and the Work of Ethnographers in Atkinson, P. A. Coffey, S. Delamont, J. Lofland and L. Lofland (eds.) (2001) *Handbook of ethnography.* London: Sage.

Somekh, B. & Lewin,C. (2011) *Theory and Methods in Social Research* (2nd ed.). London: Sage.

Stanley, L. and Wise, S. (2010) The ESRC's 2010 Framework for Research Ethics: Fit for Research Purpose? *Sociological Research Online.* 15(4).

Stark, L. (2010) The science of ethics: Deception, the resilient self, and the APA code of ethics, 1966–1973. Journal of the History of Behavioral Science, 46: 337–370. doi: 10.1002/jhbs.20468

Stark, L. (2012) *Behind Closed Doors: IRBs and the Making of Ethical Research.* London. The University of Chicago Press.

Stark, L. (2013). Reading Trust between the Lines. *Cambridge Quarterly of Healthcare Ethics.* 22, 391-399. doi:10.1017/S096318011300025X.

Stewart, P.M. Stears, A., Tomlinson, J.W. Brown, M.J. (2008) Regulation – the real threat to clinical research. *British Medical Journal (BMJ 2008; 337: a1732)*

Swanson, J.M (2001) Questions in Use. In Morse, J.M., Swanson, J.M. Kuzel, A. J *The Nature of Qualitative Evidence* (pp 75-110). London: Sage.

Taylor, C. & White, S. (2000*) Practising Reflexivity in Health and Welfare: Making Knowledge.* Buckingham: Open University Press.

Timmermans, Stefan, (2012) The Seven Warrants of Qualitative Health Sociology. *Social Science and Medicine, 77, 1-8.*

Tracy, S.J. (2010) Qualitative Quality: Eight "Big- Tent" Criteria for Excellent Qualitative Research. *Qualitative Inquiry*, 16(10), 837-851.

Tracy, S.J. (2013). *Qualitative research methods: Collecting evidence, crafting analysis, communicating impact.* Chichester. Wiley-Blackwell.

Turner, S.M (2006) Mapping Institutions as Work and Texts. In *Institutional Ethnography as Practice* ed Smith, D.E. (pp139-161). Oxford. Rowman and Littlefield.

Wiles, R., Crowe, Charles, V. and Sue Heath (2007) Informed Consent and the Research Process: Following Rules or Striking Balances? *Sociological Research Online,* 12 (2) doi:10.5153/sro.1208

Wiles, R (2013) *What are qualitative research ethics?* London. Bloomsbury Academic.

 Van Willigenburg, T. (2007). Reflective Equilibrium as a Method in Health Care Ethics. In *Principles of Health Care Ethics: Second Edition* (pp. 207-213). John Wiley and Sons.

Williams S. J. (2003) *Medicine and the Body*, Sage, London

Wilson, A and Pence, E. (2006) U.S. Legal Interventions in the Loves of Battered Women, in Smith, D. E. (2006) *Institutional Ethnography as Practice*. Oxford. Rowman and Littlefield.

Wing, J. K., Curth, R. H., & Beevor, A. S. (1998). HoNOS: Health of the nation outcome scales. Report on research and development. London: Royal College of Psychiatrists Research Unit.

Wolf, S. (1996). *Feminism & bioethics: Beyond reproduction*. New York: Oxford University Press.

World Medical Association (2013) Declaration of Helsinki. Adopted by the 18th World Medical Assemble, Helsinki 1964 as amended by the 64th WMA General Assembly, Brazil. Retrieved 11 April 2015 from http://www.wma.net/en/30publications/10policies/b3