

The Work of Phase I Ethics Committees: expert and lay membership

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Abstract

Previous research has noted that members of research ethics committees are unclear about the extent of their roles. In this study, research amongst members of independent ethics committees (IECs) about how the 'expert' and 'lay' roles are understood and operationalized offers an explanation for this lack of clarity.

IECs were selected for study because they have only addressed one type of research (Phase 1 'healthy volunteer' studies) and this limited remit suggested that it would be in such committees that the member roles would have become most pronounced.

Drawing on findings from the sociology of professions and employing a phenomenological approach to understanding, 20 semi-structured interviews with both expert and lay members of these committees revealed that a number of members were not only unclear about the roles, but unclear too whether they, or certain of their colleagues, were in which membership category. Notwithstanding this fact, and paradoxically, the 'expert' designation was seen as granting its members a privileged position on the committees. The expert member was seen to be either a medically qualified member or one tightly associated with the medical model. Such a repository of expertise being with the medical model privileges this model in ethics review such that other matters formally to be scrutinized by ethics committees become marginalised.

Participant safety was the prime concern of the ethics review for IEC members. This relegated other matters including the adequacy of the insurance arrangements, the

readability of the consent forms, the fairness of the inclusion criteria, and so forth, into areas of lesser concern. That this occurs though when the science, the safety and the methodology of the trials are already – separately - subject to an independent analysis by a body of experts, whose statutory role is to concern itself with these issues such that no trial may occur without their sanction, is of significance. IEC members were cognizant of this duplication of role but unable to resolve it. The situation could be accounted for as due to capture by the medical model and a cognitive dissonant process.

Members' training and education were found to have been neglected because under the medical professions' gaze no other type of knowledge was considered necessary in ethics review. The study revealed that the medical profession's dominance of such committees accounts for the members' role uncertainty and as such allies itself to Freidson's theory of professional dominance. If such a concept has been thought to be an obsolete one, this study suggests such a notion of the status of the theory is premature. The medical model's status is implicitly accepted such that nothing else need be considered.

The research calls for further studies to corroborate such findings in other research ethics settings and for a debate about what society wants its ethics committees to focus upon in their review.

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My research would not have been possible without the cooperation of members of Independent Ethics Committees (IECs) up and down the land who agreed to be interviewed by me. I also wish to thank members of my own IEC committee who indulged me whenever I raised general questions about what we were doing in the committee and who helped me to see what they saw.

I doubt that the interpretation I place on my findings will be shared by all those whom I interviewed, but I trust too that my argument is clear enough for readers to form an opinion and that a debate about the functions of RECs can now move forward productively.

I wish to record my thanks to my supervisors, Professor Robyn Martin for motivating me to get some publications under my belt, and Professor Hilary Thomas whose calm experience kept me on-track when the going got difficult.

Abstract

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1. Introduction

This research reports the perspectives of members of independent ethics committees (IECs) about the expert and lay members' roles. IECs are a sub-type of research ethics committees (RECs), and the lay members' role (in particular) on RECs has been noted to be poorly understood (e.g. Dyer, 2004). This research helps us to better understand it. The research also reveals several other aspects of IECs, and by extension RECs, which have not been clear before and which will be of interest to scholars of such committees.

RECs are notoriously difficult to access for those wishing to subject them to research (De Vries, 2004), and IECs have been particularly impenetrable because of a combination of their low profile (McHale, 2004) and the commercial sensitivity that surrounds the studies they review (Beyleveld and Sethe, 2008). This study, by its very discussion of IECs and their practices thus breaks new ground. The research reveals not only the perspectives of members of IECs about the member roles on such committees, but reveals the members' approach to ethics codes, how they address the insurance arrangements concerning the studies which they review, and their involvement in assessing the clarity by which the participant information sheets are expressed. The research also explains how members were recruited and it discusses the training members have had. Important issues also emerge concerning the medical dominance of the committees and the concomitant implications

this has had for both appraising the science and ethics of the research which the committees are required to consider.

The research engaged in was qualitative, and as typical of such research, the direction of the research needed to accommodate emergent issues and themes. One particular issue that arose with more frequency than initially envisaged concerned the extent to which an ethics committee (EC) should review the science of the research. Another body already had the specific task of conducting a scientific review, having been constituted with that task in mind.

A key question for research ethics then concerns the extent to which it is the function of a REC to review the scientific quality of the proposals put to them given that they are not explicitly constituted with such a task. Whilst such a question has already been answered in the governance arrangements of NHS RECs and in their standard operating procedures, it nevertheless proved to be a fundamental issue for the work reported here. The issue appears repeatedly as the study progresses, and even where it does not make an explicit appearance it is always in the background.

An associated question, asking why there are 'expert' members on RECs if it is not for such committees to appraise the science underpinning the research, is nearer to the original focus of the work that follows, and the two questions run in parallel throughout the study. But such questions

as posed are too pointed and as such are likely to by-pass the real dynamics of the committees. The question to be asked and understood – the research question here – is one that additionally provides a rare glimpse into the workings of committees which have largely escaped scholarly observation, yet whose operations and procedures have been key determinants in authorising research involving human subjects.

The main question this research sets out to answer is epistemological (although it is not one which is difficult to conceptualise) and may be put simply as ‘how do members of research ethics committees conceive the ‘expert’ and ‘lay’ roles on their committees?’ No satisfactory account for this has been obtained to date despite several researchers (with Dyer (2004) being amongst the most prominent) noting members’ lack of clarity about their role. An explanation for this lack of clarity has proved elusive. Answering this ostensibly simple question should thus potentially open up an important understanding of exactly what committee members are actually trying to do. And with that understanding most else about such committees will be seen to pivot.

Subsidiary research questions address how members respond to particular issues; what, if any, guidance they follow; how members relate matters of ethics to matters of science; how they determine the adequacy of insurance; and what level of training is necessary for the roles.

Further elaboration about the research questions is provided at the close of the literature review where relevant questions are teased from the extant literature as being of interest to the community of research ethics scholars. The understanding obtained from this research is intended to enable a more informed debate amongst the wider society about what such committees are to do, and will have important implications for member recruitment, training and development too.

Some readers may point either to legislation as suggesting that the committees' tasks are their duty "to protect the rights, safety and wellbeing of human subjects involved in a trial" (Art. 2(k) of the Clinical Trials Directive*), or to the statement of purpose of NHS RECs, which has been adopted by the National Research Ethics Service (NRES). This states: "The purpose of a Research Ethics Committee in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants" (Department of Health, 2001: para. 2.2; and see para. 3.1.1, 2011). However, such terms - 'rights', 'safety', 'well-being' and 'dignity' – are, as shall be demonstrated, all contested notions. This contestability, coupled with that the REC shares its role and responsibility with others, as described in the *Research Governance Framework for Health and Social Care* (Department of Health, 2005a), further stands to blur role clarity. This problem is then further exacerbated by a lack of practical clarity in agreeing what precisely are the roles and

* Directive 2001/20/EC of the European Parliament and the Council of 4th April 2001 on the approximation of laws, regulations and administrative provisions relating to the implementation of good ethical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001, p.34

responsibilities of both the 'lay' and the 'expert' members of the committees.

1.1 Personal interest

The study focuses on human-subject research ethics review and in particular on REC members' perceptions of their roles and functions.

Such a topic may have an intrinsic appeal:

"I can't say exactly when I was captured by issues in human research ethics.... Whenever it was, I was struck by the unavoidable and seemingly irresolvable exquisite moral framework of clinical research: that it involves using a person as a means to someone else's benefit, and does so while applying and refining what are among the most impressive expressions of humanity: ingeniously crafted scientific ideas.

Nearly as soon as I acquired an appreciation for the richness of this framework, I was also struck by the richness of the history of research involving people and by how difficult it can be to identify circumstances that satisfy the diverse moral requirements of ethical research" (Moreno, 2005: 105).

Like Moreno, I have also been intrigued by the task of contemplating the ethics of human subject research. When I set out on the research programme that has now culminated in this dissertation I did not anticipate the interest in research ethics that I have developed. I had been appointed as a lay member of an "independent pharmacology ethics committee" (despite having no pharmacological knowledge) only a matter

of months before enrolling on the programme. It was the doctoral programme, coupled with the novelty of my new role, which gave me cause to think about my experiences as a committee member in a more detailed way than I suspect I would have done without the course's influence.

The course also encouraged me to write and to get published. From a position of having no publication record I have now had over two dozen peer-reviewed papers published, most of which relate to ethics, and research ethics in particular. Many of these will be referred to in this dissertation. Although I did not know it at the time, these publications were acting increasingly like jigsaw pieces giving me a sense of working towards completing a larger, if, at any one time, unknown, final picture. New linkages continued to appear with ongoing contact with the research ethics community. This dissertation itself has furnished a corner or two and possibly a connecting edge to the puzzle which will help me on my way to my project of understanding RECs.

Role uncertainty was something I experienced as a new member of an ethics committee. The committee did not operate as I had anticipated it would, and I wondered if the fault was with me. My new colleagues did not seem as convinced about the roles as I expected and I could find no published material on the workings of the type of committee I was involved in: my curiosity grew.

1.2 Independent Ethics Committees

The ethics committee I had joined had been established by a pharmaceutical company in the 1980s to review the procedures proposed for their new drug compounds before they were first administered to human 'guinea pigs'. The Welwyn Committee was originally associated with Roche and each of the other committees had originally been established by a pharmaceutical company.

Although such committees were termed 'independent ethics committees' (IECs) they typically had their base on the property of the pharmaceutical company which had established them. The Clinical Trials Directive of 2001 and the lead up to it caused a change in perception about this and greater independence was created by relocating the IEC meeting places to neutral venues, and empowering the IECs to review the protocols of any pharmaceutical company. The IECs were no longer pharmaceutical company-specific.

IECs were finally absorbed into the NHS REC structure at the close of 2011 – more will be said about this later – but not before I had managed to conduct my research and discern the reason why REC members experience role uncertainty.

These points will be discussed in more detail in subsequent chapters but firstly, in order especially for those who may not be familiar with the workings of RECs and the key problems and issues associated

with them, the following chapter is intended to provide a background. This helps set the scene in which the work of IECs and RECs is to be understood. A literature review section then follows. This section comprises two chapters, the first of these provides a sociological accounting of professions which will help frame the findings, and the second describes key published research that has been undertaken on the workings of RECs. A discussion of the research methods occupies the subsequent chapter (chapter 5) and then there follow three findings chapters, the breakdown of which is intended to help the reader digest the material at a reasonable pace. A discussion chapter finally advances the significance of the key findings of the research and indicates areas for further study.

2. Background

2.1 Response to scandal

In order for research involving human subjects to proceed, there is a requirement that the research proposal receive a favourable opinion from an ethics committee. The requirement for review arose following such outrages involving unethical human research practices as were witnessed in the Nuremberg Doctors' Trials (Schmidt, 2006), as were exposed by Beecher (1959,1966), and as further revealed in the Tuskegee Syphilis Studies (Jones, 1993). The National Health Service has required ethics approval since 1991 (Department of Health, 1991) where NHS patients and (until the revised version of the *Governance Arrangements for Research Ethics Committees (GAfREC*, Department of Health, 2011)) facilities or staffs are involved. Although virtually all pharmaceutical research was also subjected to independent ethics scrutiny from even earlier (e.g. Curran, 1979; Laurence, 1984), there was no legal requirement for an ethics review of any clinical trial before the Clinical Trials Directive of 2001. This was not implemented into UK law until 2004 (as The Medicines for Human Use (Clinical Trials) Regulations 2004, S.I. 2004/1031).

In most of the world, committees set up to review the scientific merit and ethical acceptability of research proposals involving human subjects are known as research ethics committees. The first mention of

committee review in an international document was in the Tokyo revision of the Declaration of Helsinki (World Medical Association, 1975). This followed experience in the United States, where the first federal document requiring committee review had been issued on 17 November 1953 and applied only to the Clinical Centre of the National Institutes of Health. On 8 February 1966, the Surgeon General of the US Public Health Service (USPHS) began requiring all those in receipt of USPHS grants in support of human subjects' research to specify committee review:

“(1) Of the rights and welfare of the ... individuals involved, (2) Of the appropriateness of the methods used to secure informed consent, and (3) Of the risks and potential medical benefits of the investigation.”

Historically, the RECs' primary focus had been on safeguarding the rights and welfare of the research subjects. This is actually rather a vague set of instructions. For example, it may be the case that:

“we must show concern for the well-being of subjects and not ever let the temptations of research lead us to lower our level of concern from its normal, appropriate level. But what is the normal, appropriate level? What does 'concern for well-being' even mean?”
(Hawkins, 2008: 34)

Elsewhere I have argued that the meaning of the term 'welfare' in the UK's Health and Safety etc. Act of 1974 is in fact still unclear and this despite employers having had a legal responsibility to safeguard the welfare of their employees for approaching four decades (Humphreys,

2007a, 2007b). Unsurprisingly then, that particular legislative requirement has arguably failed to secure anyone's welfare at work and indeed has failed to result in a successful prosecution. It is difficult to believe that the same term is operated with any greater effectiveness by ethics committees.

From 1978, in response to gay activism over access to experimental AIDS medication (Wachter, 1992), the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (National Commission) in the US, added a requirement that ethics committees also ensure equitableness in subject selection. (In passing one can note that in the US, Institutional Review Boards (IRBs) are the effective equivalent of RECs, and in Canada similar committees are termed Research Ethics Boards (REBs). A glossary of terms is provided as Appendix 1.)

2.2 Science/ethics divide

Despite such mandates to protect the rights, safety, welfare, dignity and, later, even the opportunity to participate in research, there has also been a continuing controversy concerning whether the REC has an obligation to approve or disapprove the scientific design of the research protocol (e.g. Levine, 1986). Those who argue that they do have such an obligation note that ethics codes require good scientific design and that the risk to subjects necessarily relies on a prior determination about the scientific design (e.g. Dawson and Yentis, 2007). Opponents, while conceding these two points, argue that RECs are not designed to make

expert judgements about the adequacy of scientific design. Rather they should form an opinion about the *value* of the science (“the humanitarian importance of the problem to be solved” – as para. 6 of the Nuremberg code (1947) put it) and leave the scientific issues to be assessed by others. They must ensure that the science has been appropriately reviewed – but not necessarily review it themselves. This debate is an important one, and proved central to the research which is to be reported below.

2.3 Expert and lay role divide

The Surgeon General’s 1966 memo, already referred to, had called for a prior review by “a committee of [the investigator’s] associates”. The U.S. Congress however wanted human experimentation to be scrutinized by ‘outsiders’: “For the proper regulation of the powerful professionals of modern society, we need a combination of insiders and outsiders, of professionals and citizens” (Commission on Health Science and Society, 1968: 1265). Accordingly the guidelines were refined on 1 May 1969 to indicate that a committee entirely composed of medics or scientists would be inadequate to perform the functions expected of it. This was a clear indication that Congress at least did not believe that the science as such was the real problem. Rather the problem to be tackled centred on what the research intended for fellow humans. For the humanitarian aspect of the research a moral, rather than scientific, review was required. For that no expertise would be necessary, indeed ordinary ‘citizens’ would be good enough.

In 1973, in response to the Tuskegee revelations (Jones, 1993) that further unethical medical research had been perpetrated on US citizens, a National Commission was established to determine how to prevent further similar research scandals. Its eleven members were drawn from “individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioural and social sciences, philosophy, humanities, health administration, government, and public affairs” (US National Research Act § 201, cited by Schrag, 2010: 55-6).

In the UK meanwhile, researchers had been quick to follow American influences (Neuberger, 1992; Nicholson, 1993; Schrag, 2010) primarily in order to be eligible for USPHS research funding (RCP, 1967). Pappworth (1962, 1967) followed Beecher (1959, 1966) by drawing attention to the state of clinical investigations in the UK. Seeing the moral necessity he also called for a REC to be established in every regional health authority area and for committees to have at *least* one lay member (Pappworth, 1967).

The call for lay participation grew very much as a consequence of the Beecher/Pappworth revelations and also out of the thalidomide* tragedy of the time (Rothman, 1991). The extent of the scandals being revealed, especially in America, caused the public to realise how much

* A highly effective sedative drug often prescribed in cases of morning sickness because it was thought safe in pregnancy. Used from 1957 it was implicated in birth defects and withdrawn worldwide by 1962.

power they had given the medical profession to conduct themselves with effective *carte blanche*, and they began to see that as patients, they too had rights – including rights to decide what happened to their bodies. The first Declaration of Helsinki setting out a code of ethics for medical researchers was issued in 1964 by the World Medical Association in order to begin to take charge of the problem from within the profession. Its 1975 version required ethics committees to review proposed research.

In a survey subsequently carried out in England and Wales during 1982-3, 254 RECs were identified with 53% of responding RECs indicating that they had just one lay member and a further 8% having no lay member at all (Nicholson, 1986a). That research found that the RECs were unclear about the nature of their task, and similar research a decade later found that the situation had little changed, noting as it did: “The fundamental flaw in their operation was their own lack of clarity as to what their task should be” (Neuberger, 1992: 44). Dyer (2004) found the same problems and the present research will demonstrate that this remains the position today.

The Royal College of Physician’s guidelines of 1984 had indicated for its part that the objectives of ethics committees were “to facilitate medical research in the interest of society, to protect subjects of research from possible harm, to preserve their rights, and to provide reassurance to the public that this is being done. Committees also *protect research workers from unjustified attack*” (emphasis added, Laurence, 1984: 1).

Yet one suspects that this final sentence betrayed the chief concern of the profession as the research workers being referred to were, in most cases, fellow medical professionals.

2.4 Criticisms

Such guidelines certainly did nothing to protect the process of ethics review from being the target of complaints. The main criticisms have come from researchers themselves and so one should be cautious of at least their potentially biased perspective. Their oft cited claim is that research is unnecessarily hampered by such reviews. The process has been implicated in unnecessary delays (Ahmed and Nicholson, 1996; Ledford, 2007) and has been tarred with being inconsistent, such that identical research may receive a favourable opinion from one committee but be rejected as unethical by another (e.g. Cave and Holm, 2002; Edwards et al., 2007; Schrag, 2010). Accusations about the lack of skills, knowledge and understandings of ethics committee members have also been made (e.g. Hoffmann et al., 2000; Schrag, 2010; Stewart et al., 2008; Williamson, 2008; Wisner et al., 2011). Harding and Ummel (1989) demonstrated that the committees could also be too lax. Cheung reported “[s]tudies have shown that 34%...[of] institutional boards, have never modified any research applications or rejected a research proposal, and that committee decisions relied heavily on physician-scientists, who make up the vast majority of the boards. Most decisions arrived at by the board members were based largely on technical issues rather than ethical matters” (2007: 146). In Canada an official report cuttingly found that “enhancing the competency of some REB [research ethics board]

members...would greatly improve the functioning of the REBs on which they sit” (Experts Committee for Human Research Participation Protection in Canada, 2008: 31). According to such criticisms whatever the committees were doing they were not doing it well, and had not done it well for decades. Virtually whenever RECs have been the subject of comment they have been castigated: “As has been stated frequently in the Bulletin, however, there is no evidence that even a minority of the committees, as constituted and working at present, are doing their existing work properly” (Nicholson, 1986b: 6). In particular, questions arose about the suitability of members to perform ethics reviews. It has often been remarked for example that at least some members seem to concentrate their efforts on criticising the grammar of the information sheet and informed consent document (Angell and Dixon-Woods, 2009) and sometimes go so far as even “judging proposals based on the proportion of spelling and typographical errors” (Schrag, 2010: 170). Stark (2012) explains that this alleged pettiness can be accounted for in that some reviewers view the level of apparent attention to detail as illustrated by completed application forms and so on as a metric for how carefully a researcher might conduct a trial or attend to participants. Despite this though, RECs have their own reputation for spelling and grammatical errors (Schrag, 2010; Nicholson, 1997). They allegedly add nothing of value, and are more likely to get in the way of research rather than help good research to progress. Too often, it is claimed, research is subjected to inappropriate modification by ethics committees (Bond, 2012; Schrag, 2010).

It is helpful to be alert to the fact that not all RECs are identical. Such a caution is most clearly articulated by Hedgecoe (2012a) who draws attention to what he terms the isomorphism of the differing bodies that act as research ethics committees.

An isomer is a chemical entity having an identical atomic formula but a different arrangement of those atoms compared with another instance of that chemical. The chemicals have features in common but are also capable of acting very differently. The analogy is helpful – NHS RECs differ from IRBs which differ from REBs; different European Union states' RECs, although based on the same common Clinical Trials Directive, are comprised of differently qualified individuals and so on. Whilst NHS RECs may review protocols which may not to be performed in the locality where the REC is based, in the USA most IRBs are institutionally-based. In the USA too, a relatively new group of 'for-profit' IRBs have developed, these IRBs by contrast review studies due to take place at locations that no member of its committee has any affiliation with.

The pharmaceutical industry has attempted to address the variety of practices that might have existed in RECs by championing international legislation based on the industry's own common standard of ICH-GCP (e.g. Commission Directive 2005/28/EC and Humphreys, 2007c), and there are now proposals to revise the European directive on clinical trials (2001/20/EC) to further narrow variation amongst committees by

attempting to formally separate the scientific review from the ethics review (Europa, 2012).

There is scant literature on IECs and so for insights into the operation of RECs one must, perforce, utilise the nearest set of literature available whilst noting any differences. That literature concentrates largely on the numerically larger group of IRBs (in the USA), Canadian REBs and the UK NHS RECs. As the literature does not specifically address IECs, consideration of this fact, and of the variety of RECs and their isomorphic practices, needs to be kept in mind.

What goes on inside ECs however is invariably such that only its members can know what is acceptable to it, and in this subjectivity their power becomes great indeed. It becomes for them to decide to either permit research to occur in a particular way, or prevent it altogether. Such 'normalising judgements' of a REC create a productivity such that the subjects (the researchers) will police themselves in accordance with the REC's requirements. However, the normative is artifactual, having no reality beyond what it references. In producing requirements about what is to be regarded as ethical research, the ethics committees effectively stultify ethics, coming to regard matters ethical as necessitating rigid rules to be imposed inflexibly (Toulmin, 1981). Thus instead of what actions are ethically appropriate being for each individual to determine autonomously, they become heteronomous impositions. Such 'games of truth' (Foucault, 1997), whereby the 'right' stance is positioned as

incontestable, aim to create individuals as subjects of knowledge and thus pawns to those wielding power. Individuals are thus expected to orientate themselves and their behaviour towards a majoritarian position (the norm). However with ethics there is nothing to be objective about, other than intersubjectively. Ethics is usually seen to be about doing the right thing, with the right motives. This need not necessitate a single way of doing things. Ethics committees however do not always view ethics in this way and tend to bind themselves to their own precedents, often with unrealistic expectations of harm that may befall those researched (Haggerty, 2004; Schrag, 2010; van den Hoonaard, 2011).

Juritzen et al. (2011) suggest that the members' knowledge/power modality creates 'docile bodies' of researchers who go on to police themselves in accordance with what is created and legitimated by the committees.

Such 'power plays' where the EC seeks to redesign the methodology proposed by the researcher are accepted because the EC has a status of independence and a deemed expertise. This alleged expertise is questionable however. For example, in the case of IECs, the Medicines and Healthcare products Regulatory Agency (MHRA) was established on 1st April 2003 as the UK national 'regulatory authority' and given as a specific task responsibility for assessing the science and safety of Phase I trials. The responsibility for the science and safety of such

trials is thus with the MHRA, but, as will be seen, ethics committees continue to insist on performing their own review of the scientific design.

There is no reason why an EC should not concentrate on the ethics of the protocols, and leave the science and safety aspects of the studies to the authorized experts in the MHRA. The MHRA employs its own technicians and contracts with external scientists and academic experts specifically to conduct the necessary assessments. In contrast it is virtually impossible that members of an EC will have expertise in all - and very often, any - of the aspects of the trials that need to be considered. Committee members' 'ignorance' has been acknowledged by the Royal College of Physicians for its members (Hoffenberg et al., 1986). Fisher (2009) in the US also found for example that not one physician even claimed to understand the science behind the clinical trials they were party to as researchers. If anyone might be expected to understand the science behind the clinical trial they were acting as an investigator of it is surely these physicians. Her observation thus highlights the lack of knowledge physicians in general can be expected to bring to a REC. Petryna (2009) too reports the widespread view that "the average physician... [does] not know enough about drugs" to be able to comment adequately on the testing of experimental compounds (p.57). This is a point also picked up by Abadie (2010), who notes:

"During phase I the professional knowledge required in drug development is mostly supplied by biostatisticians and experts in toxicology. *In contrast to later phases in drug research, no*

specialized knowledge about a particular disease or medical condition is required' (p.22, emphasis added).

In another, but still telling, context, Hubbard too has noted how the pharmaceutical industry's practice of detailing has long exploited the fact that amongst physicians "there is often a significant deficiency in their knowledge of pharmacology" (Hubbard, 2009: 110). There is thus distinct evidence that a typical medical member will bring but little relevant expertise to the review. S/he can only be an expert in comparison to those who have no recognised clinical knowledge or skill set. The history of the committees suggests that the term was selected with medical members in mind, and very probably by them too (Hoffenberg et al, 1986).

The model process of research ethics review of new medicines is explained by Edwards:

"The regulator [MHRA] assesses the safety of all new drugs tested within clinical trials... the ethics committee may not be in a position to assess risk in the same way [it will not have access to all the evidence and may not have the relevant expertise available to it] but refers to the regulator's expert judgement...

... [T]he ethics committee...must nevertheless endorse this judgement [of the regulator] as well as ensure the whole protocol is ethical...they must ensure that the procedures for consent are good and that the systems for managing and minimising any high risks are robust...

... [I]t is the regulator which assesses risk and the ethics committee simply checks this assessment and the way the investigator intends to manage risks. There are scientific experts on committees however who are in a position to understand the risks and explain them to the other members” (Edwards, 2010a: 99-100).

In an earlier article, Edwards (2010b) explains this by pointing out that whilst “ethics committees are not constituted to review the science of a project they must assess the social benefits of research and [thus they] have an important role in *checking* that the science has *been* peer-reviewed” (emphases added, Edwards, 2010b: 58).

It is an important point, and the distinction between re-reviewing and accepting that something has been properly reviewed already, must be understood if ‘double-jeopardy’ is to be avoided. The REC must see evidence that a proper review has taken place; where the REC has evidence that such a review has already taken place they should not take it upon themselves, arguably, to dismiss that review. The science *must* be satisfactory, as if it is not the research may be unethical (either dangerous or wasteful of resources) – the issue is *who* should be responsible for the scientific review.

At the risk of belabouring the point, GAfREC clearly states:

5.4.2 RECs should receive guidance on the wider regulatory and governance environment for research and its reliability so that they can assess the assurances they receive. RECs will accept credible assurances that others will do what is expected of them.

(a) A REC need not reconsider the quality of the science, as this is the responsibility of the sponsor and will have been subject to review by one or more experts...

(c) Where others have a regulatory responsibility, a REC can expect to rely on them to fulfil it. If the law gives another body duties that are normally responsibilities of a REC according to this document, RECs do not duplicate them. For example, the Medicines and Healthcare products Regulatory Agency has the primary legal responsibility for considering the safety of the research it regulates.

Thus Edwards' description accords perfectly with section 9 of *GAfREC* (Department of Health, 2001; para. 5.4.2 *GAfREC II*), Recommendation 2 of the Warner report (Department of Health, 2005b, see also COREC, 2006) and the NRES standard operating procedures (SOPs) (see Humphreys, 2011), but despite all this it has not been a process EC members chose to adopt in practice. It has also been the practice that submission to the regulator and the EC are made at the same time ('in parallel') and this can mean that it may not always be possible to check that the regulator *has* assessed, properly or otherwise, the protocol. But again there has been no requirement that an IEC be constituted in such a way as to grant it a legitimate claim to such ability in any case. It has also been the case that the 'experts' on a committee may have had no relevant experience and all, in theory, could be either non-medical (e.g. therapists, podiatrists etc.) or long into their retirement. There have thus been no reasonable grounds for an EC to claim the ability to perform an adequate scientific review of a protocol: RECs were not formally constituted with such an aim.

2.5 Committee types

Various types of research ethics committees exist. In the UK the NHS RECs are possibly the most well known. Some of these are 'recognised' to review clinical trials (Type 1: healthy volunteers anywhere in the UK; Type 2 - currently in abeyance – patients in a single region of the UK; Type 3: patients anywhere in the UK); the rest are merely 'authorised' to review other NHS research. In addition, committees may be 'flagged' as specialising in certain types of research such as involving children, prisoners, medical devices and so on. Fifteen NHS RECs are also recognised by the US government as IRBs – although these are not required to follow US legislation (personal communication to the researcher, 2011). There are also, amongst others, university RECs (and within a university there may be faculty, departmental and/or school RECs); what McHale (2011) terms the "specialist ethics or ethics and governance committee attached to a particular research project"; there is a National Social Care REC; and until late 2011 when they were absorbed into the NHS REC system, there were 'recognised independent ethics committees'. These dealt *exclusively* with Phase I drug trials in healthy volunteers and were 'stand-alone' committees, so little known outside their circle of contacts that virtually nothing has been published about their workings. The only exceptions to this which I am aware of are Anon (1989); Hibbert (2008); and Ramsay et al. (1977). Neuberger (1992) mistakenly claimed "Phase I studies are...rarely encountered by a research ethics committee" (p.10). In fact though we have known very little about the workings of any ethics committee (Citro, Ilgen and Marrett,

2003; De Vries and Forsberg, 2002; Hedgecoe, 2012a; Schrag, 2011; Speers, 2008; van den Hoonaard, 2011). This research shall eventually concentrate on this latter, now defunct, group – the IECs - but in this chapter (as in the literature review which follows) necessity requires a discussion based largely on IRBs and NHS RECs because they have dominated the literature.

Part of the reason for a lack of publications about independent ethics committees (IECs) has been due to the confidential nature of their meetings. Article 11 of the EC directive states “(1) Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities...(d) the favourable opinion of the Ethics Committee...[and] (3)... shall ensure that the confidentiality of the data is strictly observed” (and see Beyleveld and Sethe, 2008 on this). Such regulations clearly hamper even the observation of the activities of the committees lest sensitive, commercially confidential matters be disclosed inappropriately. (The directive was written under the direction of the pharmaceutical industry (Humphreys, 2007c).) For this reason McHale could discover little about them, and was only able to indicate that “While it appears that in practice private organisations do frequently have ethical review committees...overall commercial competitive pressure frequently result in private sector research activity being of lower visibility” (2004: 722). In France, researchers who included the author of the relevant law, wanted to evaluate the operation of their national REC system. They found though

that “the law which would ban any access to the data, even anonymised, to an outsider, even sworn to secrecy, would ban any study on the opinions rendered by the committees” (Fauriel et al., 2004: 313) and had to adjust their methodology accordingly. Commercial sensitivities are thus one barrier to permitting researchers gaining access to these committees.

I was a lay member of an IEC from 2006 (appointed alternate vice-chair in 2007) until 2012 which was after the data gathering phase of this research. I am also a lay (my original appointment letter stated I was an ‘expert’) vice-chair of an NHS REC, an ‘external’ member of a university’s Science and Engineering REC, and a trustee director of the Association of Research Ethics Committees. I do not believe any other researcher has been in such a privileged position, especially in relation to accessing an IEC.

2.6 Lay involvement

Whilst Pappworth (1967) had called for lay representation on RECs, Nicholson has noted that: “[t]here was little interest at the Department of Health and Social Security, and none at all from any patients’ groups” (Nicholson, 1993: 14). This seems odd as the Patients’ Association had been formed in response to Pappworth’s revelations, but Hedgecoe (2009) has been able to offer an explanation for the lay presence. His paper revealed that lay members essentially first slipped on to the scene as an unintended consequence of making use of hospital boards as ethics committees in those institutions where research that might ultimately be funded by the USPHS was to occur. Hospital boards

at that time were dominated by the medical profession but comprised a few non-clinical members such as hospital administrators. (See also Hazelgrove (2002) on the history of RECs in the UK.)

Once 'lay' members were on the committees they could only offer their *inexpert* (non-clinical, or lay) opinions of course: 'lay' in the context of RECs thus essentially means 'non-clinical'. Such members are specifically defined as not being expert members ("lay member' means a member of an ethics committee, other than an expert member" – para 1, sch. 2, S.I. 2004/1031). Their specific role though has never been defined, and no official guidance for how the roles should be interpreted by the members (whether expert or lay) has been given.

The governance arrangements for NHS RECs (*GAfREC*, Department of Health, 2001, 2011) require that at least half of the lay group be comprised of persons who have never been clinicians or researchers – 'lay plus' members in the NRES jargon. Another way of reading this of course is that up to half the lay members *could* be comprised of retired clinicians. The legislation does not specify particular roles for particular types of members, and that there is no adequate explanation in the literature has been remarked upon by several writers, as shall be discussed below. Before the clinical trials legislation of the early twenty-first century, both the IECs and NHS RECs, followed the RCP's guidelines, at least until the early 1990s when the Department of Health introduced guidance for its committees (Department of Health,

1991). Thus these two types of REC shared some common structural and administrative beginnings.

Even professional 'bioethicists' would be classed as 'lay' members (unless they also had a clinical background). The legislation, and even the NHS governance arrangements (Department of Health, 2001, 2011) for its RECs, has thus privileged clinical experience as deserving of the expert designation, with all other professions being termed 'lay' in comparison.

A common misperception is that 'expert' adheres to any expertise. A barrister for example would be a lay member despite having legal skills. The designations ('expert' and 'lay') thus become confused where RECs are involved. Sometimes US-based writers, especially, use the term 'lay' to mean 'non-professional'. For example: "In restructuring IRBs, an effort must be made to include more non-affiliated and non-scientist members, but regulators should go further. It would be wise to also require lay membership on local boards [as in our survey]... nearly all the 1161 members...were professionals of one sort or another" (De Vries and Forsberg, 2002: 214). This professional dominance is of such note that part of the literature review will specifically examine its pertinent features.

Commonly too, amongst NHS RECs, a statistician can be a regarded as an expert on one committee but as lay on another, yet para 1, sch. 2 of the Clinical Trials Regulations (as amended by para 5(2) The

Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, S.I. 2008/ 941) only permits a statistician to be an expert member if that statistical skill has been acquired in relation to clinical research. Strictly, this would only become an issue if the REC concerned was 'recognised' rather than merely 'authorised' (as explained above). In fact, as my research goes on to note (see section 6.3), IECs rarely, if ever had a statistician as a member and this was because in Phase I research the concern is with safety and tolerability (only one or two serious adverse effects may be enough to halt further progression of the trial) rather than efficacy. The new *GAfREC* though no longer includes statisticians as illustrative of the expert category (Hutchinson, 2011). And as for the bioethicist, they at least will have background knowledge upon which to base ethical arguments. However, as there can be no experts in 'what is the right thing to do', whose opinion carries essentially becomes a matter of power or influence, and thus very likely a matter of little more than how the numbers stack up on either side of the 'debate'. It is thus of significance that the medical members have a practical majority on the committees. Typically about two-thirds of a committee's members are 'experts' most of whom are physicians and the majority of the rest are usually comprised of professions allied to medicine (see Appendices 2a and 2b).

Anyone can ask a question in committee and if members do not have clear roles then it is likely that issues of power and/or ego will surface. There have been a number of scholarly articles critical of ethics

committees and their members' lack of relevant skills, knowledge and understanding of research practices (e.g. Hoffman et al., 2000; Schrag, 2010; Stewart et al., 2008; Williamson, 2008; Wisner et al., 2011). Thus according to such critiques it is, for example, not uncommon for researchers whose clinical trial has been devised in conjunction with a highly experienced team, approved via a rigorous peer-review process, and sanctioned by an independent government body, to find their research proposals subject to further, often vague and inadequately informed, questioning by members of a REC. As Hedgecoe puts it: there is a "longstanding... range of UK researchers' complaints about the iniquities of research ethics review...the inherent injustice in having to submit an application to bodies lacking the required expertise..." (2012b: 678). Such RECs will be comprised of lay and other members who may have little or no experience of the particular type of research involved, or indeed, of any research at all. Thus, according to those who complain (e.g. Dingwall 2006, 2008b, 2010; Schrag, 2010, 2011), not infrequently too the REC will want to impose some further obstacle that bears their imprimatur before the perfectly reasonable and wholly adequate research can commence. The researcher-applicant will, it is implied, be forced to become like the Emperor in Hans Christian Anderson's fairy-tale, who, confronted by his new clothes (in the guise of the new ethics requirements), finds himself in the awkward position of having to acknowledge the excellent quality and fineness of those 'clothes' or admit he lacks the 'wisdom' to see them. It is then only when away from the REC that:

“Researchers [can] complain that RECs are neither sufficiently qualified to make such scientific judgements nor formally authorized to do so” (Dyer and Demeritt, 2009: 58).

This sorry state of affairs has been much grumbled about, mainly *sub verbo*, for years by the research community, but the problem has been seen to have an intangible element to it which resists a remedy. After all it is not easy to say that an ethics committee is wrong, at least not in committee to the faces of the members tasked with the ethics review, and especially before approval has been granted. Weblogs though exist which chronicle some of the alleged absurdities encountered by researchers e.g. www.institutionalreviewblog.com , <http://researchethicsblog.com> (and see also Hamburger, 2004 and Schrag, 2010).

Hedgecoe provides a more emollient perspective on the work and value of RECs (Hedgecoe, 2008). He instances cases of RECs proactively promoting research – by, for example, making suggestions to get around issues that the REC would otherwise see as obstacles to ethical research; in deciding that ethics review could be dispensed with; and by accepting as committee members those with qualitative research expertise. He is also able to distinguish between ‘hostility’ towards, and ‘lack of familiarity’ with, qualitative research, and he noted no instances of the former attitude in his research. Clearly there *is* another side to the debate about how RECs treat researchers, especially those of the qualitative ‘variety’.

If though there is a problem with ethics review, as many researchers allege, one possible reason for the problem, as revealed by Dyer (2004), could be due to the lack of clarity amongst REC members about their understanding of how they should engage with their role, be it expert or lay. She finds that the extent of this lack of role clarity has created at least one controversial unethical situation in that it seriously risks wasting resources and people's time. Other unethical consequences have also been strongly suspected and these shall be discussed below. One might wonder, for example, why there are 'expert' members – and indeed why they occupy the majority on most UK RECs - if it is *not* the role of an ethics committee to review the science of a protocol. Such scrutiny of the 'science' is declared in the official guidance to REC members, and it has been reiterated numerous times by NRES, its predecessor and other bodies, as being primarily the responsibility of the research sponsor and *not* of the REC (e.g. Department of Health, 2001, esp. para. 9; Department of Health, 2011 para. 5.4.2; Edwards, 2010a; Humphreys, 2011). In the case of clinical trials of investigational medicinal products (CTIMPs) and medical devices, the MHRA has the role to review the science/methodology proposed (Humphreys, 2012a). Student research is subject to academic critique by the supervisory team in the university (Humphreys, 2008a) and any statistical arrangements required in the research have to be verified by an independent statistician before submission of the protocol can be made to the REC (Williamson et

al., 2000). The REC will receive confirmation that such scrutiny has occurred. One must not forget either, that:

“Scientists, as scientists, have nothing special to offer towards technical decision-making in the public domain where the specialisms are not their own... [and] scientists’ supposed referred expertise about fields of science distinct from their own is nearly always based on mythologies about science, rather than on science itself” (Collins and Evans, 2002: 250, 260).

The duties incumbent upon REC members arising from their expert or lay status have nowhere been clearly stated. In this it is not difficult to perceive the problem that has attracted so much criticism: ethics committee review is easily distracted into ‘inappropriate’ areas at, too often, the idiosyncratic whims of those who happen to be on a committee. It has been claimed that the looseness of the reviewer roles is particularly open to chaotic outcomes. Thus researchers find inconsistency not only between committees but also between one meeting of the same committee and its next meeting, depending on which members are present and who have tendered their apologies (Dyer and Demerit, 2009). Considered in this way, RECs can appear disposed to so unpredictable an outcome that it is difficult to see how such committees can legitimately be thought to be any advance over professional self-regulation.

At this stage one can rationalise the following potential explanation. IECs have for most of their existence been autonomous bodies and so will

have decided for themselves what to address in, and how to go about, the ethics review. It was not until the clinical trial legislation of the early 2000s that this situation altered. Members, appointed as they were as professionals and lay people, can surely only have believed that as those statuses were prerequisite to their engagement they must have been intended to have some bearing on what their role was – even if it was not made explicit.

Despite, or because of this, Dyer (2004) has discovered that actually many lay members recognise that their role is unclear, and that to be worthwhile and valuable members they need a much greater degree of role clarity within which to function. Dyer's (2004) paper examining some of the rationales for engaging public participation in health service decision making bodies discusses lay-members' understanding of their role in local RECs (LRECs). She found members to be unclear about their role and called for a more defined role for them if they were to challenge the expert members' technical rendering of the research reviewed. In the absence of a clearer role, the lay member can, arguably, appear as little more than a party to a public relations exercise aimed at lending questionable legitimacy to a process, affording it the hallmarks of fair and sound decision making. Such 'legitimacy' inoculates the system against criticisms of the process because it supposedly provides an element of democracy.

In her paper Dyer also examines what it might be, if anything, that non-experts can contribute to technical decision-making. She suggests there are two broad areas where the lay member might conceivably have a distinct role compared that the expert. Lay members, she notes, have lived experience and knowledge of “the particular” – although what such experiences might be relevant needs to be established. (Hedgecoe (2012b) may offer the answer to this as he notes the value of ‘local knowledge’ in assisting in ethics review. There is certainly no reason to suppose that lay members will not have unique experiences which may be brought to bear on occasions in ethics review.)

The second broad area Dyer suggests is what she terms “non-certified expertise” drawing on Collins and Evans (2002). This is expertise acquired without formal training, and she gives the example of an AIDS activist – someone with expertise of living with a particular illness. Whilst both of knowledge of ‘the particular’ and ‘non-certified expertise’ could indeed be valuable in particular situations it is not clear however how these might be recognised, in any regular way, for the purposes of recruitment to RECs.

Dyer is also able to recognise that “public participation can be conceived as primarily concerning values...[such that p]ublic participation provides a check on science being taken inappropriately from the laboratory to the real world beyond” (2004: 341). In this connection Dyer notes that an LREC review is “explicitly an ethical and not a scientific

review” although as she also notes how the LREC debates she observed were embedded in a scientific rationality.

Dyer’s work (2004) thus particularly alerts us, in the context of the research to be reported here, to the fact that at least part of the lay members’ role could perhaps be to act as a foil, or public brake on over-eager science. Whether engagement with such a role is indeed one that IEC members have adopted, and if so, whether and how such a role has been exercised by them in ethics review shall be addressed in the discussion section of this dissertation.

2.7 Politics

Ethics itself is ‘political’ in that it is an attempt to persuade others of the rightness of a particular course of action which ought to be recognised as appropriate (Humphreys, 2008b). What is wrong to one group though can be right to another. Many social issues demonstrate this: abortion, cloning, right-to-die and so on, to select just a few from the realm of medicine.

Such politics are alleged to occur where it is claimed that research is approved essentially based on knowledge of the investigator:

“Sometimes one hears academic and research colleagues say, at approval... committees, that ‘I know his work and I think based on his previous track record we should approve his/her application.’ The lesser experienced committee members, or lay members, would not

have the confidence to challenge those who are the acknowledged experts in the field...” (Cheung, 2007: 146).

Such a virtue ethics approach as this, which arguably attempts to at least partly recognise the moral character of the actors, may have their advocates, but as Cheung implies this sort of practice would for many represents an improper approach not least in that it excludes those who do not know the individual researchers, and so in this there may be a clue about what type of member has most influence in the REC’s decision-making process.

The governance arrangements (Department of Health, 2001 and 2011) note that committee members “are appointed in their own right”, and it has been suggested that the rationale for this:

“may rest on an assumption that the moral concerns which should mobilise the REC’s work do not come from particular professional or other interested groups but rather from society as a whole, of which all mature and responsible citizens are members. If this is the assumption, it seems a good one. ‘Sound judgement’ in matters of morals comes from experience of living in society as a whole, and not from working in any particular profession... [Thus] it is to insist that the moral conclusions which should be drawn in the light of specialist clinical information are nonetheless [to be] drawn on the basis of wider concerns – concerns which we are qualified to promote, if we are qualified at all, simply by living responsible lives” (Evans and Evans, 1996: 108).

Parker has suggested:

“[W]hat the lay members represent are the political or ‘ethical’ standards used by the government to achieve public acceptance of medical research. The lay member’s particular ethical expertise is an awareness of what is acceptable to reasonable people” (2009: 153).

Lay membership is thus seen as a political mechanism – as has expert membership - but both may be about to enter a new phase, for Shergold (2008) saw evidence of a:

“significant [and international] shift towards involving the general public in debating a nation’s position on fundamental questions of research ethics. Although the great majority of ethics panels around the world now include lay members, this [new] movement aims at a broader and in some respects ‘more lay’ decision base” (p.28).

Shergold saw lay members as legitimating agents and their increasing use in such a role has been identified by others too (Glasby and Beresford, 2007; Moreno and Berger, 2010). Tranøy though heralded such a prospect over two decades ago:

“bioethics is no longer the prerogative of physicians – a natural consequence of the fact that the moral problems of contemporary biomedicine are no longer simply or mainly a concern for the medical profession. They are communal and shared concerns in the broadest sense” (1990:18).

Having now provided a background to the research, and noted the uncertainty of both the member roles and the scope of ethics review – in particular whether it should extend into the science/methodology where

that has already been independently reviewed - the next following chapters provide a literature review to identify how the main issues and debates in research ethics review as it has focused on committee member roles has developed. But the literature review itself commences with a review of the literature on the professions for that oeuvre's insights into the concept of experts and indeed expertise because, as this chapter has seen, the issue of professions arises with such frequency in discussion that it is likely to have significance. After the literature review (chapters 3 and 4) the subsequent chapter then explains the methods by which the research was conducted in order to understand the question of how members perceive the expert and lay roles (chapter 5). Other chapters then go on to analyse the evidence which was gathered (chapters 6 through 8) and then to discuss and interpret the findings (chapter 9).

The current research thus provides evidence about how members of independent ethics committees have perceived their roles and how the roles of the expert and lay members are understood by those members.

3. Literature review: the professions

3.1 Introduction

This literature review has two main aims, each of which are addressed in, and form, separate chapters. The first chapter considers the different ways the literature describing professions has understood that concept. Professions have coveted expertise and so an understanding of the latter term will benefit from understanding the former concept. Understandings of professions will subsequently be used to articulate discussion of the research findings.

The second chapter (chapter 4) addresses a more specific set of key works which underpin and describe the current state of knowledge about how 'expert' and 'lay' roles on RECs are understood. Particular gaps and deficiencies in the literature are highlighted, and the identified gaps are subsequently used to help shape questions which the current research will tackle.

With the prior analysis of professions, the literature about RECs can be read to reveal a medical professional dominance of committees. It is for this reason that the literature review commences with a review of the development of the theoretical literature which has attempted to understand the professions. The debate is seen to have been dominated

by sociological enquiry with expertise emerging as a feature very much associated with the professions.

3.2 The Functional Understanding of Professions

Accounts of professions have recognised them to be a type of business model in the service sector which sought to protect members via a variety of barriers to entry (e.g. Collins, 1990; Johnson, 1972; Krause, 1996; Larson, 1977). These barriers were designed to maintain market position against interlopers – non-professionals (also known as ‘amateurs’ - a derogatory term) who offer to do allegedly equivalent services. As well as being about ‘control’, professions have also been concerned with ‘content’, and the notion of professions being closed groups applying abstract knowledge can be found in many discussions of professionalism (Abbott, 1988; Dingwall, 2008a; Freidson, 2001; Larson, 1977; Wilensky, 1964).

The sociological examination of the professions quite early on recognised that any group providing a particular set of services may make a claim to professional status, but the success of that claim will be determined by whether the wider society recognizes the presence of sufficient determining traits as to legitimate the appellation of ‘profession’. A profession’s status can thus be thought of as being located on a continuum, with its precise point being decided by how a particular society at a particular time has perceived the occupational group’s status (Abbott,

1993). Amongst the most frequently identified ideal-typical traits suggested as demonstrative of professions included an extensive period of education; institutional training; work autonomy; a professional code and association; skill based upon theoretical knowledge; licensure; self-regulation; public service and an altruistic ethic; exclusion, monopoly and legal recognition; high status; individual clients; and indeterminacy of knowledge.

As no absolute agreement as to the core set of traits which would define a profession evolved, and given the inchoate nature of the term 'profession' and its attendant plethora of definitions, Freidson (1983) pointed to the necessity for researchers and writers to clarify what *they* meant by the term, whenever they employed it. Which occupational groupings were accepted as being professions were also a function of the particular culture (see Larson, 1977), but arguably the professions have been essentially an Anglo-American concept, the term being used rather differently, if at all, in for example, Germany (Kocka, 1990), France (Geison, 1984) and Asia (Evetts, 2003).

Such taxonomic approaches attempted to account for the claimed distinctive characteristics in terms of social function, and were posited on the premise that the professions performed some special role in society (Turner, 1996). Tawney (1921) for example viewed the professions as able to bring about balance in a society threatened by the primacy of individualism. Professions were seen as giving a rather different message

to society: less self-interested and more community-focused, professions enabled society actually to 'function' rather than disintegrate (Neibuhr, 1932). Altruism was thus an important trait.

The structural-functionalist school is often associated with Parsons (1951). He perceived professions as providing a stabilizing force in capitalist society, by counter-balancing capitalism's crude profit-seeking behaviour. He saw in the professions official commitment to various forms of personal service and community welfare such that they embodied a disinterested commitment to community values. For some commentators this approach failed to adequately account for the supposed moral basis of professionalism (e.g. Wynia et al., 1999) yet Ray and Reed (1994) felt able to detect, in a Weberian analysis of the professional vocation, a notion that a profession positions itself above the mundane or base motivations and sought instead to do what was 'right' rather than pursue personal interests or financial rewards.

3.3 The power perspective

Other scholars, such as Hughes (1958) were critical of such approaches as falling for the public relations hype of the professions themselves, and he emphasized the material and symbolic benefits a person derived from professional status. The independence (an inevitable consequence of indeterminacy) of the professions meant that it had to be the profession itself which would determine who could do what, and thus the archetypal professions were self-regulating with a monopoly to

practise and the right to be judged by a court of their peers in professional conduct cases. Even in civil matters the wider courts gave professions considerable discretion - as illustrated by the *Bolam* test (*Bolam v Friern Barnet Hospital Management Committee* (1957) 1 WLR 583) which effectively excused a professional from a charge of negligence where it could be shown that the actions performed by the accused might also have been performed by other members of the profession. (*Bolitho v City and Hackney Health Authority* [1988] AC 232 only marginally tightened the test.) Many professions were also able to enjoy excusal from jury service – suggesting official recognition that they were in some sense, special citizens, almost part of a parallel legal system.

Johnson (1972) also emphasized the power dimension and this way of seeking to understand professions forms the second main sociological approach to evaluating professions. Here the traits were seen not so much as about ultimately establishing whether an occupation was a 'profession', but about how the amassing and development of those traits allowed occupational members to develop for themselves more power, status and privilege.

Freidson, noting the monopolistic power of the professions, highlighted their ability to suborn allied occupations – permanently maintaining the relative status with the doctor at the top and the nursing and other health professions populating decidedly lower professional or even semi-professional rungs. This was his theory of professional

dominance (1970). In the dominance there was a suggestion of an imbalance in the relationships between the professional, the co-workers and the client. The theory implicated issues of trust, exploitation, subordination and suppression, and the dominant professional was placed under a cloud of suspicion, but protected by a saintly aura or at least a cloak of indeterminacy. Freidson did not quite abandon his theory of professional dominance (Dingwall, 2008a) but as inroads into professional dominance came to the fore he gave greater emphasis to other aspects of professionalism such as it resting on an official belief that the knowledge and skills of a particular specialization required a foundation in abstract concepts and formal learning. Professionals were thus expected to employ these foundations in discretionary ways and so had a claim to a special status of trust (Freidson, 2001). In turn, this level of trust enabled the rules governing professionals' work to be minimized and they were increasingly expected to manage themselves under conditions of even greater trust in their discretion and exercise of good judgment.

The Marxists of the 1970s noted how professional status and dominance contributed to the keeping of a disciplined and subservient working class. For example, not only would the doctor sanction the sick role (no other group could do this) but, as Navarro (1978) explained, it was the medical profession that legitimized the Health and Safety at Work etc Act 1974 and the health and safety professionals it spawned. It did this, by, amongst other things, maintaining the fiction that much

occupational ill-health was in fact the worker's fault for not obeying the system put in place to protect him.

More generally, Fisk's (1980) Marxist account of ethics illustrated how that notion is constructed by dominant classes to recreate and reinforce their values in society. Ethics has no independent objective basis: what is right being determined from the viewpoint of those whose interests are being promoted.

Larson (1977) perceived that the professions 'captured' the State to create regulation in their interest. To the extent that the professions are seen as cooperating with the State in the control of populations one may talk of a demand theory of professionalization (legal and economic privileges being demanded by the professions from the State in return for such cooperation).

Foucault (1977) saw the professions as a major part of the 'disciplines' that were used to control society. As a technology of power, 'discipline' is a wide and general category moving beyond the State, which, by its omnipresence, can regulate social behaviour. For many of the professions, the main instrument of this discipline was the 'gaze', often witnessed in the examination. This might be the entry test(s) to become a professional or, equally, could be seen in the questioning of the plaintiff or defendant, the physical inspection of the patient, or even in the confessional. Evetts (2003) similarly noted how amongst a contemporary

workforce a professional discourse could be used to invoke a 'professional myth' to exercise a controlling influence over an occupational group who were being encouraged to think, act and be 'professional'. Thus if one failed to do exactly what was expected the discipline was the admonishment that one had failed to act professionally. Juritzen et al. (2011), for example, suggested that the stipulations of RECs create docile researchers who go on to self-police their own ethical behaviour in accordance with what the REC has instructed.

Williams also inclined towards a demand theory account:

"To obtain official recognition as professions, occupational groups had to demonstrate that they incorporated the principal characteristics of a profession, namely, high moral standards, including a strong commitment to the well-being of others, mastery of a body of knowledge and skills, and self-governance. They did this by forming membership organisations that adopted codes of ethics, established educational requirements and developed disciplinary procedures to protect the public from unethical or incompetent practitioners. In return, governments granted the associations and their members a great deal of freedom to exercise their occupation and usually gave them a monopoly over its practice" (Williams, 2009: 48).

Dingwall (2008a) has suggested that the positions of Freidson (1986) and Johnson (1995) might amount to a supply theory of professionalization, for in such analyses as theirs, the State was seen as

having a more independent role, granting market privilege to a profession where it coincided with a State purpose.

Abbott (1988) was not wholly convinced by either the demand or the supply theory, and was at best unsure how the actors (State and profession) came to manipulate each other: it was certainly possible to see the State as conferring powers on the professions, or as confirming their claims.

Illich's (1974) concern was about the dependency professions fostered. Rather than allowing people to face up to life's vicissitudes, as they formerly might, hopefully to emerge as stronger, better, individuals, and perhaps even allowing their community to assist them in their struggles (so strengthening social bonds), he noted instead how such a morally communitarian ethos was supplanted. People increasingly avoided their neighbours and simply turned to the professionals and their offer to put the problem right in privacy, and without creating a sense of reciprocal obligation (other perhaps than in terms of due deference). In healthcare, misery at the increasing alienation from community and a loss of sense of self-worth were the iatrogenic consequences. The ill could merely keep taking the tablets.

Feminist scholars have also been highly critical of (male dominated) professions. One such critique, both wide in its scope and

also interesting in its suggestion for remediation, suggests that experience, at least in some circumstances, can be as good as expertise:

“The movement’s critique of physicians is extensive. Women cite serious communication problems. Physicians frequently are patronising, detached, disrespectful, racist, homophobic, and unwilling to trust the reports of their women patients. Subjective experiences of illness and treatment are frequently ignored...

Medical professionals now claim to be experts in subjects that formerly were the territory of non-professionals. Thus, child rearing and aging are matters to discuss with our doctors...

In a sense, the medical world defines women as inherently defective throughout life, in that we ‘require’ a physician for all our normal female functions.

Movement women believe the greatest hope for change comes from the woman consumer’s acquisition of knowledge, for this can provide the basis both for presenting an authoritative critique and for becoming a less dependent and more assertive participant in the health care system....Goals include greater patient control and the demedicalization of childbirth,... and even abortion, if it is performed by qualified non-professionals. Indeed ...a...network of self-help groups has emerged in which some ‘experienced’ participants perform early abortions” (Dresser, 1996: 147,148, 151).

The notion of expertise was thus openly challenged and shown as a product of knowledge with a corollary implication that to keep expert status the professions had to find ways of controlling access to the knowledge.

3.4 Ethical code

Traditionally, the professional 'professed' a belief which invariably incorporated a requirement to uphold an oath (Lester, 2009). He (generally, but later also 'she') had to subscribe to an ethical code which effectively acted as his client's service guarantee when it was difficult to judge the quality of the service being offered, especially when its final result may only be known years ahead (and perhaps even subsequent to the demise of one – if not both, or all - of the parties involved). A code of ethics indicated a 'higher calling' than mere commerce and suggested its members had a personal overriding objective of seeking to do the right thing in all matters. Because of this and their education, a professional would expect, and be expected to, speak out ('profession' deriving from the Latin for 'speaking forth') on matters of public policy for example, and so had to be seen as independent of both the State as well as at least of certain aspects of commerce. The professions therefore emphasized trust, discretion and honest dealings - and thus competence (as cognitive dissonance could not allow a person to profess to uphold such ideals whilst simultaneously believing they were incapable of performing the tasks they would undertake for their clients). Thus members of the medical profession for example – and at least in the ideal representations of such persons - would do all in their ability to secure the life and health of the patient. The lawyer would protect the rights of the client. And both, like the cleric, would maintain client confidentiality to the absolute. Such trust depended on the professional being perceived to be above moral reproach in all matters, socially as well as in business.

The strong tie between the professed oath and religion was usually seen as a product of the Church's monopoly on education. In the West, historically, universities only taught aspects of the Christian faith and expected their student-adherents to acknowledge the creed, necessitating that education and an oath were inseparable. But even as the Reformation graded into the Enlightenment and the universities taught the newer (profane) disciplines, the oath was kept. Thus it was that the professions were linked to higher education, and over time it was the educational requirements, practical training and increasingly even licensing which encroached on the religious and effectively reduced the 'professional oath' to ritual status. Rationalism (certainly never emotionalism) underscored the professional's education and training, and characterized the (male-dominated) professions.

The concept of 'profession' thus came to acquire "two related meanings: (i) an occupation that is characterized by high moral standards, including a strong commitment to the well-being of others, mastery of a body of knowledge and skills, and a high level of autonomy; and (ii) the collectivity of individuals who practice a profession" (Williams, 2009: 48).

3.5 Expertise

Professions have strongly advocated the notion of expertise, and have had a strong vested interest in identifying and controlling what it was that defined 'professional expertise' (Larson, 1990). Expertise and the

disposition to apply that expertise responsibly thus contend to be defining traits of a profession (and in this show how the trait and power theories can overlap). Expertise has required competence, and the correct disposition required a code of professional ethics. After expertise and a code of ethics, a third defining trait was that the professionals identify themselves as belonging to a recognised body. By their professing to practise according to the standards expected from members of the professional body, those who avail themselves of the professional's services could expect that the services be rendered according to a standard of quality. This was reassuring to the service user where she herself could rarely judge the quality involved – especially as the final outcome may not have been known for many years (well after any bill had been paid and perhaps even post mortem). Even the traditional British professional's practice of billing in guineas reinforced the notion that the service quality received was often of an unclear, indeterminate, nature.

3.6 Moral basis

Nonetheless, there would appear to have been an inevitable requirement for a moral basis to underpin a profession. In the case of medicine that moral basis was the need for the provision of a certain standard of health care for the community. Whenever a certain level of aggregate need arose then:

“what is required is collective or joint action on the part of many persons. Accordingly, a cooperative enterprise or institution is

established that has as a collective end the provision of health care to the needy many...

Where such collective responsibilities to assist can most effectively be discharged by establishing institutions and institutional roles whose institutional duties consist of providing such aid, such as doctors and hospitals, then members of the group who have the collective responsibility have a derivative responsibility to establish and support such institutions.

Further, members of a given group may have collective moral responsibilities towards the membership of that very group, that is, the group of which they are members" (Alexandra and Miller, 2009: 77, 79).

Each profession thus needed to establish its legitimate right to determine and provide the correct standard of service and to do this it emphasized its members' skills, training, education, qualifications, licensure, peer-acceptance and the like. Professionals, in thus laying claim to be the experts, accordingly expected monopoly rights to practise the profession.

However, inroads into such claimed expertise, and the exalted positions the professions came to hold, developed with expanded education which in varying degrees undermined the informational asymmetry which had traditionally so characterised professional service and which had given the professions much of their esoteric power base.

From universities being for the few and Christian men only, they became increasingly not only for both sexes but simply for the many. The consumer movement and patients' associations also developed from the 1960s and promoted the notion that the patient should have a say in the treatment they were being offered. The internet too has meant that knowledge was far more accessible than it ever has been (e.g. Nettleton, 2004).

With all this, the 'wonder' at medicine diminished, as the population began to understand more and more about how their bodies worked. Members of the public began to arrive at the doctors' with their own wants, rather than merely prepared to accept what the medical profession decided they needed. Some wanted the 'pill' to control their fertility and so liberate them from nature, others wanted antibiotics despite having a virus, and collectively they wanted all manner of medicines to minimise their health deficits. And not just on the traditional medical model. Health was increasingly about what the consumer wanted not just what the doctor believed was appropriate for the patient – or what was socially affordable. With more people benefiting from enhanced educational opportunities so more often would the doctor find the patient to be the smarter – either about the specifics of the illness (e.g. Rogers, 2010a), or in general. Patients armed with newspaper articles or internet findings tended to put their doctor in the 'backseat' (Ahluwalia et al., 2010). Even worse for the medical profession was the fact that the customer was no longer the client – the NHS (and insurance companies) had ensured the

separation of the payer from the patient/client. Increasingly there was a role for big business too as the pharmaceutical companies and the other research organizations such as the Medical Research Council employed medical professionals as salaried researchers. The medical profession increasingly faced conflicts of interest – were they to promote patient health or corporate profits?

3.7 The historical incision

Sociological approaches to the professions, which revealed important perspectives on the professional agenda and how it contended and fared in society, have been rivalled by the approach of historians of medicine. The two disciplines' understanding of the phenomenon can eventually be seen to share many similar insights, but it was the historical record that illustrated the progress of the professions, and clearly showed the progress of the medical profession as being about creating a distinction in skill-sets which separate and ranked the various professions. For this reason it is appropriate to temporarily switch tracks as it were and follow the thinking of some medical historians about the development of the medical profession. Here it is notable that the medical profession has concerned itself with creating and maintaining a social position for itself such that other (non-medical) approaches were, at best, relegated to the side-lines and not permitted to interfere with the medical approach.

History shows us that in 1803 Thomas Percival coined the expression 'professional ethics' to reflect his new conception of

professionals as members of a self-regulating learned occupation, dedicated to the service of society and the care of others.

“Percival’s new concept of a profession that was inherently ethical, compounded three somewhat different notions into a new conception, *laying the groundwork for centuries of uncertainty about what it is to be a professional*. The three conceptions that Percival compounded were [1] a conception of the professional as someone playing a role governed by its own internal morality of service to others, [2] the idea of the professional as bound by a social contract in which social privileges are conferred on a learned occupation in exchange for social obligation to serve society, and [3] the notion of the professional as a member of a fraternal society, bound by its own self-imposed rules” (emphasis added, Baker and McCullough, 2009: 291).

His first two concepts may strike one as being probable suspects in having driven the functionalist approach, and the fact that there were two supportive concepts adds credence to why this approach might have been thought to have sufficient strength of support to contend as the early ‘front runner’; the third concept justifies an approach based on the notion of ‘power’.

Thus, and against such authors as Pellegrino (1979) and Pellegrino and Thomasa (1981), the origins of the modern concept of a profession:

“have nothing to do with the Hippocratic Oath, or with any other aspect of ancient Greek medicine... [Indeed] originally the term, profession, simply meant one’s occupation – the occupation one declared to the [Roman] tax collector under oath. The term lacked

any moral connotations and it was not associated with collective self-regulation or with service to others” (Baker and McCullough, 2009: 290).

Baker and McCullough reinforce this by noting that in 1541 usage of the noun phrase “the medicynall profession” indicated that there were several medical occupations – at least including the apothecaries, physicians and surgeons.

Johnson’s *Dictionary* of 1755 demonstrated that the term ‘profession’ was then synonymous with the concept ‘liberal profession’ and had clear normative implications deriving from the term ‘liberal’ and designating literacy and formal, advanced, education. The term ‘profession’ still meant ‘occupation’ (as it always has), but the liberal occupations were those of the educated classes (Baker and McCullough, 2009).

Liberal professions were of course not options available to the working classes. Whilst the upper classes had no need to work, and could rely on their inherited estates and wealth, the working class had no choice but to work and essentially engage in labour intensive work. Middle class gentlemen however, lacking sufficient property, needed income but could not demean themselves by labouring. So it was that Percival adopted the Ciceronian belief that “occupations suitable for gentlemen...involve special *rules* that carry with them role-specific duties or offices of *service to others*. This commitment to service allows a true

gentleman to accept the demeaning fact that compensation is associated with these occupations; they are thus social 'roles' that true gentlemen can properly play without lowering their gentlemanly status" (Baker and McCullough, 2009: 293). Percival thus *reversed* the notion that a gentleman could take up certain learned occupations without demeaning his status by transferring the concept of a profession into something that could *make a gentleman of an office holder*. Percival's goal was to turn the mere *occupation* of medical doctor into a *profession*, which would have a favourable social status against which the consumer or patient could contrast the rival healthcare providers of the time. Howard-Jones (1982) in fact claims Percival perpetrated a 'marketing hoax' to persuade the public to place their trust in the medical doctors rather than with rival providers of treatments.

To this end, Baker and McCullough have also explained how Percival took the Lockean notion of a 'social compact' to legitimate what otherwise should have been perceived as an oxymoronic idea - a *private* practice being a *public* trust. Percival's calls for self-regulation were also purposively designed as a seemingly remedy to the existing practice of publically castigating rivals, which only served to damage the perception of doctors as a whole.

In Baker and McCullough's account it was thus Percival who invented the concepts of the modern profession, professional ethics *and* medical ethics. Percival's concept of a profession was of a self-

regulating, educated occupation and public trust, bound by its own morality and dedicated to serving others. Of course, the joints of these crafted features of the profession came to be loosened over time, and then largely concealed by events, persons, myth and the unintended consequences of change. If one were to uncover the layers of historical development however, the medical profession as originally envisaged by Percival could still be found. Parsons was thus justified in seeing professionals as socially-oriented, and not merely out for their own ends. Such an apparently 'rose-tinted' view of the medical profession may actually not have been so far from the truth - at the time it was still not particularly well-paid, and those who went into the profession often did so with altruistic intentions. As Lundberg, an American physician writes, "Medicine was a caring profession in those days [and into the 1950s]...That system stands in stark contrast to the one that exists today... Patients knew their doctors then. Physicians talked to them, and they tried to follow the doctor's advice..." (Lundberg, 2002: 1, 2, 3). The change, Lundberg tells us, came with the commercialisation of medicine.

The commercialism and bureaucratisation of healthcare have also been seen by others to have eroded medical autonomy with the dictates of corporate or public budgets, or the algorithms of the health maintenance organizations, revealed as the true arbiters of what care a patient would receive.

"The GP and consultant contracts are de-professionalising, and have had the effect of simultaneously demoralising and enriching

doctors. We've lost the volitional work of the doctors and far too many of us are now just working to rule" (Rogers, 2010b).

No longer was the medical profession seen as solely concerned with the centrality of the patient (although this still had its occasional heuristic function when it came to 'clinical decision making' in the face of NHS attempts to manage the service). The fiduciary relationship had taken a bashing on one side, and on the other, patient lifestyle choices supported by 'patient rights' meant the traditional model of professionalism was being pushed to a consumer-vendor model.

3.8 Scandals

If the separation of the payer ('customer') from the patient ('consumer') was a massive inroad in to the power base of the profession as it pitted the doctors' supplier power against the NHS's buyer power, its timing too was unfortunate for the profession, as other circumstances (especially socialism), culminating at around the same time, served to weaken the power of the professions. In medicine for example, the birth of the NHS came about the same time as the judgements at Nuremberg which cast aspersions on the integrity and trustworthiness of the medical profession just as Dr Crippen had seemed to do a few years before the war. The initial response was to shrug off the events as more to do with Nazism than medicine, but the World Medical Association recognised the problem and began fighting back behind the scenes, eventually countering in 1961 with its Declaration of Helsinki to clarify that 'proper' doctors did not do such things as the Nazi doctors had.

The thalidomide tragedy of the early 1960s was a further set-back, as were the revelations of Beecher (1959, 1966) and Pappworth (1962, 1967). Increasingly, events such as these, and the Tuskegee story (Jones, 1993) could not be quite offset by the countervailing success of medicines that actually worked, or new technologies such as kidney transplants and heart surgery, the conquering of smallpox and the general success of other vaccinations. For far too many it was becoming clear that the medical profession needed more supervision, and could not be entirely trusted to manage to keep its own house in order.

Scandals such as Alder Hey, the Bristol Children's Hospital, and those involving such disparate medics as Drs Ledward, Meadow, Wakefield, and Shipman were, cumulatively, difficult to ignore (and these just in the UK). In South Africa, numerous doctors privileged apartheid at the expense of health care (Silvoe, 1990), and in the Soviet Union too many psychiatrists conspired with the State to misuse psychiatric diagnoses (Pelligrino, 1995). The mystery of medical professionalism, traditionally defined within a foggy construction involving expertise, autonomy and ethics, was revealed in moments such as these as suggesting that whatever the mystery was, it was not something that the medical profession alone could be relied upon to manage appropriately.

3.9 Indeterminacy

If it has been the notion that the professional was an autonomous expert whose adherence to a code of ethics both acted as a guarantee and justified the social licence the public gave them, then the heart of the problem of the profession was its indeterminacy: even with a wider level of general knowledge the patient still could not always really know what the service offer should comprise, particularly when confronted with the complex and 'messy' reality of their own situation. Even if the patient knew what treatment was required, s/he could neither perform the procedure required, nor even keep a watchful eye on proceedings given the depth of anaesthesia that usually accompanied surgery. The consumer was thus virtually blinded at times, if not to the 'what', then often at least to the 'how'. Thus the professions *had* to be given a measure of trust, and indeterminacy has been the traditional problem (or strength) of the professions. Jamous and Peloille (1970) however pointed out that where knowledge was made exoteric or when it could be systematized then there becomes a possibility for both external intervention and social control. Society's greater knowledge base (evidenced in the widened participation in higher education and the ease of access to information via the internet) certainly challenged indeterminacy. For the professions, everything hinged on society's trust. The various scandals and social and technical developments – such as the introduction of surgical performance tables - have altered the

traditional relationship that patients have had with their doctors and have largely served to undermine this trust (Dingwall, 2008a; Lundberg, 2002; see also Humphreys, 2007d).

3.10 Medical ethics

Armstrong (2007) saw bioethics, the 'invention' of a seamless history of medical ethics stretching back to Hippocrates, and evidenced-based medicine, as three strategies of the medical establishment to recapture the traditional notion of medicine as a profession, despite encroachments made upon it. Such encroachments could be regulatory (Flynn, 2004; Nettleton et al., 2008), but would also include budgets and clinical guidelines; 'standards' of care (when surely incommensurate); the promotion of patient consumerism and satisfaction surveys; revalidation; deliberate destabilizing strategies such as, in the UK, the imposition of 'walk-in' centres and 'commissioning'; and the self-harming, disuniting practices of the profession itself with the incessant specialisation of medicine (paediatric histopathology, clinical cytogenetics, paediatric neuro-oncology,...) encouraged by both ever easier transport enabling greater choice, and increasingly near-instant global informational flows (which allowed the patient to contradict the doctor's 'expertise').

However, it was not in the interests of service users to be unable to trust the professional, as judging the service quality remained an elusive pursuit. A high standard of conduct was therefore to be required from professionals as a sort of alternative metric where it was not desirable that the client be expected to assess, or even be asked about the standard of

service they had received. Professionals were thus expected to live up to the public's (vague but firmly-held) expectations that the professional was in fact trustworthy. This professional obligation to fulfil the expectations the professions themselves fuelled was mythically premised on a duty to keep a promise (the Latin 'profiteor', to profess, emphasized the oath-like formal commitment of the professional) to live in accord with their professional ethical code.

However, as Hooker pointed out:

“Professional codes of ethics are... not really codes of ethics, but codes of expectations. They represent an attempt to define for the public what the profession promises to do, so that professionals know which promises to keep.

Professionalism and the promises on which it is based are possible only if professional conduct is predictable. If professionals did what they individually think is ethical, rather than what they have agreed upon collectively, their conduct would be unpredictable.

[Thus,]...professional ethics is not ethics. It is the identification of expectations that professions have created” (Hooker, 2006: 3, 6, 8).

In this it could be argued that such an understanding of ethics as was promoted by the professional bodies was almost to deny that ethics was about the autonomous self seeking to do the right in all things. Following guidance could *discourage* ethical thoughtfulness, and as Steare (2006) suggested, such an approach to ethics could be regarded

as, at best, at the immature end of the moral spectrum (see also Humphreys, 2010a).

Increasingly, the medical profession taught 'professionalism' to its aspirants. 'Project Professionalism' (ABIM, 1994) sought to identify professional traits and, as far as these may be objectively assessed, they were indeed taught and assessed in medical schools. It was as though professionalism had been given a life of its own, the artificial creation of one man became 'naturalised', 'real' and objective. Rather than leaving sociologists to attempt to discern the characteristics of the professions, the medical profession thus attempted to take back the lead.

Whilst the professions sought to bolster the traditional tools that guarded them – their professional ethics, licensure and an emphasis on specialist knowledge - the damage to the professions had been done. They are no longer excused jury service, and the concept of a professional as anything special has nearly collapsed such that a contemporary usage of the term would encompass virtually anyone engaged in paid employment (Evetts, 2003). The world has changed and any strategies to shore up the dignity of the professions cannot realistically now exclude a more knowledgeable public. Evetts (2003) for example has argued that professionalism in general has become less about an expert group maintaining its occupational position, and more of a mythical-ideal aspiration promoted by owner-managers through which they hoped to set the standards they could expect from their staff,

especially when supervision was difficult. In this, rather ironically, whereas a profession once claimed to be the embodiment of trust, which the customer could rely upon, increasingly the buyer was expected to impose aspects of professionalism on the service worker in order to extract some service quality. In fact, society generally has lost much of its former trust in the 'professions' and increasingly kept them under gaze itself. One way it has done this has been to impose lay members on the professions' regulatory bodies (Stacey, 1992), and even stipulating what the professional was to do in particular circumstances: in medicine for example, National Institute for Health and Clinical Excellence (NICE) technology guidance is mandatory and departure from NICE clinical guidance can be subject to subsequent requirements to justify one's actions.

Thus the literature on professions indicates that they have been a mechanism for control and for the protection of an occupational group, and that they have tendencies to mythologize that group's social role, often via a professional code of ethics. Their power-base has been in their indeterminacy but this has been increasingly capable of being undermined with wider access to information. As this study progresses, it will be of interest to see not only if and how the heralded changes in the fortunes of the professions as they confront, in particular, greater general education and access to knowledge, are reflected in the experiences of members of research ethics committees, but also to try to discern to what extent the concepts of professions has shaped REC practices.

The literature review now turns to review how the literature has discussed the 'expert' and 'lay' roles on ethics committees. Much of the account is seen to be either dated or reflective of practice in the United States, and not infrequently both 'flaws' can be seen to be simultaneously evident. Nevertheless, where RECs are concerned, little has perceptibly changed over the decades, and so this literature still has value.

4. Literature review: expert and lay roles on committees

The concern of this chapter is with how the academic literature has attempted to account for the roles of the expert and lay members of research ethics committees. Member roles have been problematic, and remain unclear. Indeed, it is the lack of clarity in understanding the role of the expert and lay members on RECs as has been revealed (e.g. by Dyer 2004), and what the implications of this are, which are to be pursued in the qualitative research that shall form the substantive element of the current research.

Whilst it was the broad aspects of the literature on professions that were of interest for the review in the previous chapter, in this chapter the requirement was for a greater depth as well as breadth. For this the research necessitated a more extensive literature search. As bioethics as a discipline was established in the USA (see e.g. Fox and Swazey, 1984; Evans, 2012) many of the journals that have specialised in research ethics over the years have been US-based, and the US too is where the specialist on-line search-engine of the Kennedy Institute of Ethics' National Reference Centre for Bioethics Literature is located. This reference centre has intentionally collated relevant material since the early days of the discipline and its international scope offered a comprehensive coverage of the field of enquiry. An advantage of its search-engine was that ETHXWEB, rather than requiring the insertion of the various possible

combinations of terms to capture the different ways of describing RECs - IRBs, REBs, "ethics committees, research", "research ethics committees" and so forth – offered a ready code ("18.2") to designate all such permutations. Thus searching for ("expert" or "unaffiliated" or "non-scientific" or "lay" or "community" or "member" or "role" or "roles") and "18.2" identified papers of interest which in turn indicated other material of interest and so instigated further iterations to identify additional sources. Material that had not been digitised, such as the *Bulletin of Medical Ethics*, did not escape consultation either. The complete set of this bulletin was available to me in the library of the Royal Society of Medicine, London. Electronic theses were also searched through the British Library (<http://ethos.bl.uk/>).

It was possible to discern in the literature three broad chronological approaches to concerns about REC member roles. The first, which I date from the mid 1970s was primarily based in the USA and largely led by philosophers interested in applied ethics and the situation of the new ethics committees there. Representatives of such literature include Veatch (1975), Robertson (1979) and Williams (1984). A second strand from the mid-1980s picks up a broader interest group as other academics and practitioners gained an interest and the attention began to move outside the US. Here empirical work commenced and Fox and Swazey (1984), Nicholson (1986a, 1986b, 1986c, 1989, 1990, 1993, 1997) and Neuberger (1992) illustrate the attention given by sociology, medicine and philosophy respectively, with the latter two attending to committee

structural matters in the UK. From the 2000s a more sociologically interested set of academics became more critically involved including Dingwall (2006, 2008a, 2008b, 2010); Dyer (2004); Edwards (2010a); Hedgecoe (2008, 2009) and Hunter (2006, 2007a, 2007b, 2011) to name just some from the UK. In the US and Canada, social scientists such as Schrag (2010), Evans (2000, 2010, 2012), van den Hoonaard (2011) and Stark (2012) also became interested as the ethics committee scene entered a mature stage and it became possible to discern trends and practices, and perhaps the unintended corollaries of those practices. Their especial concern has been with the alleged imposition of the biomedical model of ethics review on to social science research.

Throughout this time – some four decades – proportionately few researchers have been able to research the ethics committees from the inside, and much of the research that has been done has involved surveys, with interviews being something of a rarity. De Vries (2004) has claimed that REC members have been notoriously reluctant to become subjects of research themselves, and van den Hoonaard has noted “there are virtually no published materials concerning the perspectives of committees” (2011: 39) whose activities, he suggested, are hidden by “a veil of secrecy” (2011: 10).

4.1 Committee composition

Veatch (1975) provided one of the earliest accounts of the expert/lay issue and argued that the REC was an intermediate case between two models of the review committee. The ‘interdisciplinary

professional review model' made up of diverse professionals such as doctors, lawyers, scientists, and clergy, brought professional expertise to the review process, whilst the 'jury model' reflected the common sense of the reasonable person. In the latter model, he believed that expertise could disqualify one from serving. However, he felt that both professional and jury skills were required on RECs as dominance by the professionals made it more difficult to be responsive to the informational needs of the reasonable person or to be adept at anticipating community acceptance.

Robertson (1979) argued in favour of correcting the 'structural bias' of professional domination by the inclusion of a 'subject surrogate' – an expert advocate for the subjects' interests. At about the same time too, Department of Health and Human Sciences' regulations in the US began to encourage IRBs to consider including members from relevant communities (such as those affected by AIDS if the study was relevant to that community) or from persons who know about or are experienced with particular subject groups (e.g. paediatric nurses if children are to be researched). The situation is similar in the UK in that, for example, NHS RECs may be 'flagged' as specializing in particular areas of research. However evidence suggested that the spirit of such recommendations has not always been embraced by the institutions. Just as in the UK 'flagged RECs' were often optional for researchers (NRES SOP v. 5, para 1.13, September 2011), elsewhere it remained the case that:

"It's not unusual for IRBs in large institutions to have three to four times the minimum required membership, [whilst keeping] with one

non-scientist, non-affiliated member flying solo. In the alphabet-soup world of the highly credentialed, the input of these singleton community members is easily overlooked – or, worse, discounted. Does this power imbalance make for credible research review? Not really” (Bauer, 2001: 7).

Such a comment raised the suspicion that lay members were unwelcome in IRBs, being merely tolerated because of the legislation that insisted on them. There is less overt evidence for lay members being ‘unwelcome’ in UK RECs – but in the next section the contributions of Legood (2005), Richardson (2007), and Stacey (1994) at least hint that some lay members may perceive themselves as positioned as inferior to the experts.

Williams (1984) believed that in the case of IRBs, because they were so dominated by professionals, they were more likely than a layperson to place a high value on the benefit of developing new knowledge and so downplay risk. In particular they (i) shared an unwillingness to be thought paternalistic, and preferred instead to recognise the autonomy of the subject; (ii) found it easier to adjust the consent form in order to assuage their consciences about paternalism/autonomy rather than re-write the protocol; (iii) tended to be pro-research; and (iv) as a group could be persuaded to accept more risk than would individuals.

In the UK, a 1986 report by the Royal College of Physicians on healthy volunteer research recommended that there be a minimum of three types of member:

“Membership should comprise at least:-

- (a) *Medical*: both those occupied chiefly with clinical care as well as experienced clinical investigators; a general practitioner should be included whether or not the Committee reviews projects in general practice.
- (b) *Nursing*: a nurse who is in active practice with patients.
- (c) *Lay*: i.e. one, or perhaps better, two persons not trained in or practising any medical or paramedical discipline.

It is important that the community should have confidence in Ethics Committees and provided that the membership is seen to be broad and not exclusively medical and the lay members to be persons of responsibility and standing who will not be overawed by medical members, such confidence should be forthcoming.

Experience has shown that lay members, though they may not grasp some of the niceties of some research projects (*nor do some of the medical members*), are invaluable, particularly on issues of consent and information to subjects. A lay member with legal training can be of great value and his/her role should be a general one, not simply to answer questions of law.

Both sexes should be represented” (emphasis added, Hoffenberg et al., 1986: 16).

Interestingly, as the report suggested, 'nurses' were then seen as a distinct membership category although no reasonable rationale for this proposal appeared. The definition of lay is also of note as, coupled with the medical and nursing definition it is possible to see here the origins of an option for the lay role being available to retired medical members and, as has happened, to non-practising nurses. Retired medical members subsequently managed to maintain their 'expert' status.

4.2 The lay member

Outside of the area of REC investigation, more general research on expert and lay roles in other committees has noted dissatisfaction with the term 'lay' as it has tended to minimise the contribution such a member could make and discounted supposedly non-relevant, but equally 'professional', skills.

A strand in sociology, especially that of health and illness, has explored lay understandings or knowledge of health. Stacey (1994), a prominent authority on the topic, preferred the term 'people knowledge'. She argued that as all people are of equal worth, all views should be heard. She also noted that people are not just consumers of health but that they also produce it: they care for themselves and others for example. As Zola (1973) pointed out, they do not always use medical professionals when seeking care. 'People knowledge' derives from experience, and, being based on personal experience and anecdote, contrasted with evidenced based medicine. Stacey's dislike of the term 'lay' was because

it demarcated those not in the relevant profession, who lacked qualifications, who were less competent, and for whom the term suggested a lesser moral worth. Instead she emphasized that an attribute of professionalism was 'service' and so indicated that 'experts' should respect the views of the 'lay' community at least in order to accommodate that community's level of understanding and so assist them in achieving their health maximising goals.

Stacey also observed that a health professional "may be an expert in their area, [but] faced with expertise of another kind they are just one of the people" (1994: 96). This was a point which Collins and Evans (2002) discussed at some length and arose too in other commentaries on medical doctors as reviewers of research about which they may be very ignorant, yet where they were still accorded 'expert' status, as will be seen.

Whilst Stacey has been in the vanguard of those sociologists who would seek to de-privilege the ontology of expertise and the epistemology associated with it, others have chosen to emphasize other aspects of the concept. Jewson (1976) for example, had pointed out that lay subjectivity was compromised by the objectivity of the expert, and Prior (2003) similarly came to doubt the possibility of 'lay expertise', pointing to its oxymoronic status with expertise being concerned with generalisable, scientific, knowledge rather than experience. Pasveer (1989) had noted that the objectivity/subjectivity divide could only be further widened by the

introduction of new medical technologies. Such developments and 'break-throughs' though mean that the medical profession needed to become ever more specialised to manage such emergent technologies, and so any of its individual member's skills and level of expertise had to be appraised in this light. It was also however increasingly possible for non-medical people to gain knowledge in very narrow fields of personal interest because of widened education and universal access to information via the internet. They could become more knowledgeable about certain matters than many medical professionals, whose expertise would be in other, usually more general, areas.

Popay and Williams (1996) identified three important contributions that lay knowledge might add to professional medical practice. They suggested lay knowledge introduced ideas about social determinants of health, informed the appropriate level of communication, and, by offering subjective experiences of health (which can be rather different to the experiences of those with a scientific understanding of the aetiology and characteristics of a condition), could help tailor appropriate individualised treatment advice.

Three main rationales have also been offered for incorporating lay participation on to predominantly medical committees. The Merrison Committee's (1975) proposal to include a few lay members on the General Medical Council was based on the assumption that "even a few laymen will change the perspective of proceedings, for example by

preventing discussions taking place which reflect solely the common backgrounds which medical graduates will have". Hall (1991) claimed that lay members were introduced onto RECs in order to alleviate a suspicion that self-regulation merely protected professional interests. Allsop and Mulcahy (1996) noted the lay presence on RECs was because: "decisions might have to be made about the balance of advantage between gains in knowledge...and some risk to participants. It was argued that such decisions should not be left to doctors but be decided by a more broadly based group" (p.150).

In a different, but allied, view of lay representation, Hogg and Williamson (2001) identified lay people on health service committees (and thus not necessarily on RECs) as falling into three broad categories, viz. supporters of dominant (professional) interests, supporters of challenging (managerial) interests and supporters of repressed (patient) interests.

There exists a general sense that the term 'lay' indicates unprofessional, and it has been seen by some REC members as demeaning, insulting or at least marginalising: "many lay members [have stressed their claim that they] were highly professional people in their respective fields" (Richardson, 2007: 2). The term essentially emphasized the limited ability of someone in a particular context. In the ethics committee at the University of Limerick's business school (ULREC):

"There is no lay member on ULREC, the rationale being that this committee rarely decides on individual applications. It focuses

instead on university policy, thereby rendering lay members unqualified with respect to the requisite institutional knowledge needed for committee service” (Mullins and Doyle, 2010: 135).

ULREC appeared to regard ethics as merely about adhering to university policies rather than thinking through the moral implications of those policies. In making no attempt to be independent however, it might not have met everyone’s definition of what a REC should be about. Alternatively ULREC may be viewed as unusually honest – by shunning the cynical use of lay members as an ‘independent’ source in order to achieve a politically-driven goal, it did not set out to deceive in pretending that it particularly welcomed outside interference.

Lay members were likely to believe they add value. INVOLVE, a public involvement organisation associated with the NHS, surveyed lay members of NHS RECs in the autumn of 2008 about what such members felt they brought to the ethics committee. The research findings (Simons et al., 2009) were essentially of a demographic nature but of interest was that 52% described their professional (occupational) background as forming the specific perspective they brought to the REC, 39% identified bringing a patient, carer or service user perspective and 20% described their perspective as being a potential research participant. The survey consisted of check-box solicited responses and less directed responses could have been more illuminating.

As for the expert role, the literature has generally tended to regard this as straightforward: the expert was there to give expert advice on matters within that member's purview (EULABOR, 2005, and see below). The role of the lay member though was less clear and several studies have looked at this.

Nicholson (1986c) reported that "[a]lthough the principle of lay membership of research ethics committees may have been accepted [and he dates this to 1967 in both the US and UK], the purpose of such membership is by no means certain" (p. 165) and by "no means universally accepted" (p. 157). Dyer too has noted,

"we must be clear what we expect lay people to contribute and how we expect them to do so. In answering these questions we must grapple with contested epistemic and socio-political claims about expertise... the actual role of lay members is vague and inchoate... When we fail to address what we want the public to contribute and how, we risk wasting peoples' time and endangering further the relationships of trust between experts and non-experts" (Dyer, 2004: 340, 347).

The Clinical Trial Regulations define the 'lay member' as any member of an ethics committee who was not an expert member (Sch. 2 (1)). Expertise was defined in terms of science and research such that any non-clinical practitioner – even a member of the clergy - was regarded as 'lay.' The *Governance Arrangements for Research Ethics Committees* (GAfREC; Department of Health, 2001) took its lead from such

regulations. As such governance arrangements apparently sought “to create a very different lay constituency than that of the hospital chaplains and solicitors of the past” (Dyer, 2004: 342), it would be interesting to discover to what extent lay membership still consists of clerical members in our increasingly atheistic society, and why such religious officers feel they make suitable members of such committees. Whilst NHS REC annual reports do show several ordained members, as so many committees give the occupation of the lay members as “lay member” (sic) it was not possible to use these sources with any confidence for such a project. One or more clerics were included in my research sample, but I could not pursue this line of enquiry with them for fear of jeopardising their anonymity.

‘Lay’ members then were:

“defined by something they are not rather than by something they are. They are named for the skills or knowledge they do not have rather than the skills and knowledge they do have... The ‘lay’ person is, in this sense unknowledgeable, indeed, we might say, ignorant” (Legood, 2005: 135).

Porter (1986) has confirmed that this was also the position regarding the lay (‘non-scientist’) member in the United States of America.

Both Cownie (2006) and Tucker (2006) have noted how lay members, probably because their roles can be perceived as so nebulous that they can find little other to do, tended to engage in tinkering with

grammatical matters. Angell and Dixon-Woods (2008) have also explored this and found in studying the correspondence sent by RECs when explaining their decisions to would-be researchers that grammatical matters were not always improved by the REC. By adopting a role as amateur grammarians, one may suspect that lay members have missed their true vocation on the committee, whatever that may be. They have seemed in taking this role to have betrayed their sense of having a merely tokenistic place on the committees.

This situation was also an international concern as a report for the European and Latin-American systems of ethics regulation of biomedical research made clear:

“Although the role of professionals is relatively clear and is obvious from their professional specialisation, what the role of the Community Representative constitutes is not as clear. UNESCO, for example, speaks of the ‘lay’ representative or representative of the local community or local values. The WHO Operational Guides for Research Ethics Committees refer to ‘people who represent the interests or concerns of the community’, who might be professionals or non-professionals. In some cases, they are put on the same footing as ‘representatives of patients with a particular illness’. In others, they are defined by their membership. For example, this occurs in Chile: Technical regulation 57 defines the Community Representative as a representative of an ‘organisation with an extra-institutional basis’, leaving the definition of the individual characteristics of this representative broadly free. The same non-definition would seem to be perceived by the community representatives themselves. For example, in a survey recently

conducted on community representatives of research ethics committees in the USA meeting at a conference concerning these issues, it was found that more than half stated that they did not know the limits of their role” (EULABOR, 2005: 6).

The correspondence between international ethics committee arrangements was accounted for by Schrag (2010) who explained that other countries followed the US example, in part because of its experience, in part because their model was approved by the main funding body at the time (the US Department of Health), and now because of the International Conference on Harmonisation – Good Clinical Practice (see below).

Ghio has suggested that:

“[lay] members... represent people who have no academic background in the medical profession. Their goal is to represent members of the community... If something is a concern to them, it may be a concern to a future research subject as well” (Ghio, 1980: 7).

Against this though was the fact that, in the UK, letters of appointment to both NHS and IEC members have been clear that members were not appointed as representatives of anyone. NRES’s standard operating procedures for research ethics committees also state:

“2.66 REC members do not sit on the Committee in any representative capacity and need to be able to discuss freely the applications submitted to them. For this reason REC meetings should be held in private, and members should be encouraged to

raise any matters of concern” (v.4, April 2009 [para. 2.65, v.5 September 2011]).

In a questionnaire survey of non-scientist/non-affiliated IRB members, Porter (1986) reported that the ideal lay-member was described as:

“an assertive, self-confident, and intelligent individual with an interest in research and research protections. He or she should have mature judgment, be reasonably well-educated (generally a college graduate) with a general knowledge of research programs involving human subjects and the purpose and objectives of the IRB. He or she should be a sensitive person with a strong sense of ethical values and empathy for patients who may become subjects of research programs. The unaffiliated/non-scientist member has a major role in promoting full disclosure to and understanding by subjects. Such a member should have time to devote to studying protocols and attending board meetings. Perhaps most important in the opinion of those who responded is the ability to work with medical professionals and others on the IRB, and to present questions, concerns, and objections to proposed procedures articulately and in a spirit of teamwork and mutual respect” (Porter, 1986: 5-6).

However, it was likely that such qualities could apply equally to all members of the committee, just as any or all members could comment on the grammar and style of participant information leaflets.

In terms of their contribution to debate, Porter’s survey also indicated that lay members “although they were able to make a

contribution and [felt] that their views were heard and respected, [recognised] the potential for a less-than-equal role for the unaffiliated/non-scientist member certainly was present in the IRB” (ibid: 6).

This finding reportedly also reflected the findings of a study by the US National Commission in 1978 which reported lay members to be “less active than other members, but ... they did bring concerns different from those of the scientists on the review committees, and they believed their reviews were heard” (cited by Porter, 1986: 1).

In a recent contribution to the literature, Stark’s (2012) ethnographic account of IRBs identified three ‘warrants’ by which decisions were made in such committees. The professional warrant emphasized a review member’s expertise in the area under review; the objective warrant used facts or figures to make a point; and the third warrant supported its contention by reference to personal experiences. The professional warrant trumped the others and as the objective warrant tended to outrank personal experience her account indicated that the lay member would be in the weakest position from which to take part in any debate. Bond (2012) subsequently indicated a fourth warrant which accorded high value to one who raised an issue of a potential harm. Again the medical member was most likely to be able to play such a card. Van den Hoonaard (2011) also noted that scientifically trained members have tended to have the advantage over lay members in being able to

more quickly identify issues of concern in research and so lead the debate.

In contrast to a view of medical dominance, Evans (2012) believed that a bioethics profession had built up in the USA which influenced much of ethics committee activities. There is limited support for such a view however and his analysis did not consider the situation in the UK or elsewhere.

4.3 Recruitment

The methods by which members were recruited have also been studied and were of interest. Porter found that most members were recruited via a:

“‘friend or acquaintance’. A large number indicated that they had been requested to serve by the chairperson of the IRB or by members or former members of IRBs. Such members did not compete for their membership nor did they present their credentials formally or in interviews for the position” (Porter, 1986: 6).

This finding may suggest that such members were not truly representative of the public, but chosen for their convenience. As this finding was both dated and in any case related to the then situation in the USA it would be helpful to understand this matter in the context of contemporary practice in the UK. Of interest in this connection was the following anecdotal account by a lay member in the US:

“Two years ago, a friend of mine on the research ethics committee at the Sir Mortimer B. Davis Jewish General Hospital suggested I join as a community representative...

[Having joined, and] as the months went by...I think that I began to identify with the professionals – to think that I was part of the group. And since the group was made up of intelligent, hard-working, well-intentioned people who were trying to do good things, I thought: Who am I to question their judgment?

Perhaps I became less effective as a result. Perhaps I lost my outsider’s perspective – the different point of view I brought to the table...

...What is my role on this committee? Am I [a] rubber stamp? Am I a necessary bum on a chair or hand in the air required by some government regulation? Am I simply a grammarian, rearranging awkward sentences, correcting spelling errors, and throwing in punctuation marks where appropriate? Can I actually contribute anything meaningful to this process?...

As a community representative, can I really represent ‘the community’? I don’t think so. How can I represent a community that is multiethnic and multifaceted – old, young, white, brown, black, Catholic, Protestant, Jewish, Muslim, agnostic, and atheist? To say that I bring a perspective that is not medical, not scientific, and not academic is not to say that I represent ‘the community’” (Slaven, 2007: 17-18).

Here not only was the lay member recruited by an existing expert member but there was an indication of the lack of a clear role for the lay member and a tendency towards both capture and group-think.

Legood's comments were interesting in this regard too, and may offer a partial explanation of the problem. He pointed out that:

"...giving no payment for serving on an ethics committee means that it is less likely that those from lower socio-economic groups will be able to serve on the committee. As a consequence, lay members may be more likely to reflect the membership of the committee that already exists. This, perhaps, detracts from the distinctive role of the lay member for which they may have been recruited" (Legood, 2005: 136).

Such views certainly reflected the Ad Hoc Advisory Group's contemporaneous report that membership of RECs:

"is drawn in general from a relatively narrow spectrum of society, members tending to be professional in background and from an older age group. We do not have evidence of ethnic mix but doubt that RECs overall reflect the mix of the communities that make up our society" (Department of Health, 2005b: 10).

Neuberger (1992) engaged in detailed research amongst UK RECs in the early 1990s visiting over two dozen (NHS) RECs from amongst those which responded to a postal questionnaire (222 out of 241 RECs), observing and interviewing members. Her research concentrated on the formal composition of each committee and the way the committees operated in practice. At the time of her research the Department of Health guidelines suggested a membership of between eight and 12 members from both sexes, to include hospital medical staff, nurses and general

practitioners, and at least two lay members. Her research found the greatest breach was in terms of lay membership with 34% of RECs having fewer than two lay members; 28% failed to include women whilst 24% had fewer than 8 members. Some 19% of RECs had more than 12 members. Hospital doctors accounted for more than half the total membership. Neuberger noted that “Among the lay members of the RECs are those who by virtue of their training can provide a different professional input from that available within the medical profession” (1992: 20). She noted 14% of lay members were clergy and 16% lawyers. However, the guidelines did not, and do not, require that the lay membership either have, or do not have, a professional background. She discovered that the:

“general view appeared to be that sensible lay people, not moral specialists, were what was needed... Yet it was apparent from observing the committees in action that a person who was trained to think clearly and analytically about moral questions would have been a valuable addition to the committees” (ibid).

Presumably, by ‘general view’, as the majority of members were doctors, it was the medical profession’s view that those with a moral philosophical skill-set were not needed. Neuberger herself is implying though that ethics training for members would augment their role.

Stearé developed an ‘ethicability’ tool (Lewis, 2008) to help indicate a person’s ethical preferences. This may also have been useful for achieving a balanced committee, although his published work failed to

explicitly identify that such an application of his tool had been considered (Stearns, 2006; but now see Humphreys, 2010a for this).

In a summary of what was known of the recruitment of members to RECs, Anderson noted that whilst the success of recruitment to IRBs could be indicated by how long people stayed in the committee to which they were appointed, she also highlighted the fact that information on how members are identified and recruited was acknowledged as being particularly sparse:

“Although there have been calls for increased representation of lay community members on IRBs, little is known regarding their experiences or their perceptions of human subject protections and the IRB process” (Anderson, 2006: 135).

4.4 Ethics theories

The origins of RECs have been discussed earlier (ch. 2) and were seen to have originated following from scandals involving medical research. RECs were put in place in an attempt to curtail further scandals in health research. What ethics was though was never formally outlined to these committees and this may be due to its inherently subjective nature. If ethics is about ‘doing the right thing’ this may sound as though it is objective, but it is in fact much more a subjective notion. Guidelines can thus be criticised for trying to ‘codify the subjective’, and thus the ‘ethical’ element – be it in the form of a framework or particular theory of ethics - which may be supposed to underpin the workings of an ethics

committee, has been more assumed to exist than been demonstrated as operative. As Meslin et al. (1994) noted: “Several sets of guidelines for the review of human subjects research are available, but whether members of REBs are aware of them or use them is uncertain” (p.9).

Rothstein and Phuong have noted how several official reports in the US have “indicated concern that scientific rather than ethical perspectives tended to predominate in IRB deliberations” (Rothstein and Phuong, 2007: 76). This has been reported in the UK too, for example by Collier (1997) and by Nicholson (1986c). The latter reported a survey of REC chairs which sought their views on the usefulness of various guidelines, and to which their response was that very many of them were unaware of or did not use the guidelines at all. This all raises a question of not only how knowledgeable members of ethics committees are about theories of ethics, but in turn raises another question about how members perceive the functions of the committees – are the members there to ensure certain guidelines are adhered to, and if so which ones, or if not how do they decide what is ethically acceptable? Van den Hoonaard noted both that “biomedical research... forms the basis of these formal research-ethics codes” (2011: 4) and that Canadian conferences for REB members regularly “proclaim the supreme validity of ethics codes, [which were] seldom punctuated by counternarratives” (2011: 98). He also noted that despite this, REB members were not knowledgeable about the ethics codes or guidance (van den Hoonaard, 2011).

West and Butler studied their own committee and reported that that (non-CTIMP) committee's 'ethical preference' veered towards ecological ethics and ethics of caring. They did not address the 'purpose' of ethics committees (perhaps because it was thought 'obvious') but went on to suggest that

"Transparency of the ethical framework that underpins each LREC would, if disseminated to the research community, help researchers through the process of applying for approval, and could contribute, in the long run, to the quality of the research conducted" (West and Butler, 2003: 19).

They thus implied that the concern of the committees was with the methodology or science underpinning the research. As to the explicit intent of declaring the 'ethical framework' in order to guide applicant-researchers, they do not say how this objective might be achieved and the suggestion itself may be regarded as both naïve and problematic. No doubt they had in mind helping the qualitative researcher grapple with thorny ethical issues involved in, perhaps, participative or action research. Yet, to pursue their logic would seem to deliver one into an unpleasant *cul-de-sac*. For example, could a researcher apply to the 'utilitarian' committees; how might the committee decide its 'ethical framework' (is it decided by the chair?); and how might it adapt to new members - or should new members be forced to adapt to it? Implicit in those questions was another issue: how is power wielded in ECs?

By contrast, Kent (1997) after undertaking a limited survey of LREC members (none of which dealt with Phase I research) believed that they were most “concerned with the protection of participant’s rights” followed by ensuring scientific adequacy.

Hunter has suggested that “[lay] members with a formal background in ethics can be useful for picking up on more subtle ethical issues, such as issues of justice” (2007a: 25). However it is unclear whether there are more than a very few such members (and apparently none on IECs), or how well informed existing members are about the question of justice, the wider set of the four principles approach (Beauchamp and Childress, 2009), or indeed of any ethics guidance. The topic of how lay members consider such theoretical approaches to ethics review will be explored amongst the membership and reported here. Members’ attitudes towards such matters as how they go about determining the adequacy of the arrangements that are in place covering insurance, liability and indemnity, and how they perceive ‘Good Clinical Practice’ are also issues that shall be examined.

In terms of Rothstein and Phuong’s own quantitative survey of nurses, physicians and unaffiliated members of IRBs, they found nurses to have consistently greater concerns about ethical issues than other member groups, scoring more categories as ‘very important’ than the more discerning physicians. Whilst they noted that such “below-average ethical concerns of physicians [may be] ... explained as a generalized

commitment to research. Physicians might also believe that most researchers have high ethical standards, thus reducing the need for detailed oversight by IRBs” (Rothstein and Phuong, 2007: 79). Gender differences were not considered, and their observation that “[u]naffiliated IRB members rated ethical concerns similarly to all other members” (ibid) was ambiguous. It possibly meant that they consistently but independently scored similarly to those professionals associated with the institution of whose IRB they were a member, but the authors went on to say “[s]ome analysts have suggested that unaffiliated members lack understanding of the technical issues and might therefore defer to other, more influential IRB members” (ibid). That non-scientist, but not necessarily unaffiliated, members do defer on technical points seems reasonable – but surely should be countered at least occasionally by their own contributions. Or do they just follow the pack, having been subject to ‘capture’? My research findings concerning how IEC lay members cope with the technical issues (and experts) is to be reported below.

4.5 Training

Any lack of understanding of technical issues might be addressed by training, yet Allison et al. reported that in the US (as in the UK):

“there currently is no educational program in place ... designed specifically for non-scientist IRB members. Although it is not clear to us that such a program is necessary, our study suggests that some of these members may view their role too narrowly by, for example,

focusing on the informed consent document” (Allison et al., 2008: 12).

Being forced onto the back-foot of orthography and parsing (“wordsmithing”) has been the finding of other research too, as has already been noted. Sengupta and Lo (2003) as a further example engaged in a telephone survey of 32 lay members and found that:

“94% reported that their main contribution was simplifying the consent forms... 88% occasionally had been intimidated and felt disrespected by [scientist members]. Forty-seven percent of participants identified lack of education and training as a problem, and 78% wanted more intensive education and training for future ... [lay] members” (Sengupta and Lo, 2003: 212).

Van den Hoonaard reported reasons for lay people joining a REB included a belief “that they would learn about research and research ethics” (2011: 87). This could indicate that they were at least prepared to be trained.

There have been some moves in both the US (Institute of Medicine, 2001) and Canada (Sampson et. al., 2009) towards the accreditation of both members and IRBs and this is now developing greater momentum. Appraisal of UK NHS RECs is also now firmly on NRES’s agenda. Freedman and Glass (1990) had predicted a requirement for professional standards to be obtained, or at least exhibited, by RECs and so some sense of UK members’ feelings about the issues of training, education and accreditation would be interesting.

In the UK, Jennings (2012) has recognised that “[research] ethics committees lack expertise, not just on the research they review, but also on research ethics” (p.95) and called for a national consensus on what a REC training syllabus should include.

In all, the literature suggested, as Porter (1987) had it, the essential roles conceived, by the lay member, as his/her own, were to represent and protect the vulnerable mainly by ensuring that the consent documents address what a reasonable person might want to know in sufficiently clear language. The lay member though was also revealed to be almost a cipher character, subservient to the expert (medical) members. However, the research bases were generally aged, US-based and non-specific about the particular type of research the ethics committees studied engaged in. It is thus appropriate to explore these issues within the context of contemporary UK practice, and within as restricted a type of committee as possible in order to factor out extraneous variables.

4.6 Objectives

From the literature, a number of issues can be identified as being of particular interest because they have not been looked at, or the data has become aged, or because of a non-UK focus. These issues will each be addressed in the research which follows, and its focus shall be on UK independent Phase I [healthy volunteer] research ethics committees (IECs). These committees have been selected as an appropriate focus

because such committees have dealt with a very narrow range of research protocols (and, incidentally, it has generally been their protocols where risk to the subject has been the greatest and where too there has been no prospect of benefit to the participant). This affords a real chance to identify committee roles because in such a setting the roles will not have varied depending upon the type of study presented: the 'study type' variable being naturally eliminated in this environment. The objectives of the study then are:

- To understand how expert and lay members of UK independent Phase I [healthy volunteer] research ethics committees view their role and what tensions exist between the 'expert' and 'lay' designations on such committees
- To understand how members were recruited and their motivation for joining
- To capture key demographics of interest amongst the interviewees – age range, professional/educational background, training engaged in
- To discover whether such members believe they principally respond to the ethical issues that arise from an intuitive or common sense perspective, or whether they follow any particular ethics guideline(s) or theoretical stance(s) (inc. the 'four principles approach' (Beauchamp and Childress, 2009)) and if virtue ethics has any role to play

- To understand how members justify following guidelines when ethics is an autonomous discipline
- To understand how members see their role in relation to the science versus ethics debate; and similarly how they deal with legal issues or questions about insurance/indemnity, or indeed the various Declarations of Helsinki and 'Good Clinical Practice'
- To discern their feelings about accreditation – both of the committee and of the individual

Collectively these objectives will enable the following research question to be answered: “How do both expert and lay members of UK independent Phase I research ethics committees perceive those roles and what does this imply?”

Having identified the important background literature, and drawn out the key issues of concern, it is now time to introduce the methods by which the present research on how members of IECs perceive the expert and lay roles was conducted. This is the focus of the next chapter.

5. Methodology

5.1 Introduction

The aim of the current research is to explore, amongst a sample of members of independent ethics committees, their perspectives of the rationale for, and functions of, the respective roles of 'expert' and 'lay' members on such committees. Greater clarification and understanding of these roles will enable focused debate leading to enhanced role consensus and hence influence considerations concerning future training provision. Together such outcomes permit strengthening members' mutual appreciation of the two roles.

In attempting to understand the members' perspectives, the study seeks answers to a number of specific research questions which were identified following a review of the literature as detailed in the previous chapter.

This chapter describes the study's research methodology and, in particular, it (i) provides the rationale for the research approach and (ii) the particular methodology chosen; (iii) offers a description of the research sample and explains the logic of sampling from the population of study; (iv) gives an explanation of the methods used for data collection; (v) discusses the approach used in the analysis and synthesis of the data; (vi) discusses how the chosen methodology contributes to the

trustworthiness and rigour of the findings; and (vii) discusses the main ethical issues attendant upon the research.

Following Silverman and Marvasti (2008) the chapter adopts the 'natural history format' with a preference for use of the personal pronoun and a broadly chronological accounting for the research processes.

5.2 Rationale for the research approach: qualitative research

Qualitative research is anchored to the belief that there is no one truth in social matters. Such an interpretivist position regards social truths as relative - being experienced, interpreted and understood at particular locations of time and context. The intent of qualitative research is thus to seek understanding by allowing the researcher to enter into the world of the researched and attempt an holistic understanding of that world (Denzin and Lincoln, 2003; Mason, 2002). The emphasis is on discovery and description. Quantitative research by contrast has an essentially positivistic outlook, being posited on the notion that there are facts that can be discerned, typically by the testing of hypotheses. In quantitative research small differences can often be discounted in favour of the majority. Data may even be 'trimmed' to fit as 'outliers' are discarded (Helgesson, 2010), and it is the preponderance of numbers that will tend to win out as quantitative researchers typically describe the characteristics of the phenomena lying immediately beneath the peak of the normal distribution curve. Yet in the real world of real people one must recognise that different people have different opinions and that the validity of an

opinion is not necessarily proportionate to the numbers voicing it (Sim and Wright, 2000).

An interpretivist or constructivist framework of inquiry would support the ontological perspective of the existence of multiple realities, each of which are constructed and alterable by the knower. This is not to say that different realities are more or less true; rather the view is that they are simply more or less informed (Denzin and Lincoln, 2000).

Seeking the perspectives of members of IECs about the two roles of 'expert' and 'lay' suggests the appropriateness of a qualitative research approach. Bryman (2008) describes the fundamental characteristics of the qualitative research strategy as one that rejects the natural science model, emphasizes an inductive (theory-generating) approach, and seeks to explore the range of interpretations held by the different social actors.

Amongst the methods considered for obtaining my study data was the case study (or even a multiple case study) approach, but given the small number of IECs, the difficulty of gaining prolonged access to any committees, and the desire to sample as widely as possible within the small group, this approach was discounted early on. An ethnographic approach was dismissed for identical reasons. Another approach considered was 'grounded theory' (Glaser and Strauss, 1967) but this approach required, amongst other things, that the researcher approach the research without a prior set of theoretical expectations and with a

somewhat restricted view of the extant literature that concerned the topic. I excluded myself from this approach, having too much 'baggage' to enable this: I was an officer member of an IEC, I have views about the role (although they are not inflexible) and I perceive others to have different views. I have even found those differences pushing me towards a sense of role ambiguity, and also suggesting that either I or my colleagues on our committees must be doing someone – either the researcher, or the appointing authority – some disservice by potentially vacillating in the role. Dyer (2004) and others have found that this role uncertainty is potentially an issue for other REC members too.

A focus group approach was also considered but discounted because of the difficulties I envisioned in gathering participants from around the country, and by concerns about how open members might feel in such an environment: any issues of confidentiality would be subject to factors (other participants) outside of my control.

I became convinced that a series of semi-structured interviews would give me an appropriate degree of structure in which to gather data confidentially whilst also permitting me some flexibility, which was necessary because I could not predict what my respondents would say or where their comments would lead. The interview approach also had a particular benefit in that it is the least likely of all the possible qualitative approaches to meet with resistance from an ethics committees (van den Hoonaard, 2011).

5.3 Philosophical hermeneutics

Data gathering is important, but not more so than analysis. Mason (2002) has suggested the metaphor of ‘excavation’ for the process of interviewing and revealing data, and as a metaphor it is not dissimilar either to Kvale’s (1996) suggestion of ‘mining’ or Foucault’s (1970, 1973) ‘archaeology’. Uncovering though is not enough, and one has to understand what it is that one has unearthed.

In reviewing the qualitative research literature to identify an interpretive approach that would best fit with my own experience and philosophical outlook, I was particularly impressed by aspects of the Heideggerian phenomenological approach - sometimes described as existential phenomenology, or, when it is inspired by Gadamer (1976), as ‘philosophical hermeneutics’. Nevertheless, I did not subscribe to all – indeed certain key – components of the standard approach to this or any other phenomenological approach. In particular I was not interested in the ‘lived experience’ of members of RECs not least because their involvement in ethics meetings would typically engage them for just one meeting a month approximating to perhaps eight hours a month (including reading time).

A hermeneutical description of the analysis process emphasizes the need for both the researcher and researched to co-construct meaning (Koch, 1996). Kvale (1996) too draws attention to its emphasis on a

mutual joining-together and it is within the interview process that issues are raised for both parties which, when accommodated, instigate a process of coming to an understanding.

Thus the broad approach of philosophical hermeneutics can be considered as starting from the epistemological assumption that reality is context dependent: there are quite simply multiple realities. Almost every individual has his or her own perspectives on life that have arisen due to, and are continuously being re-shaped by, whatever situations are encountered on life's journey. Our unique experiences of the world, coupled with our particular cultural and background experiences (including where, when and how we were brought up and by whom) all mean that we see things from more, or less, subtly different perspectives. It is the role of the researcher in hermeneutic methodological enquiry to identify and interpret the 'hidden assumptions' that the participants hold.

Hermeneutics though can be thought of in terms of the Hawthorne effect (Miller, 2000) with the researcher having an effect on the respondent who in turn will conduct themselves in recognition of the interviewer's presence. Different answers may be given to different interviewers due to their different statuses, personalities, phrasing of questions, and so on.

Whereas Husserl's (1980) phenomenology encourages the 'bracketing' of one's experiences in an attempt to reduce the prejudice

with which one would otherwise experience another's perspective, Gadamer (1998) is more realistic and for that, more honest, in viewing this as an impossibility and hence an absurdity. Indeed one's prejudices can be used to help find intelligibility: they assist understanding. In Heideggerian phenomenology it is in the analysis that "data generated by the participant is fused with the experiences of the researcher and placed in context. The interpretation becomes a merger of data sources, or a construction" (Koch, 1996: 176).

As the knower and the known cannot exist without the other, bracketing is impossible – one cannot stand outside of the pre-understandings and historicity of one's experiences. One cannot 'unknow'. Thus, the prejudices and assumptions of the researcher are not to be bracketed or set aside, but rather are to be regarded as essential to the interpretive process.

Data can thus include the researcher's personal reflections on the topic, information gathered from research participants, and even evidence from outside the context of the research project itself (Polkinghorne, 1989).

5.4 Participants and setting

Members of independent ethics committees (IECs) were the target population of study. This group was selected because they comprised a discrete group whose members uniquely only reviewed one particular type

of study (viz., Phase I “healthy volunteer” studies). The narrow remit of the committees prevented individual members attempting to specialise in certain types of protocol as they might on other committees where members might have ‘allowed’ colleagues to take the lead on particular types of study on an idiosyncratic basis. In IECs there were no leavening studies such as student research or qualitative studies, no one could take a particular patient-group perspective (because there are no patients), and science and safety were the responsibility of another independent body of experts (para. 3.80 NRES SOPs, v.4 [13.8 v.5]). The singular focus of the IECs helped to address one of van den Hoonaard’s (2011) methodological concerns about researching RECs. He has pointed out that RECs typically deal with a diverse range of research and that this range acts as an impediment to drawing conclusions even about the EC(s) under study. Such diversity was not however a feature of IECs. In IECs the members’ roles can be expected to have become finely-tuned over the years of their existence to dealing with those issues that were thought appropriate to those members.

Other reasons added to the decision to locate the study in the IECs. Firstly these committees have never been studied before, which is of interest in itself and has the corollary that as members they were a research-naïve group. Secondly, the size of the group was such as to suggest an adequate sample response would be likely. Thirdly, as a fellow IEC member, I already had a connection with the group and so envisaged being able to gain the necessary access.

At the time of conducting the research there were six independent ethics committees in England and one in Scotland*. Of the 21 NHS RECs authorised to deal with Type I research, none of those dealt exclusively with Phase I research. None of these ECs were permitted to have more than 18 members (CT Regs sch. 2, s.3 (2)) and at least one-third of these members should be 'lay' (CT Regs sch. 2, s.3 (5) (a)).

5.5 Methods of data collection

Before data were collected, consideration had to be given to an appropriate sample size. There is no agreement in the qualitative research literature on the right sample size – it must though be 'adequate' for the methodology employed. Dey (1999) argues that the issue of sample size is almost a hegemonic relic from positivistic science and he points out that a representative sample is neither possible nor necessary in a non-positivistic paradigm. What the qualitative researcher is seeking is perspective on a topic and whilst this can be obtained from one individual such a sample size is unlikely to command any real credence amongst those seeking an understanding of a groups' perspective. Thus sampling should aim to generate a wide-enough range of views to draw a picture with sufficient depth of tone and colour, with discordant hues supplying further interest. The maximum variation sample is thus favoured.

* Capenhurst, Leeds, Manchester, Plymouth, Reading, Welwyn and Edinburgh.

The convention in qualitative research is that the appropriate sample size be predicated on the notion of saturation (Morse, 1994). Saturation is said to occur where further interviews become increasingly unproductive of introducing new perspectives (Glaser and Strauss, 1967). It is however a difficult notion and virtually impossible to demonstrate (Morse, 1995), especially in advance of the interview process. Again Dey (1999) goes as far as suggesting that the notion is inappropriate as there is always the potential for new data to emerge. Nevertheless sampling is necessary and the experiences of different methodologies have provided guideline sample sizes. Phenomenology has “at least six” (Morse, 1994) or “between five and 25” (Cresswell, 1998). Green and Thorogood (2009) suggest little new emerges beyond interviewing about 20 people. Despite such ‘target ranges’, I tend to side with Dey (1999) and believe the notion of saturation to be problematic for the reasons he gives. It is also alien to a philosophical hermeneutic approach, which would not regard ‘saturation’ as crucial given that it regards truth as essentially temporal. However, in consultation with the supervisory team, conscious of the size of the population of interest, and being uncertain of the response rate, saturation was estimated at 20 individuals. This proved to be achievable (just), and appropriate too as subjects were giving a consistent range of responses by that point.

In interviewing a sample of members of Phase I IECs I was interested in their subjective experiences about such matters as their role (as lay/expert members) in relation to the committee, colleagues, and

Phase I trials. I wanted to understand their views on such matters as the concepts which they were supposed to safeguard – rights, welfare, dignity, justice and the like; ethical traditions, especially the ‘four-principles’ approach (Beauchamp and Childress, 2009); the role of guidance versus the autonomous nature of ethics; whether there were potential dangers in an orthodox approach to ethical review, and whether subjective ethical opinions could, properly, be codified (i.e. what use were guidelines?). Similarly I was interested in how lay members approached certain technical issues (such as science, insurance, indemnity) which might be involved in the ethics consideration; what role they saw for virtue theory; and what they felt about proposals for them or their committee to be accredited.

Given this, and within a framework intended to capture issues of interest which are consistent with the research question, participants were to be asked to describe their experiences and views about the topics. However the questions were not always or necessarily going to be phrased in a particular way and participants were always to be encouraged to engage in follow-up. I certainly wanted to allow the researched to identify their concerns and engage in discussion with me, rather than wanting to impose my own pre-conceived notions. The semi-structured interview approach was ideal for this.

Interviewees were approached via their committee co-ordinators (found on the AAPEC website), who were provided with information about

the study (see Appendix 3), and asked to forward it to their members by way of invitation to participate. None of those who took up that offer to contact me as being potentially willing to be interviewed were denied an interview. Greater depth of interviewing was pursued in some areas with some interviewees where their knowledge afforded scope to do so and this helped generate greater variety amongst interviewees. A snowball technique (Bryman, 2008) was also planned with the intention that it might help in the selection of additional interviewees – for example, recently ‘retired’ members, or (if it were possible) others who had considered membership but decided against it (either before or after applying). However no such interviewees were recruited but several interviewees were seemingly able to persuade others on their committee to ‘step-forward’ for interview.

All willing interviewees were thus heard and I interviewed 20 members representing all the committees apart from the committee to which I was attached. Some interviews lasted longer or covered fewer topics in greater depth than others. Interviews ranged in length from 42 minutes to 102 minutes, with most taking about an hour. Equal numbers of expert and lay members were interviewed and in a gender ratio of 9:11. Some interviewees had to be invited twice, and some may have decided to participate only through the auspices of a colleague.

Interviews were all tape-recorded with the permission of the participants. Three interviewees required that I either suspend recording

or simply not transcribe certain parts of their commentary as they wished to provide me, but not my tape-recorder, with additional information that they felt should remain confidential.

Whilst most interviewees had been on their committee for a number of years, two interviewees had been associated with their committee for a considerably shorter period (I cannot be more precise for fear of indentifying the interviewees). Nevertheless I believe I was very lucky to elicit the 20 participants I obtained as there had been a very slow start before momentum developed which occasioned some concern about recruitment strategies (including preparing a 'plan B'). Fortunately, a number of interviewees remarked at the close of the interview that they had enjoyed the opportunity to discuss the issues as 'it made them think', and I took advantage of such comments by asking those interviewees if they could encourage other members of their committee to contact me. This proved a helpful factor in reaching my recruitment numbers.

5.6 Interview locations and mode

Interviews were conducted in London, the provinces and Scotland, in meeting rooms and apparently-quiet areas of restaurants, following negotiation with the participants concerned. Six interviews were conducted by telephone where schedules combined with distance to make a face-to-face meeting seem unlikely, and at a time when I was anxious to progress the interviews rather than lose any potential participants to holidays and the like.

5.6.1 Telephone interviews

Initially I had been wary about mixing face-to-face with telephone interviews because I had been warned (not least by the ethics committee which sanctioned the research) that there could be a difference in the quality of interviews obtained via the two media. The literature however did not necessarily indicate there would be a problem.

Bryman (2008) has suggested that telephone interviewing has certain benefits. It is cheaper, useful for hard-to-reach groups, when interviewer safety is an issue (the university's REC had thought my research was such an instance and required to know what procedures I would have in place to mitigate such a danger), or when asking sensitive questions (again the ethics committee wanted to know what arrangements I would have in place should any of my interviewees become distressed).

Sturges and Hanrahan (2004) have reported what was in effect a 'natural experiment' when they, for pragmatic reasons, had to interview almost half of their targeted respondents by telephone as it proved impossible to meet with them face-to-face. In analysing the responses obtained via the telephone interviews as compared with face-to-face interviews, they concluded that there were no discernible differences between the responses elicited by either method in terms of quantity, nature or depth. Such findings have been mirrored by Bryman's own experience of telephone interviews and he confirmed "interviewees were

quite expansive in their replies...the detailed replies suggested that the method can generate detailed and considered replies of the kind typically sought by qualitative researchers” (2008: 458).

If anything, I believe my telephone interviews were slightly the more rewarding because I was less inclined to be distracted by waitresses and crashing crockery at one location, by the arrival of an unknown third-party’s pre-school children wondering what I and my interviewee were up to in the airport’s McDonald’s restaurant, or by the next-due interviewee barging in and sitting-down in the room the current interviewee and I were already occupying. I believe that the telephone allowed me to better attend to each word, which competing sensory inputs would not have permitted.

5.6.2 Exclusion of my own committee

The decision about whether to include or exclude members of the IEC of which I was a member was not an easy one to make. I was attracted to the idea of inviting members of my committee to be interviewed as I felt this could have enabled a more focused set of questions which would help me to penetrate to the issues efficiently. For example I already knew the background of most of my own IEC’s members and could thus have launched into questions from a more advanced position. With other interviewees however I would initially have to get some personal background from them and then move the interview

forward with minimal time in the interview slot to reposition my questioning strategy. With colleagues I could also have attempted a focus group, or such a group could have been an option as part of a broader methodological approach which would have included an interview stage.

I recognised that there are generally held to be three main areas of concern where research involves colleagues: voluntariness; privacy and confidentiality; and conflicts of interest (University of Guelph, 2006). I felt too personally involved to make an unbiased decision and decided the best course of action would be to adopt the conventional position of excluding my own committee from my sample. However, as I was keen not to exclude colleagues' views from the research, I altered my planning a little. Instead of seeking participant verification of my transcripts and interpretation I sought opportunities to ask members of my own IEC what they thought about such issues in a general way (indeed I had been asking such questions for years). This helped to ensure that the understanding I was developing was still within the range of experiences of those members too. In this way I was also able to avoid the difficulties Bosk (2001) experienced when he upset his subjects as, although they accepted he had not identified them or misquoted them, they did not like his interpretations. As with Bosk, my interpretations are my own, and if they differ from those of any subject(s), like Bosk, I would say that research which does not make the reader sit up and think would have been a pointless activity.

5.6.3 Small sample sizes

By excluding my own committee I was reducing an already fairly small population of interest to an even smaller one. Two particular issues arise with small samples – the pressure to participate can be greater, and the threat of identity can be higher.

With a small population there can be a pressure on both the researcher to recruit sufficient numbers, and on the researched to participate. The interviewer/researcher has power, as Mason (2002) explains, in that they set the agenda, they control the data which emerges, they provide the interpretations and they are responsible for adequately guarding any promised confidentiality. The participant's power is in granting the interview and in the extent to which they agree to cooperate with the interviewer. The informed consent documentation and its process acts almost as a contract between the two parties – the interviewer states what he or she will do, and on this basis the participant grants or declines an interview and regulates cooperativeness. (See Humphreys, 2010b for more on the contractual nature of the consent process.)

Mason (2002) doubts whether participants in much qualitative research can possibly give truly informed consent when not even the interviewer will necessarily know quite what they are going to say at any juncture in the conversation. It is also the case that neither party may

know what interpretation will ultimately be placed upon the data obtained until the analysis of the data has at least commenced. Nor do they know if the research will necessarily be published or, if it is, where and how it will be received. The traditional way such uncertainties are managed is by promising not to identify participants. However even with unattributed quotations it is always conceivable that someone may believe that the choice of vocabulary, for example, is indicative of a particular individual. There is thus risk involved in being a participant in research, which can only be managed by the thoughtfulness of the researcher. Such risk increases where small populations are involved because the small number increases the possibility of participant identification.

To guard against identity disclosure participants in this research are anonymised. They are designated as 'E' (expert) or 'L' (lay) with a random number allocated to them (1-20 to represent the 20 interviewees). It thus cannot be assumed that 01 relates to the first interviewee or that consecutive numbers indicate members of the same committee. Where I wished to draw attention to comments being made by a particular professional, or I feared that words or context could permit associations, reference numbers are omitted and reference is instead made to their profession (nurse, pharmacist,...) or member category (expert, lay) as appropriate to better protect identities.

Of the six available IECs, a maximum population of (6 x 18 members =) 108 members was assumed. Although willing to interview

recently retired members too, which would have expanded the numbers above 108, no retired members were recruited. With an intention to interview 20 members (10 lay and 10 expert), this represented almost one-fifth of the population of interest, and with at least one person from each of the committees, it was feasible (though extremely unlikely) that an 'insider', reading the research, might believe they were able either to identify themselves, or a colleague, as being quoted. If someone suspects they can identify themselves from a quotation it is suggested that they simply do not promote the fact for no one else can know. And if someone thinks they know another person they cannot be certain and are advised instead to concentrate on the overall impressions as the findings were broadly shared.

Although privacy and confidentiality were both implicitly promised by me to my participants, they were unaccompanied by guarantees. Participants therefore had to take such promises on trust, and with a stranger. Fortunately, and again, I was not encountering a situation that others have not encountered before and the methodological literature had advice for such situations.

5.6.4 Establishing trustworthiness

The main piece of advice can be summed up as that the researcher needs to demonstrate trustworthiness. I sought to do this by emphasizing my 'insider' role. I tried to underscore the fact that I was not

a complete stranger or total outsider. I had either met some of the potential participants at conferences or training sessions; I was a member of their small group (of IEC members) and I had a modest publication history in the journal they were all familiar with. Participants could thus, I hoped, see that I did not have a history of revealing identities, nor of placing blame. For example, my own account of a training session I had organized for my own IEC in which members' moral stances were discussed had managed to avoid identities such that not even members of the committee were able to recognise each other, although they could identify themselves (Humphreys, 2010a). I was also keen to stress that there were no right or wrong answers to my questions. I was interested in people's perceptions and I had noticed that there were different views. I would be presenting the findings in such a way as not to ascribe blame or censure.

The fact that I was a colleague was meant to suggest that I understood their issues and would be able to provide immediate follow up and clarification of anything that arose in the interview. If there was anything said that the participants later regretted they need only contact me and I would remove the offending material – no questions would be asked. This was stated clearly in the participant information sheet (see App. 3). No one availed themselves of that opportunity, but there were a few occasions when I was asked to switch off my tape-recorder to permit them the extra anonymity afforded by that measure. The tapes themselves were erased after the transcriptions had been accepted by my

supervisory team, and no one outside the intimate team of just me and my two supervisors had access to the transcripts. And the supervisors would not know the identities of those involved.

5.6.5 Onerous nature of being interviewed

Wolff (2004) highlights the fact that the qualitative research process places “unfamiliar *demands*” on its participants. These include making time for conversations; surrendering control of physical space; acceding to communicative pressures; limiting one’s own communicative needs (to accommodate the interviewer); having to provide interesting data to satisfy the researcher; giving information; accepting the possibility of embarrassment and the need to question what one has taken for granted. Furthermore, such participants are typically expected to engage in a number of corollary obligations, including:

- “smoothing the researcher’s path and suggesting competent interview partners;
- answering questions they have never put to themselves, the meaning of which is initially obscure;
- trusting the researcher without guarantees;
- explaining to themselves and others what the researcher and the project are aiming at; and
- signalling that they are not disturbed, even though they are under scrutiny, and so on” (Wolff, 2004:195-6).

Put like that it is a wonder anyone volunteers at all, and it is perhaps only because interview requests, and their implications, are not always consciously thought about in terms of these onerous obligations by those who might grant an interview that research interviews occur at all.

Wolff's advice for gaining access where obstacles were envisaged from the potential participants included the need to convince informants that the research was serious; that no harm would befall the participants; that the research would uphold their right to confidentiality; that it would be minimally disruptive; and that it would be over when the interview ended.

Sixsmith et al. (2003) have suggested other tactics for overcoming such obstacles including demonstrating credibility and similarity, and building a rapport with the participants; Elliott et al. (2002) recommended showing empathy; Rist (1981) suggested making "acts of reciprocity"; Oakley (1981) advised that the interviewer answers questions and not just asks them; and Goode (2000) recommended giving feedback, as did Silverman (2005) who also advocated taking a decidedly non-judgemental stance. I would add to these tactics an offer to inform the participants of the research outcomes and, wherever possible, tangible recognition for the time and effort the participant gives.

Much of this advice was particularly relevant if I was to obtain a recommendation from someone who had been interviewed, that I was a suitable person for another volunteer to be interviewed by.

My experience was that all but one IEC was able to provide at least one interviewee initially, and that the interviewees were able to recruit others for my project. My tactic in this was to prompt participants at the close of their interview by saying how much I appreciated their time and that their responses had been very interesting and gave me much to reflect upon. This was in every case true as even the two interviews which revealed relatively impoverished data gave me cause to think about my interview skills. The typical response to such a comment of mine was something along the lines of “I’ve enjoyed it too” (L19) or “...yes, it’s certainly made me think...” (E03). As I passed the blank charity cheque (see an explanation of this below) with a reminder that the interviewee should make it out to, and pass it on to, a registered charity of their choice I asked them if they knew others on their committee who might still be available to help with my research, and I gave them a couple of spare participant information sheets to pass on.

5.6.6 A reluctant interviewee?

In the case of one IEC I suspect that the co-ordinator passed my request for interviewees just to the Chair, and that this individual may have decided not to bother members of that committee with the request. I say this because I met with someone from that committee at a training session who claimed not to have been aware of my research and my quest for volunteers. Although that individual subsequently declined to participate, the information gave me an excuse to contact that committee

again explaining that I had now interviewed at least one person from all the other IECs, and that it would aid my plans for anonymity if I could state that all committees were represented. The Chair then offered to participate, I felt reluctantly. We arranged a telephone interview. Initially the Chair seemed somewhat curt but after a few exchanges, and, especially I think after I was able to impart some news about other matters ongoing concerning NRES/ AAPEC the conversation became more relaxed and ended with the Chair offering: "I've enjoyed it." I suspect that as I had been able to share a quasi-confidentiality with the Chair and thus presented myself as no less vulnerable than the interviewee that this must have been reassuring for the participant and aided their engaging with me.

5.6.7 Atypical volunteers

As volunteers, my interviewees were probably typical in being atypical. Generally it is held that volunteers are:

"not likely to be a random sample of the population. They tend to be better educated, of a higher social class, more intelligent, more social, less conforming and possess a higher need for approval than non-volunteers. This means that the external validity (the confidence to generalise to the population) is reduced" (Burns, 2000: 18).

Fortunately, as the existence of such a phenomenon is recognised by a wide group of researchers it has become subject to a number of remedial responses. The relevant remedial factors I would point to to help indicate the generalizability of my findings, notwithstanding the self-

selecting nature of my volunteers, include the commonality of responses, that these accord with other findings, and that they are within my experience with both IEC and NHS RECs.

5.7 The analytical approach

In order to understand one's data one has to know it, to see features in it (or indeed surprising absences), and to notice linkages and emphases. Coding is often advocated as crucial for organising and to 'get a handle' on one's data (as Mason (2002) puts it), yet meaning is not inherent in codes and there is a danger that in coding one can distance oneself from the very data one is attempting to analyse and become familiar with (Seidal and Kelle, 1995). This was a concern always occupying a place at the back of my mind and probably contributed to an allied discomfort about whether I wished to avail myself of any software that was available to help with the coding process.

I was concerned that having to learn the mechanics and technical aspects of such software might only serve to distract me, and further distance me from the data (scrolling around a screen is enough to engender in me a sense of remoteness from the data which does not arise by turning pages). I was also concerned about the cost, especially for a one-off, small-scale project not involving other coders, and I could not decide on the most suitable product (an issue compounded by noting the frequency with which newer versions were produced). However, I became convinced that the practical experience of using such software

had a pedagogic value, and so identified and used the freely-available HyperResearch (v.2.8.3) which proved easier to learn and not quite the distraction I had anticipated, although I did find I had a clear personal preference for having the transcripts physically in my hands (or covering the carpet). I was thus able to immerse myself in the data in my own way and was not restricted in this to those times when I had my computer powered up. This was an important factor for me as it often tended to be whenever I was doing something else that I had a 'eureka moment' and needed to quickly check something in the transcripts. I doubt I could have done this as efficiently if I had to wait for the computer to power up as I found that the mental contents of such moments were always fragile, prone to self-destructing if not dealt with promptly. Presumably this sort of experience is not uncommon, as Lewins and Silver observe "[o]ften the most insightful thoughts occur at unexpected times, away from the computer, and away from the data" (2007: 228).

As I had already identified certain thematic areas of interest it was these that I initially sought to code (advocated by Miles and Huberman, 1994), but as I was also interested in member-generated accounts of their experiences and perceptions I was alert to the possibility of coding some of the data in terms of those member-generated categories too. In addition I was especially alert for the presence or absence of certain issues being raised by some interviewees which others might not have mentioned. I also recognised that:

“Sometimes ideas of considerable interest and theoretical significance may be expressed only once... That which occurs repeatedly is not necessarily theoretically significant, and that which occurs rarely is not necessarily theoretically unimportant. Furthermore, some concepts may be significant by their absence” (Sim and Wright, 2000: 160).

For me, this recognition underscored the validity of the hermeneutic philosophical approach, as I anticipated that my own understandings and expectations might themselves, especially in engaging with the research subject’s point of view in the hermeneutic circle, spark ideas which could themselves become data.

Interview transcripts were prepared and analysed for content with the codes (or ‘databits’ as Dey (1993) terms them) and any higher level ‘themes’ identified as soon after each interview as was practical. At this time too my semi-structured topic guide was reviewed ahead of subsequent interviews. New transcripts also enabled the re-visiting of the coding process of earlier transcripts, and codes and themes were reviewed iteratively (‘constantly compared’) throughout the data-gathering stage.

By gaining familiarity with each interview transcript I thus attempted to identify some features within them which ‘spoke’ to me about the interviewee’s experiences, thoughts, and so forth. As several such interviews each revealed such data, I was able to re-evaluate topics, content, and other data, which caused me to continually re-imagine and

develop the eventual codes. I prefer to think of the process as making links and developing groupings of ideas.

Prior to the interviews and based on the imagined initial interview structure, I had anticipated codes that might embrace categories and themes that could offer clues to the *ethical theoretical bases* underlying member's approaches to ethical issues (e.g. deontological, consequentialist, utilitarian,...); why members thought there should be members designated as 'lay' and 'expert' on the committees (*'justification of role'*); their (educational, occupational) *background*; whether they tend to lead or follow (*'negotiation of role'*) – whether lay members' ideas are offered in support of the experts' views, in parallel, or even if they tend to commence debate. Whether they saw certain matters as properly *falling to the consideration of lay members* with others being more in the purview of the experts, and if they are, then any joint areas would be of interest. I wondered if the circumstances surrounding their *appointment* had any bearing on their subsequent behaviour. For instance if they were appointed following open advertisement would they be more likely to be genuinely interested in promoting ethical research, and self-development and accreditation? Conversely, if they were approached and asked to join, would they tend to be more acquiescent and allow others to determine the issues to be debated? What *expectations* had they about the roles and have these changed at all? What *training* have members had and how did they choose particular training events?

Even as the interviews commenced however, refinements to my categories of interest began to impose themselves with some immediacy as many of the anticipated notions proved to be too broad, and I found it would be impractical and far less interesting to pursue all those potential links I had in mind. Instead it was more practical and, indeed, I felt, more appropriate, to delve deeper with certain topics which the early interviewees raised, as they arose, and because they appeared interesting. Thus, as Mays and Pope (2000) predicted, I moved towards an ever tighter coding system, albeit that part of this was during the interview stage rather than solely at the analysis stage.

Although inter-rater coding was never feasible within my limited resources (itself another factor in my not wishing to invest in expensive qualitative analysis software), I did not consider this fact to be problematic. The methodology of hermeneutic phenomenology would deny the notion of 'aberrant coding' because it is more interested in accounts of the evidence as understood by the researcher (there never being just one 'true' account to be demonstrated).

My supervisory team, faculty and indeed fellow students all offered suggestions about the sorts of issues I should consider being alert to. There was no shortage of potential coding possibilities, initially including such varied issues as a member's occupational history; where the REC's monthly meeting was located and its times; attitudes to the medical or other professions, to AAPEC and NRES; attitudes towards technology

(inc. MHRA, the EU, the pharmaceutical industry); reimbursement levels; time commitment; attitudes to training and education, and so on. This was becoming out-of-hand. However, when I eventually saw, in the transcripts, what it was to be an expert my thesis began to reveal itself to my conscious mind and I concentrated my 'coding' around the evolving thesis as I saw explanation dawn over the horizon. To some extent then the codes supported the emerging theory as well as helped to reveal it – it was not then a unidirectional activity but involved iterative processes.

5.8 Trustworthiness and Rigour

Questioning the rigour of qualitative research occasionally provides sport for those whose view of the world accepts only that which can be shown by positivistic science. Qualitative research however addresses other concerns, such as those tending to begin with 'why' or 'how' and which cannot so readily be considered by numerical analysis, and it attempts to explain how the findings have been arrived at from within the perspective of the methodological stance adopted by the researcher. Koch concisely explains the situation in relation to the approach of hermeneutic philosophy:

“In the last two decades the issue of rigour (initially referred to as reliability and validity) in qualitative research has persisted as an hegemonic legacy of empirical-analytical research, and continues to challenge new researchers as they shift from a conventional empirical-analytical paradigm to alternative paradigms... It is evident [though] that the language and concepts are changing which...

[increasingly] signals a reconceptualising of the notion of rigour” (Koch, 1996: 178).

Thus the problem of rigour in part centres on the co-construction of data – and the fact that the hermeneutic approach recognises that the researcher is not unprejudiced in the matter and that therefore he will naturally *interpret* what is revealed, and come to a view that will be reflected in the research outcome. The reader of the research needs therefore to be able to see how the findings have been arrived at, and then has a choice of accepting or rejecting the researcher’s findings – and may co-construct their own, alternative, findings too.

Silverman (2005) advocates a process of ‘constant comparison’ (the term originated with Glaser and Strauss, 1967) which allows the researcher to check on the reliability of the findings by constantly comparing one set of findings with other findings in an iterative fashion. Indeed, he calls for ‘comprehensive data treatment’ such that one’s generalisations should apply to every data set, or be explained away. ‘Deviant-case analysis’ similarly asks the researcher to use the deviant cases to re-orient their thinking, and modify their ideas accordingly. Such processes proved invaluable to my arriving at my eventual explanation for the phenomena under study, and caused me to discount prior ideas which did not fit all the facts.

At a rather different level of concern about validity, Lofland et al. (2006) identify three particular “kinds of contaminating error and bias”

which they suggest the researcher might unwittingly occasion. They warn against 'reactive error' whereby the interviewer or observer's presence alters the scene such as to preclude a true witnessing of what one wished to witness or hear; 'perceptual or interpretative distortions' which are caused by the observer's personal perspectives; and sampling errors caused by failures in obtaining reasonable representation of a relevant range of perspectives.

Their solutions for these possible problems include demonstrating appropriate sampling strategies to capture the full range of experience; having a team of researchers; and a strategic selection of informants – selecting informants who are positionally different within the group being studied. Unfortunately, their last two suggestions in particular would have proved impractical for my research. I did not have the resources for a team of researchers, nor was I blessed with great numbers of volunteer interviewees. I would also have doubted my abilities to explain to an ethics committee that I proposed to engage in a practice that is not clearly an example of 'fair subject selection' especially given my lack of prior research experience. Nevertheless, and yet again, the impossibility of these suggestions, only further justifies the appropriateness of the methodology adopted (although this does tend to disregard Lofland et al.'s concerns somewhat).

Reliability – or repeatability – as an indicator of the quality of a study is a concept that some see as being something ill-fitting with

qualitative research as this type of research does not share the positivistic paradigm of quantitative research. Rather, as qualitative research's interest can be in eliciting the range of responses and opinions that might be held on a subject, one can expect that opinions will vary between individuals and over time. Nevertheless readers will want to attempt an assessment of the quality of the research and there are a number of approaches by which this may be done. Guba and Lincoln (1994) suggest 'dependability' as a more appropriate criterion (replacing reliability), and within this they propose sub-criteria of both 'trustworthiness' and 'authenticity'. In terms of these criteria I suggest that the fact that I was a fellow REC and IEC member meant that my respondents would not be likely to accidentally mislead me and this, coupled with the fact that my findings 'ring-true' to my own experience gives me a sense that the research is 'dependable'. However I am clearly not without a conflict of interest in such an assessment and so must leave that ultimate determination to the reader. For those qualitative researchers (such as Mason, 2002 and Silverman, 2006) who see the notion of reliability as being more transferable into qualitative research I would refer to my adoption of some of their suggestions to do with enhancing reliability such as making the research process transparent by describing the research strategy and data analysis methods in a sufficiently detailed manner.

On a more mundane level too, Dey (1993) suggests reliability can be enhanced by what he terms 'low-inference descriptors'. He advocates

tape-recording all face-to-face interviews and carefully transcribing the tapes but then suggests presenting long extracts of verbatim accounts to help contextualise comments to aid the perception of reliability. These suggestions have been taken up, and I have also explained the inclusion criteria for the research, which can help the reader to gauge the representativeness of the instances reported. Another technique to enhance this would be by demonstrating inter-coder consistency, but as I have already explained, this, for me, was unaffordable, as it must be for most unfunded student research.

Reflexivity is key to issues of rigour and validity and it requires the identification of the preconceptions brought to the study by the researcher including such matters as personal and professional experiences, motivations and qualifications (Koch, 1996). Given that my worldview regards 'facts' as at least potentially subjective, and that all description is necessarily interpretation, I recognise that my 'real world' may be differently perceived from the 'real world' of the participants of the research, and I have acknowledged that my very presence might have affected the behaviour of the phenomena I was observing. I believe that the qualitative research I engaged in can offer only a construction of a situation, as I perceived it – but it is submitted that this is all any qualitative research can offer (and arguably even quantitative results are influenced by the choice, wording and positioning of questions). This 'construction' is of value nonetheless, for as different researchers develop new perspectives, new knowledge emerges. It is the position of the

methodological approach I adopt that the findings should not be regarded as universally applicable, but rather should, being inductively generated, proffer one or more 'interesting' ideographic perspectives which should serve to inform about comparable situations.

Although neither theory construction nor generalizability are aims of hermeneutics, which seeks understanding rather than theory, I depart sufficiently from such a 'pure' hermeneutic phenomenological approach to enable me to offer a theoretical position as a research outcome. However I adhere to the perspective that it is not the subject-participant's meaning that which is necessarily prime: rather it is the result of the dialectic interpretation that is to be regarded as the main outcome, and it will be this interpretation that will make the research contribution meaningful to the reader/consumer. There is no 'objective' knowledge outside of human existence, and it is thus an inter-subjective objectivity which will be offered.

5.9 Ethics considerations

Prior to seeking formal ethics approval of my research I believed that its main ethical concern centred on the establishment and preservation of the anonymity of the participants. This would be ensured by not referring to any detail or description that could lead to the identification of any participant in the final report. As all participants would be familiar with the conduct of ethical research, I supposed they might have had their own preferences or requirements for engaging in

interviews and accordingly I was willing to engage in negotiating around any personal requirements.

NHS 'Research and Development' approval was not required as no interviews were expected to occur on NHS premises or involve NHS staff (or patients). Ethics approval for the study was thus sought from the relevant REC at the university where my research was registered. This being the University of Hertfordshire's Faculty of Health and Human Science's Research Ethics Committee for Nursing, Midwifery, Social Work, Criminal Justice and Counselling.

A participant information sheet was prepared (see Appendix 3), and signed informed consent was to be sought from each participant prior to the commencement of each interview and after ensuring that participants had had at least seven days to consider their agreement to be interviewed. Participants were to be reminded that they did not have to answer any questions they did not wish to and that they might withdraw from the interview at any stage – in both instances without having to explain themselves. Interviewees were to be offered a token sum in appreciation of their time and trouble. This was to be paid by a Charities Aid Foundation cheque which could only be cashed by a registered charity.

Once I "had ethics" (as all researchers say when their research proposals have obtained approval from the ethics committee) the

interview stage of the research could begin. In the next set of chapters I report the principal findings of those interviews. The first of these chapters looks at the broader issues of lay and expert membership including how recruitment to the roles is organized; what has sustained motivation for membership; and how members understand the functions of the two roles. Following that, the next chapter concentrates on how the committees function – looking at roles in relation to science and safety; how ethics theory and guidance materials are utilised; and how the adequacy of insurance levels are assessed. The third findings chapter concentrates on members' training and education for the roles, but also includes an important, if parenthetical section, which I offer as a form of counterbalance lest any reader form a biased perception of IEC members which I recognise might otherwise inadvertently arise from the presentation of other findings.

6. Findings: 'lay' and 'expert' membership

6.1 Introduction

The literature review revealed a scant, almost non-existent, knowledge-base concerning independent ethics committees, and a limited one about the internal working practices of RECs in general. Such deficiencies, as has been seen, have partly been due to the confidential deliberative processes of ECs generally, exacerbated in the case of IECs by the commercial confidentiality surrounding pharmaceutical research. Partly they are also due to the concomitant fact that the work of the IECs has been conducted in a small and closed community which has largely avoided attention. Although there has been some important research carried out in the UK and elsewhere, the majority of the research undertaken on the internal workings of ECs has tended to be United States-based and/or has now become dated.

The research reported here not only brings matters up-to-date, but also addresses, from an emic perspective, how members of UK IECs have understood the paired roles of expert and lay members. An emic perspective is that of the 'insider'. I was able to engage at this level because of my membership of the very type of EC that this research concentrates on and my resultant familiarity with the key issues and many of the concerns shared by members. This chapter, the first of three that report the findings of the research, addresses this issue of the expert and lay roles in an attempt to explore what is distinct about the two roles. The

following two chapters go on to understand the broad areas of responsibility that the committees address (chapter 7), and the extent to which training and education are required for the roles (chapter 8). The themes explored in these three findings chapters derive both from the literature review which suggested them as key topics of interest to the overall research question, and in part they emerged during the research itself.

The particular themes surrounding the expert and lay roles that are addressed in this first chapter of the findings set of chapters are best appreciated as a whole. However, to aid analysis, the themes are presented discretely under the following heads (i) recruitment and retention; (ii) member categories; (iii) motivations for continuing with the role post-recruitment; and (iv) how members conceive the two roles of expert member and lay member.

6.2 Recruitment and retention

Interviewees had been members of an IEC for up to three decades. The mean length of service was 9.4 years (lay members 10.4 years; expert members 8.4 years). Table 6.1 below illustrates the length of time the different interviewees had served on their IEC.

All members were recruited to their EC via a personal contact. Even where the position had been advertised – and this has only begun to become the practice relatively recently – it was the fact of a personal

contact that had been decisive in the appointment. Any recruitment advertisement for an EC will tend to have a limited circulation, often on the practical grounds of cost-effectiveness. Even whilst it is being displayed this is largely for form however as a parallel recruitment strategy will also typically be undertaken by existing members of the committee who will be encouraged to consider approaching those they know who might be interested in joining the committee (on such a practice see McGee, 2009, 2010; and Humphreys, 2010c).

Years	Expert	Lay
<5	4	3
6-10	4	4
11-15	0	0
16+	2	3

Table 6.1: Interviewee length of membership on IEC

All interviewees lent credence to the view that it is not necessarily what one knows so much as who one knows that enables advancement. Members were typically ‘headhunted’ by those already on the committee who knew them, in a personal or professional capacity, as potentially interested, probably knowledgeable and/or not obviously difficult, and possibly available at a convenient time. Expert members typically took charge of matters:

A very good friend...who was a member said 'we're looking for another physician, with experience of an ethics committee, would you be interested?' (E12).

I've also got two of my protégés on the committee (E02).

Lay members were also typically identified by an expert member, and of my sample none had been recruited by a lay member. One lay member who had been a clinical trials 'guinea-pig' was recommended for IEC membership by a Principal Investigator (PI), and recalled: *"Someone [expert member] just phoned me up and said would I like to be on it" (L01)*. Another lay member knew a senior member of a pharmaceutical company and *"he rang me up one day to say they needed a lay member [and put me in touch with an expert member on the Committee]" (L07)*. A further lay member explained *"I was approached by one of the other committee members [named expert]" (L06)*.

It was the expert members who had established the committees and it has been these who have tended to become committee officers (Chair, Vice-chair) too.

6.3 Expert or lay?

As all interviewees had 'professional' backgrounds, and because professionals have recruited colleagues and friends for committee positions over the years, and because those recruited have tended not to

surrender their positions, the committees even today characterise the British middle-class society as it did even several decades ago. In this respect they might be said to reflect the composition typical of NHS RECs which have similarly appeared to struggle to reflect the changing ethnic background of the UK (Department of Health, 2005b; Simons et al., 2009). All interviewees were thus, at least phenotypically, identifiable as 'white-British'. Eighteen of the 20 interviewees were over age 50, and eleven were male. Demographically therefore they were representative of the population of interest.

Not all participants could be clear about whether they fell in to the 'expert' or 'lay' category of membership. Initially this was surprising and indicated that IEC roles might not be as dependent upon expert or lay status as initially supposed. For categorization purposes in this piece of research the unsure (or unconvinced) members were recognised on the basis of their status as given in their committee's then most recent annual report (2009/10).

Interviewees spanned a spectrum ranging from those who believed themselves to be very clear about their role status, to those who were far more uncertain and even rather unconvinced about their expert or lay status. Of those interviewed, only the medical members (doctors/ dentists) interviewed could all place themselves into the expert category 'clearly', but even here there was some evidence of discomfort with the term.

Well I'm only a professional [...] using the term 'expert' [...] may not be fully accurate. You are only up to the standard that you are in your profession. Are you an expert above other members of your profession? I wouldn't class myself as an expert above other members. I'm just equivalent to other members of my profession (E13).

Amongst the nurses interviewed uncertainty as to their designation was evident. Other lay members, whilst recognising their label, nevertheless felt they had valuable expertise to offer too:

[Even though] I'm often asked questions about my perspective and I have some insight I'm not regarded as an expert member (L01).

Although recorded as a 'lay' or 'expert' member in the annual report and for 'official' purposes, the categories had limited practical value:

[W]hen I am in the lead role I am usually under the heading 'expert' because I understand the science [...] I don't really care what you call me ['expert' or 'lay']" (L11).

I'm supposed to be an expert but...well I haven't got expertise obviously (E14).

[T]he terms are a bit elastic (E20).

Of the two role categories (expert and lay), toxicologists could be found in three categories as one interviewee was unable to decide with which category to align, suggesting that even the 'official' record of their status might not be wholly reliable:

[A]ctually, I might be in transition to expert because I've some involvement with clinical trials... the actual tipping point is involvement with clinical trials.

No statisticians were interviewed, nor were any such members of an IEC during the period when interviews were being arranged. Whilst potentially eligible for an 'expert' status, such a role is not particularly pertinent to the type of protocol seen at an IEC meeting where the research looks primarily at establishing the safety and tolerability of the novel compound.

A hearing aid dispenser - or any other member of a profession allied to medicine referenced by article 5 of the Health Professions Order 2001 - by contrast would be deemed a healthcare professional and so whilst still practising would be regarded as an 'expert'. Thus an 'expert' member need not have relevant clinical or research experience. With the exception of doctors and dentists who are regarded as experts 'for life' (i.e. even decades after retiring), healthcare professionals such as pharmacists and nurses are only regarded by the clinical trials regulations

as 'experts' whilst they remain in practice. However it is unclear how much practice is required to maintain the status. For some professions, registration with the professional body - such as the Nursing and Midwifery Council - could be regarded as a basis because that requires evidence of practice. Other professionals, such as pharmacists, can set themselves up in a consultancy role, never really retire, and remain on their professional register. They can thus keep a claim to their 'expert' status. This pharmacist, in a rather circular fashion, believes that being on an ethics committee,

Keeps me right up to date with developments. I learn a great deal (Expert, pharmacist).

Equally, in addition to being uncertain about their expert or lay status on the committee, several interviewees admitted to being equally uncertain about the status of their colleagues. Interviewees were thus not apparently aware of the detail of the legislation that defines and regulates the composition of the committees:

I'm 99.9 per cent sure [the committee] only have the one lay member [me] (L10).

[T]he retired nurse I would count as an expert really, I don't know, I don't know her official title. I'm not the Co-ordinator, I don't know

who is an expert and who is a lay person but I would count [the retired nurse] as an expert (E20).

I: What about [your committee] now, is it chaired by a lay person?

R: Let me just think... [long pause] No (E18).

I: You must have more than two lay members, haven't you?

R: Oh, perhaps we have...How many are you supposed to have?

About three or four? (E08)

I: So what's a typical lay member on your committee, is there such a thing?

R: Um, well, I suppose they are mostly people who are clerics, I would have to look through our list of attendees to see who is down as 'lay'. We've got quite a few nurses...? (L11)

Thus the evidence here suggests that official member roles are not regarded as crucial to the operation of an IEC by the members, who remain untroubled by their or their colleagues' designations on the committee.

6.4 Motivations

When asked what had motivated them to join their committee, many interviewees referred to the personal contacts that had initiated their membership. Outside of the research ethics committee community few had occasion to be aware of the existence of IECs at all. Such

committees were largely unknown even to members of NHS RECs. In such circumstances advertising committee vacancies has not been a straightforward task – not least has been the question of where one should advertise to best effect. To circumvent this difficulty, as many interviewees were able to testify – and as has been noted - traditionally members have been headhunted, rather than being personally motivated to seek out and join a committee. So why did they continue to serve on these committees once they had experience of them? Their answers ranged from the purely altruistic to its opposite.

I think it's interesting, it's not a huge demand on my time, it's contributing in a very small way to medical progress, because I have a background knowledge I haven't found it a problem. It's as simple as that. I mean there are people who come on [to the committee] who have no background who seem perfectly happy to do it (E04).

I really enjoy it. I don't enjoy seeing what the post brings for it. I just find it very interesting...and there's the charity side of it of course (L17).

The 'charity side' referred to here, reflects the fact that the members of IECs, although volunteers, have not done their work gratuitously. For their committees there have been numerous overheads that have needed covering such as indemnity cover, administration,

training, travel costs of members and so forth. IECs have charged those seeking an ethics review of their protocols and the pharmaceutical industry has thus paid for the services of these independent committees. Any 'surplus' has been distributed amongst committee members to donate to one or more charities of their choice.

[W]e had always met and donated the money to charity every few months. You know each of us would have a thousand quid or whatever to donate to charity and we could split it I don't know £800 to one charity, so much to another... (E08).

This position ended when AAPEC took over the managerial and appointment role for the IECs in late 2007. At first AAPEC was unwilling to pay members anything over and above their expenses, but the volunteers were quick to point out that the necessary expertise would not stay where it went unrewarded and they initiated negotiations over the matter. According to one interviewee:

In the end AAPEC said 'OK we'll pay £50 a protocol.' We basically said, we don't want £50 per protocol because that's like piecework, a plumber gets more than that and we'd rather not be paid than be paid per protocol. We're not on piecework, a lot of our work is involved in looking at...er...monitoring premises, doing site visits, doing amendments to protocols, looking at advertising material er and a whole range of other activities as well as the protocol so we

said we could have a meeting which we used to do where we had no new protocols but we had a three hour meeting looking at amendments, looking at safety reports, looking at end-of-study reports all of this and so what we then, we made a very strong case to the AAPEC board. What we said was take the average number of protocols over the past five years and pay that. And our average worked out at four times £50, £200 per meeting. For those who attended. And that's what happened (E18).

This amount was in payment to both expert and lay members equally and coincidentally was the same amount as Hedgecoe et al. (2006) had noted members of Swedish RECs received. Ironically though, instead of receiving a sum of money made payable to a charity of the member's choice, with the arrival of AAPEC, charity payments were deemed too administratively complex and eventually all members had to be paid directly so that tax and national insurance could be deducted at source. Even this situation could not be sustained however, and members were surprised to discover a changed set of arrangements set out in the revised *GAfREC* (Department of Health, 2011):

4.3.9 REC members are unpaid volunteers. RECs may not charge an application fee or seek any other financial contribution or donation for or on considering a research proposal for which their review is required... Members receive no payment for contributing to the review of applications at scheduled meetings or for attending such meetings.

As one informant had already noted though, whilst “[members of] *the NHS Committees don’t get paid*” (E14), NHS REC members who are employed by the NHS had the time they spent on the committee and any associated training classed as ‘official duty’. GPs and dentists, who are not normally employed by the NHS but who are more typically self-employed and contracted to provide services for the NHS, may obtain payment for locum cover whilst on committee work and whilst undergoing approved training. Non-NHS staff who are members of an NHS committee by contrast do not get paid for their time or effort. Any such people are likely to be retired lay members. IEC members were not paid for attending training but they were paid for attending site-specific assessments. The situation could be described as convoluted, although, as another interviewee was keen to point out, “*all these things about Independents [IECs] being grasping isn’t true*” (E20).

In April 2011, just as paragraph 4.3.9 was announced, it was also decided that the (NHS/IEC) Chairs’ honorarium would increase to £3500 per annum.

As most members (whether expert or lay) had referred to their charity payments as a significant motivating factor in their continuing with the role (many being members of long-standing) it was of little surprise that the withdrawal of payment resulted in the dissolution of the AAPEC committees with their functions transferring to NHS committees from October 2011.

6.5 Roles

Despite there being tension about undertaking voluntary roles for money, interviewees were sure that there were distinct roles for members. The experts were thought to comment on the science involved, whereas the lay members were thought to put themselves in the role of the volunteer and consider if the information to be given to the participants in the information sheet and in consent documents fairly represented the reality of the situation so that participants' consent could be properly informed.

For the expert I think it is an evaluation of the science behind the proposed study... What I am looking for from the lay people is to catch the things that the layman is not going to understand in the consent form (E12).

However, despite a generally held view of there being at least theoretical roles, in practice the distinction was never held and any distinctions broke down in several ways. Firstly, although an expert member could include virtually all clinicians, interviewees tended to conflate 'expert' with 'medical member' thus suggesting the latter group held a privileged position:

Well...the experts are there purely because they do understand the medical side of it and you must have that if it's a medical problem,

you can't possibly expect lay members to make decisions on medical questions without any background knowledge at all (E04).

The interview sample was thus clear that the experts who mattered were those who could say something about the investigational medicinal product (the test drug) – this might be from a medical, pharmacological, or toxicological point of view. Typically this was in terms of either experience with the specific drug or with the class of drugs to which it belonged. No other expertise gained recognition in practice and this despite a ubiquitous presence of nurse members who are potentially recognised as belonging to the 'expert' group in the governing legislation. It was thus clear to the members *what* the expert role was – even if it was less clear to many of them who the experts *were*. (Toxicologists are not classed as 'experts' by the legislation, but often have been considered as such by IECs notwithstanding this fact.)

Another way in which any role distinction was essentially 'technical' rather than practical was that no group wanted to be restricted. Thus for the expert members there was no desire to confine their roles too rigidly, and they wanted to be able to comment whenever so minded:

I think everybody has got to look at everything really (E04).

The thing is, I don't think the role is as distinct as may be [members on] other committees might think, I don't know if that is the case. I

guess that you might say, and people may have said to you, that the lay members play a bigger role when it comes to deciding whether the language and the content of the volunteer information document, or whatever you want to call it, information sheet whatever, is couched in such a way as to be intelligible easily to prospective volunteers and that may be more of a lay thing but I don't think that happens too much at our committee. I think the expert members have a say, quite a big say in the way in which the volunteer information document is written (E20).

As the experts took an interest in the information sheets, the lay members might also involve themselves in the drug's mechanism of action:

I'm also interested because of my background in how the drug is working and what the outcome is going to be and I find that very interesting and, but I sometimes have to struggle to keep up with some of the toxicological and all the rest of it as I suspect most of the committee does...I want guidance from the experts on the committee (Lay member, former nurse).

I've occasionally looked up the drug for myself and raised questions about dosing levels, side effects, whatever, purely because I couldn't understand the logic behind the plan (L01).

This latter quote, whilst not the typical perspective of a lay member on an IEC, nevertheless demonstrates that as the issues raised in committees tend to be standardized ones involving these sorts of matters, and because the relevant logic is always presented in either the protocol or the investigator's brochure, both of which accompany an application, given time, lay members can learn the process for determining whether a drug protocol is likely to be 'approvable' by their IEC. The lay member here is also revealing how central to the IEC's ethics review is the science.

Whilst lay members are typically expected to deal with matters such as the 'readability' of the information sheet, and are not *expected* to comment on the drug's pharmacology they may do so if inclined and feel capable of doing so. The following excerpt demonstrates that, over time, there is often almost an expectation that all members will come to see the review in the same process-driven way:

I: How does that differ from the lay person's role?

R: It doesn't, it's both. But if you are the so-called expert on the committee there's certain things you have knowledge of that the lay people may not simply because of the work that you have done in the past, so you come from a different angle...

I: But going back to the expert role on the independent ethics committee, what is that role?

R: There is a wide variation [...] the separation into lay and expert seems to be a bit odd in some ways [...] we've a wide spread, and

it seems a little bit arbitrary at times when it is decided whether someone is an expert.

I: ...I wonder how that differs from the role of the lay member?

R: It doesn't, it doesn't

I: Is there any differences in roles – expert, lay – in looking at the informed consent documents?

R: No, I think once people have been on the committee for any length of time [...] we ask each other, can you add anything? (E16)

Similarly, the expert member cannot be artificially divorced from his or her membership of the human race and thus cannot be excluded from having a view on any matter that might interest anyone. The expert member is inevitably effectively a 'lay member with more'. Thus there cannot be a rigid demarcation as to who does what unless the expert member was given an explicit (and thus effectively a veto) function.

This expert's experience though had suggested to him/her that the lay members cannot be relied on to fault-find the readability of information sheets:

I often read more closely the patient information sheet which isn't written clearly or as much in layman's language as perhaps it should...

I do wonder quite how the lay people fit in. Some people go through and find typos and things like that, word-smithing, frankly they don't know much, well nothing about the pharmacology when it comes to procedures and what goes on. They pick that up over time I suppose, given time, but it is a bit hit-or-miss really. A strange set-up, an ethics committee (E08).

E08's reference to the importance of pharmacology indicates a key role for science and other experts emphasized the importance on their committee of their scientific backgrounds.

You need to have a very good knowledge of pharmacokinetics; you need to have a good knowledge of pharmacology (Expert, pharmacist).

A toxicologist is vital, according to one toxicologist, in order that the committee can *"interpret the animal tox[icology] data because a lot of medics can't in fact do that terribly well"*.

[Y]ou look at the specific drug and based on your background knowledge you [...] make a reasonable decision as to whether it's going to be reasonable to use it at the dose that they suggest or not [...] safety is rather crucial (E04).

Indeed safety is very much a concern for the whole committee as the following quotations demonstrate.

I: What are expert members looking for?

R: Basically the safety is huge [... you need to] know that what they [the sponsor, the personal investigator] are saying has been researched and they're not just saying [so...] we have to... [ensure] just as far as we can see everything has been covered from the safety point (L09).

[T]he main concern [for the IEC] is the patient or the subject. The subject's safety is the number one priority [...] So the first thing is, what I think that, I think what the lay people expect from the experts are...is the information with which we have been supplied at this moment, adequate to allow you – experts – to believe that the protocol doses are reasonably safe? (E12).

I aim to make a useful contribution to their safety and managing risk (E13).

To ensure that the [trial will be]...definitely safe, safe for the volunteer... (L14).

But always coupled with the safety aspects is the scientific rationale:

We have a strong consensus for if the science isn't valid it isn't an ethical trial so we have to find at least a reasonable scientific justification before we'd approve a trial (E20).

[W]e can interpret most of the scientific stuff and look to our experience with similar drugs (E02).

Yet there are occasional clues that the concentration on the science and safety of the research reviewed in IECs may be over-emphasized:

[W]e might pick up something fairly obvious (E12).

It's been put to us...that we should look to the validity of the study, is it justifiable and the answer is always 'yes', is the design going to accomplish those objectives, and the answer is almost always 'yes', we almost...take them as read, we have debated them occasionally but they with us are rarely a problem. Then you say is it safe? And that can be a debate at times...but generally safety isn't too big a problem. The real difficulties we have...is the communication of the information to the volunteers where we can get tied up in minutiae (Toxicologist).

6.6 Chapter Summary

This chapter investigated member roles and found that a number of members did not know whether they themselves, or which of their colleagues, were an expert and who was a lay member, and thus could

not be clear about whether there were particular roles for the different member types.

Whilst both expert and lay members get involved in deciding if the information sheets adequately express the reality of the trial, the scientific rationale for the trial and its associated safety connotations privilege the opinion of those advocating the medical model approach. This means the experts – and within this group, the medical members – are the key actors. It was this group too that was found to organize the committees.

In the next chapter the findings of how IECs performed their specific tasks in coming to an opinion on the ‘ethics’ of research are presented. In this a privileging of science was seen.

7. Findings: the committees at work

This chapter concentrates on how the committees have functioned. The particular themes addressed are (i) how the committees have understood their role in relation to science and safety; (ii) whether, or to what extent, members employed particular ethics theory approaches and articulated ethics review guidelines; and (iii) how the committees ensured the adequacy of trial insurance arrangements. This chapter also addresses the concept of 'dignity' as an issue of committee responsibility.

Whilst each interview addressed all the themes reported on in these findings chapters, emergent themes also arose which, practically, could not be discussed with all interviewees. One particular additional theme that arose during the interview phase of the research concerned the concept of 'dignity' as an ethical issue in research. Because this topic arose following some national debate about the issue after the interview process had commenced, only eight of the 20 interviewees could be asked about this concept.

7.1 Science and the MHRA

For eighteen out of the 20 interviewees, issues of safety were always the main concern, and thus a distinct role for their IEC to police. Their committees addressed safety very carefully by ensuring that the trial was scientifically sound; that the drugs involved were administered at a dosage level commensurate with either what the toxicological data or

previous human studies had indicated was a likely safe initial (often sub-pharmacological) dosage level; that dose escalation levels were appropriate for the type of molecule in question, that procedures were in place for monitoring any adverse side effects, and that appropriate stopping rules had been established. All interviewees were clear that no protocol would be approved by the IEC unless the members were satisfied about the trinity of the science, safety and methodology. All of these specific matters were considerations that the Medicines and Healthcare products Regulatory Agency (MHRA) have had within its established remit to consider when it has looked at the proposed identical protocol that the IEC was considering. So given all this, what did members believe to be the role of the MHRA?

I: What's the role of the MHRA?

R: ...I haven't really looked into it (L14).

I: Well what do you think the role of the MHRA is, if it's an ethics committee's role to look at the science and safety?

R: [long pause] ehm...

I: I didn't say these were all going to be easy questions.

R: No [laughing]. I think, I think, erhm.... The MHRA... I've never worked with regulatory bodies so I don't know the details but from what I understand they have erhm physicians, statisticians, ...erhm some lay people... they have expert chemists, ...pharmacokineticists,... toxicologists, veterinary surgeons and their

task, I think, is to review all the animal data...to ensure that as far as possible, the next step of taking the drug into man is reasonable (E12).

There was universal uncertainty about the role of the MHRA amongst the interviewees, which raised the question of whether there was potential for 'double jeopardy', with the ethics committee replicating a role that the MHRA was specifically constituted to address. Interviewees however emphasized the need to ensure safety, and had no concerns about 'double-checking'.

We're looking at it only in as much as we've got to make sure that the protocol defines what doses are going to be used and why doses have been picked and that those are sensible doses and that the escalation rate is sensible. Now the MHRA do this as well (E03).

I would hope that they [MHRA] are [...] looking at the drug profile [...] But I don't know [what they do] is the answer. They must do, mustn't they? I wonder...whether they look at it [the research proposal], you know give a kind of broad-brush approval and then leave us to read the small print and sort out some of the typos ... do you know what I mean? (E08).

In part this double-checking could be attributable to an uncertainty about quite what each party – the IEC and the MHRA – was to contribute

to the trial application process, even though interviewees acknowledged that the MHRA was there to check the science, safety and methodology of the protocol.

Er...well... the MHRA are, they are looking at the safety of the molecule, they are looking at the animal work, they are looking at, we hope, the science and methodology (E18).

Well obviously that is technically the role of the MHRA; they are the ones who should be reviewing safety of drugs. However the MHRA are not infallible. (L01, making reference to the Northwick Park incident where both the MHRA and an NHS REC approved the protocol.)

Another lay member whilst acknowledging that the MHRA was officially supposed to look at the science and safety behind the IMP argued that the MHRA were “so new to it” after the Clinical Trial Directive that they could not be relied upon:

[T]here was actually very little experience in the MHRA of looking at the data for Phase I studies (L11).

When pressed, respondents had difficulty in providing credible justification for their committee’s involvement in considering the science of the protocols:

I: Well what do the MHRA do that expert members on the ethics committees don't do, or vice-versa?

R: I think it's a grey area. I mean the MHRA obviously have defined responsibility, [and] they are looking at a much bigger dossier of information [too] (L05).

I: [S]o there are two groups looking at safety?

R: Two groups. Yes.

I: Is that the intention, do we need both of them?

R: I think we do, I think we do because some ethics committees are not as on the ball as we are and therefore I think it is a good idea. You can't have too much checking (L09).

R: The expert members generally are those who are able to look rather further into the detail of what is being asked and presented and in effect to back-up MHRA in trying to work out whether there is any wool being pulled over anybody's eyes...

I: The experts are there to sort of act as a backstop for the MHRA?

R: Yes. Now this is one in which I am still finding out as I go... [T]here is always the possibility that there is something they [MHRA] miss that our experts will pick up (L15).

The expert members were just as uncertain:

I: [So] whose role is it to look at the safety?

R: Yes it seems two people [IEC and MHRA] are, and maybe one could say that is a double safety-net...I am still unsure of where the ethics bit fits in versus... assessment of toxicology, safety data, the science of it (E13).

Well it is double checking in a way, there's no way around it (E20).

The MHRA is very hot on stopping rules and so is our committee and that's one of the areas where there is overlap (E03).

One toxicologist agreed that “we can leave it to the MHRA to make appropriate decisions on the science and safety” but elsewhere in the interview acknowledged personally looking at these very issues in some depth on their IEC. Indeed the consensus view, if there was one, was that even if there was ambiguity about whether the MHRA should have the role of being responsible for the science, safety and methodology, it was still the role for the IEC too.

One ‘expert’ though did emphasize a slightly different understanding of the main role of the MHRA and suggested that it was the MHRA’s role to look at the protocol with more attention to the facilities and skills available to the research unit where it was proposed that the trial be undertaken:

They [the MHRA] scrutinize the proposed protocol or study. They have to satisfy themselves that the unit that is carrying out the

study is capable of doing it and have good practices for all the various things that are involved in the study and that can vary from study to study. They have a role in inspecting the units as well and ensuring that they have Good Clinical Practice and good methods for everything, so that is their role and periodic inspection to make sure that the unit keeps up its standards as well and to investigate if anything goes wrong in a trial whether there was any set-back in standards or anything like that (E16).

Thus the members – both expert and lay – were demonstrably unclear about their committee’s role in relation to science/safety and its overlap with that of the MHRA. However it was at least ‘probable’ that their committee’s role was to be satisfied about the science, safety and methodology of the protocols, and that if this was the case then this was ultimately in the ‘experts’ domain.

This was the key difference between the expert and lay members. The findings were indicating that the experts (and generally the medically qualified) decide whether the trial should go ahead in their traditional peer review professional approach to the science. They approved or rejected proposals. It was thus, as was seen in the previous chapter, that lay members are expected to concentrate more on the information sheet and consent form and whilst their concerns could cause a non-rejected protocol to be subject to provisos, it was the expert view of the science-safety-methodology tripos that was crucial and even though this was also

considered by the MHRA. Arguably ethics have not been a feature of IEC review.

Nevertheless, even where other areas of potential concern which may be more distinctly – and perhaps less controversially – attributable to the IECs, an absence of clarity persisted, as the next following sections demonstrate.

7.2 Ethics

If the members of IECs – both expert and lay – largely believed it was their role to ‘ensure’ the MHRA’s job was done properly (by duplicating the MHRA’s role) and so also sought to review the science (methodology) and safety aspects of the trial, how did they regard the ‘ethics’ issues, which must have been for the members of the IEC alone?

The evidence suggested that the ethical (as opposed to the scientific) aspects were immaterial to the committees’ deliberations:

I: When you look at a protocol do you have any particular ethical approach?

R: I’m not in any school of philosophy or ethics. I just look at it from a fairly broad view and decide whether it’s safe or not...I don’t think that ethics comes in to what we do a lot to be honest. We’re basically just making sure that these drug companies don’t do dangerous things (E04).

Debates about ethics hardly apply [it's more about the science and safety...]In Phase I we are not taxed by what most people think of as ethics (L11).

I'm not sure about the ethical aspects (E02).

In contrast, one member actually complained that expert colleagues strayed away from issues of ethics and concentrated on the science:

[T]here was almost power-play between different experts on the committee. ... [T]he terms of reference should be clearly displayed if not electronically through a projector... [they] should be sent out with every pack to remind committee members what it is they are there to consider (L10).

Although this member (who was cited earlier as indicating that he or she understood him or herself to be the sole lay member on their committee) was unique in some ways, the immediately preceding quotations also demonstrate that ethical issues, as distinct from issues of science and safety, did not feature prominently in IEC discussions.

Another member, who acknowledged having learnt ethics theories as a student, was asked:

I: [Have you been] able to bring in any of those theories into play in your Phase I ethics committee?

R: No, not really (L15).

And with this the respondent gave signals that the interview should move on, presumably feeling that there was no role for an ethics theory approach in IEC review. Indeed, throughout the interviews with both expert and lay members it was very clear that ethics theories do not feature in IEC discussions, and that science is privileged.

7.3 Guidelines

Despite there being a plethora of guidelines available to help ensure ethical research, how EC members utilise that guidance has been unclear. Eckstein (2003) had referred to the existence of several hundred such guidelines. In order to gauge awareness of the breadth of medical research ethics guidance amongst the interviewees, the researcher noted that the three most frequently mentioned in the literature are (i) the Declaration of Helsinki (“Ethics review in the UK is largely based upon the Declaration of Helsinki” (Academy of Medical Sciences, 2011: para. 8.2.1) as subsequently endorsed in para. 5.3 of the revised *GAfREC* (Department of Health, 2011)); (ii) the International Conference on Harmonisation – Good Clinical Practice (E6) (ICH-GCP, henceforth GCP) because it is ubiquitously cited in pharmaceutical protocols presented for ethical review; and (iii) Beauchamp and Childress’s *Principles of Biomedical Ethics*, because this is often said to be the *lingua franca* of ethics review (at least in the West). Although personally familiar with this

latter work, my own experience was that few fellow EC members had heard of it. Yet because it has been so frequently cited in publications on research ethics, an awareness of it might still be a reasonable surrogate marker for someone's general level of reading around the topic. Awareness of the work could thus indicate some wider research ethics reading whereas no awareness would indicate little, if any, extra-curricular reading.

The following lay member, having acknowledged some ethics training as an undergraduate, was asked if familiar with the four principles approach of Beauchamp and Childress:

R: O yes. I've read it all.

I: What's the four principles approach in... [Respondent cuts in]

R: Pass. It's gone in one ear and out the other (L15).

Similar responses were obtained from all the interviewees, thus again indicating a limited expectation that any debates which address wider aspects of matters from ethical viewpoints were likely to have occurred in IEC meetings.

If members were largely unacquainted with this classic, if not wholly uncontroversial, research ethics work they were also largely unaware of the other 'classics' selected as representative of the field, such as the Declaration of Helsinki or GCP. This was the case whether

the interviewee was an expert or a lay member, as the following illustrative quotations demonstrate.

I: Well in your reading have you come across things like the Declaration of Helsinki, Good Clinical Practice, the 'four principles' approach, anything like that?

R: Yes.

I: [Waiting for more]

I: Well, when you look at a protocol do you consider those principles at all?

R: Yes I suppose so. More subconsciously now than actively I suppose. In what way are you thinking?

I: Well, sometimes you read something that more or less says, implies, that the four principles approach is the approach that all ethics committees everywhere follow, and yet my experience is that no committee follows it.

R: Well they probably don't (E08).

I... [D]o you follow any particular ethics theory approach? Are you familiar with Beauchamp and Childress? The 'four principles'?

R: No.

I: No? What about theories of ethics? Do you follow any?

R: Well... in terms of do I apply any particular theory? No. Have we received any training in that? No. Would training in that be beneficial? A question I should ask myself, well, obviously, yes.

And I don't see anyone else [on my committee] applying particular sets of ethical theories. As members we read the material and it's just a gut reaction. Does this seem right? (L01)

I'm not sure the Declaration of Helsinki and its various updatings still exists (L11).

7.4 Virtue ethics

Given that so few members of ethics committees (and none of the interviewees) acknowledged engaging in debates in which theories or principles of ethics were brought into explicit discussion in committee, I considered whether, perhaps in an unrecognised way, notions of virtue ethics were employed in IEC review. As a minimum I wanted to know if ethics reviewers attempted to take a view of the character (or 'virtue') of the principal investigator whose protocol they would review.

Interviewees had acknowledged that their committee originated to serve one particular research organisation, and that the situation changed with the introduction of the Clinical Trials Directive. In the light of this Directive, IECs could no longer remain (independently) tied to one research organization and typically physically moved their meetings away from the host pharmaceutical research site and accepted for review studies from any researchers. These relocations were intended to signal greater independence, but potentially meant that the committee members would not know the investigators so well and thus would presumably find

it harder to determine their character and suitability as a researcher. Virtue ethics concerns itself with a person's character, and could help address this matter. For this reason it has been the practice that the investigator's curriculum vitae is requested by ECs as being potentially helpful to committee members in obtaining some understanding about the investigator. It will say something about his/her experiences, research interests and level of training amongst other things. However all interviewees saw the résumé as another formality which apparently added nothing to their review.

This interviewee was not unusual in seeing both the insurance certificate and curriculum vitae in similar lights - as something to be checked off, but no more:

All we are doing is saying yes. We're ticking a box. And similarly with the CVs of the investigator. Tick (E03).

7.5 Insurance

Not all interviewees saw the matter of insurance as appropriate for a perfunctory act and agreed that it was an area of difficulty for them. The fact that “[w]e're not insurance experts” (E20) was evident from all interviewees.

I think it's very important [coming to a view about the level of insurance cover arranged for the proposed trial] but I place my full

trust in colleagues on the committee because they know more about these matters than I do (L09).

I trust that the other members of the committee are dealing with that aspect, I hear the comment 'Is insurance in place?' and the response is 'yes it is'. I don't ask the figure. I haven't specifically thought about it myself (E13).

Another respondent, acknowledging that it was the ethics committee's responsibility to ensure an appropriate level of insurance was in place, also acknowledged that there were no guidelines, and that no one really knew how to go about it. IECs had been awaiting guidance for, at the time of interviewing, some eighteen months.* In the intervening period members had felt that the best that could be hoped for was that the committee make:

sure [...] as much as possible that the volunteer knows what the position is with indemnity [...] Everyone is sort of hanging up in the air a little bit [ahead of the guidance] (E16).

Insurance documents are always looked at; they are sort of global documents often out of date. We pick people up on expired documents, but I don't think we have ever said 'no' based on the

* Guidance was finally published in late June 2012. See <http://www.nres.nhs.uk/applications/guidance/phase-1-trials-guidance/?entryid62=143941> (accessed 13.7.12)

amount of cover... We've never [...] rejected any trial based on them (E08).

Some informants though felt the review of the adequacy of the insurance in place for the trial was not a responsibility of the ethics committee:

I would have thought the responsibility for insurance should be the responsibility of the MHRA (E03).

7.6 Dignity

During the period when the interviews were being conducted, NRES announced a review of its 'mission statement' - that NRES committees are to protect the health, safety, welfare and dignity of participants in research. Although this review was subsequently abandoned because it was thought to potentially conflict with the independence of the Academy of Medical Science's (2011) review of health research in the UK carried out on behalf of the new coalition government, opportunity was taken, as and when a situation arose, to ask some of the interviewees about their thoughts on these terms. Some interviewees could not be asked because the issue arose after they had been interviewed, others were not asked because the topic did not fit in well with the interview. Of the 20 interviewees only eight were asked about the notion of dignity, and in hindsight inadequately so in view of its complexity.

Although ‘dignity’ is a multivariate concept (Humphreys 2010d), in Kantian terms humans have dignity because a price cannot be placed on their worth – the very fact of their humanity means they are uniquely valuable. Whether others view dignity in this way may of course be questioned but because in Phase I studies there always exists this potentially undignified element of paying the participants, the term seemed to have a valence in Phase I ethics review where members of the committees are obliged to look at the amount offered to the study subjects in exchange for their participation and cooperation. There is however no record of an IEC having ever prevented, or even delayed, a study on the basis of questioning the sum offered to subjects and so I believed it would be interesting to know whether members understood dignity in this Kantian sense.

One informant believed the broad-term phrase about ‘safety, health, well-being and dignity’ derived from the European Directive (in fact the phrase pre-dates the Directive), and that dignity meant:

[N]ot asking volunteers to do something that they feel uncomfortable doing, medically or whatever, treat the person the same as you would want to be treated yourself (L05).

For E13 dignity was about “*caring, ... integrity*”, and for L06 it was about recognising the subject as “*a human being with emotions...under levels of pressure or perhaps doing something which could be potentially*

embarrassing, or uncomfortable...”; L01 saw it as treating the subjects “in a way which doesn’t embarrass them, which doesn’t abuse their goodwill and the fact that they are volunteering, that makes sure they have a certain standard of comfort, and also don’t take advantage of them”. L09 too took dignity as about respectfulness for the volunteers’ feelings (as did E14 and E03). Unsurprisingly, none of the interviewees was really clear, and they could not easily distinguish wellbeing from health or from dignity, and safety for them was allied to health too. None of them though chose to relate the idea of paying a participant for engaging in research with the notion of dignity, and the NRES mission statement was not referenced by any in the subgroup of interviewees with whom it could be discussed.

7.7 Chapter Summary

This chapter has revealed the findings concerning the IEC’s work – members’ (preeminent) engagement in science/safety, their lack of knowledge of ethics theory, their non-adherence to guidelines, their difficulties with ensuring adequate insurance, and their lack of clarity concerning terms such as dignity, welfare and the like. It has indicated the absence of a clear structure of approach for members, so, in the next chapter, in the final part of the findings chapters, attention is turned to the training that members have received for their role and to how they regard member training and education.

8. Findings: training and accreditation

In this final chapter of the set of findings chapters, members' opinions of their research ethics training and education, which might be supposed to have prepared them for their respective roles, are presented. The chapter then moves on to illustrate members' views of how their training and education might be developed in the future.

8.1 Training and education

According to the original version of *GAfREC* (Department of Health, 2001) current at the time of interviewing: "5.6 As a condition of appointment, a member must agree to take part in initial and continued education appropriate to his or her role as an REC member". This is clarified in a member's letter of appointment as meaning at least one day of annual training each year. The commitment is not rigorously enforced but rather relies instead on an honour-code. Members were asked about the extent of their participation in the training made available to them.

I: In your [almost two decades of IEC membership]... have you found any training of any use?

R: I haven't been on any, and that's not because there hasn't been any provided it's just that it didn't fit in with my work (L09).

L09 was not unique in not having attended the obligatory 'regular' training expected of members. It was a minority who had been to at least

one training session over the period of their IEC membership (the average length of membership of the interviewees exceeded 9 years). This lay member had been only to an initial introductory day course:

I don't think it made any huge difference to me... I can't say it particularly changed my view in any way (L06).

Another member recalled going on Phase I-specific training when first appointed but nothing since and certainly nothing about 'ethics':

I haven't. No I haven't actually. I suppose in the beginning it was time...so ...no I didn't. Um. I'm not sure there seem to be too many general ones [courses] (L05).

For others the training they have attended was so far back in time that they could not recall its content, and the interviewer's line of questioning presumably pricked some consciences as one member admitted to "*beginning to feel a little guilty*" about this (E02).

But that member was by no means atypical in terms of how engaged he/she had been with training over the period of membership:

I've not been for ages...a long time ago. Gosh...years ago (L07).

When I joined the committee there was no training available, well you observed at one meeting and then at the next meeting you were in (L11).

This interviewee however was not the only one who felt the training was unnecessary, believing “*my knowledge of clinical trials was enough not to require it*” (L17), and similarly

[B]ecause I’ve grown up in the business you see [...] there’s not [...] much that NRES could provide for me. On the other hand the courses that are provided can be very valuable for people who are coming into it as a true lay person (E03).

This might sound terribly, terribly...contrite, egoistic but I’ve been in the game long enough now and courses are only for new people coming in, they are good courses but they are no value to me (E18).

Presumably such assessments of the usefulness of the courses were made, not on the basis of actually having attended any courses personally, but rather reflected experiences of (those few) colleagues who had attended. Some though had attended and found they got little from the training:

R: I went to a one day meeting in [location] in my first year after joining the committee [...] I thought it was poor.

I: What was the subject of the event?

R: That's a good question. I've no idea.

I: Well you must

R: If you can find out, let me know [...] I wanted to go on a formal course to see where I might be hopelessly weak (E12).

Several members had only gone on what they described as 'relevant' training:

[S]uch training as I've done so far has been entirely on the context of Phase I trials and IMPs (L15).

Three interviewees had been on a course run by the Clinical Contract Research Association, a trade body which exists to promote the interests of Contract Research Organisations and the pharmaceutical industry in the UK. The course was highly regarded by those interviewees.

It's supposed to be a conference but it wasn't really a conference it was a course and they gave an indication of what, the first time ever I've heard it as to what they would expect a Phase I ethics committee to talk about and how they should structure the meeting... (L11).

This 'Cambridge conference' was residential and ran for some eighteen years between 1992 and 2009 at one of the Cambridge Colleges, usually at the end of September and lasting for two or three days. Typically it comprised a series of plenary lectures interspersed with streamed classes of which participants could select two from eight. These conferences proved very popular with those members who attended, although one interviewee complained of:

... endless lectures. I think you can have too much quite honestly, sometimes it's totally irrelevant and sometimes...I think as with anything, you do have to keep up to date, and I think all members of a committee should attend a course every...that's why I'm going on one later in the year because I felt I have not been since I went to Cambridge [three years previously] (E04).

Not all members of IECs could afford at least the time (or inconvenience) incurred by attending such training events, and a major part of the problem which was voiced by all of those interviewees who were in employment (inc. self-employment) was that:

[T]he problem is ...[our] jobs, some of us are self-employed and the difficulty is, if you are self-employed, during the working week... you can't just take a day off work to go to training. Most of which is some distance away. London particularly. It means taking, well

more than a day off because of having to go down the night before and staying overnight and returning late the next day (E19).

[O]bviously everyone has busy lives [...] And most training is in days and most people are working, to take a day off from work. For those working in the NHS fine [because approved training leave is classed as working time and no pay is lost...] but for half of us that wouldn't apply. I mean I'm self employed, if I take a day off I'm losing money, all I get back is my expenses [...] another member who's retired goes quite frequently...they have the time (L01).

Part of the reason I haven't gone to anything more [...] is because I think a lot of it is not particularly helpful, and when you look at an agenda, particularly when you live ...[a long way from London], well, you could get a night out in London, but generally it's so far away you think of the disruption to work usually, as it's never fallen on a convenient time and that's partly why I haven't gone on more (E08).

At initial training, some interviewees felt there should have been others from their type of committee if they were to have got best value from it, yet “*there was no one else on our type of committee*” (L06). However this point of view was probably reflective of the expectation that particular committees should look at particular issues, such as the science

involved. This though was arguably based on a false, or at least controversial, premise – that ethics committees should always review the science – as it wholly discounted the role of the MHRA or whatever other appropriate independent scientific review had been undertaken before any research proposal was submitted for ethics review.

Thus few members actually went on the training provided except perhaps the induction training for new members. However at any one time there have been few new members on an IEC. The non-attendance was not clearly related to the member's expert or lay status – although there was a belief widely held by members that experts did not need to go on training because it would offer them nothing they did not already know. A major non-attitudinal obstacle though was the failure to pay members to give up a day of work or annual leave to attend. For this reason, as a few interviewees noted, it was those members who were retired who were more likely to attend training events.

8.2 Competence

In the USA it is possible for members of ethics committees – 'Institutional Review Boards' (IRBs) - to become 'credentialed' members. Interviewees were asked whether a similar practice might have helped either give more role clarity to the expert and lay members, or at least helped them as individuals, and thence as whole committees, to see the bigger picture of research ethics review.

In the United States, IRB members may study a syllabus (see: www.primr.org/certification) covering the history of research misconduct, ethics review guidelines, and the extensive federal rules regarding the ethics review process. Candidates can then sit a multiple choice examination which, if they pass, is demonstrative of their knowledge of research ethics review, and consequent certification would be valid for three years. Certification can thence be maintained either by demonstrating continual education in research ethics review or by successfully re-sitting the examination. Interviewees were asked if they believed British IEC members would be interested in a similar approach to ethics review training and education.

Given that training events had just been discussed as largely an irksome irrelevance (at least for some), surprisingly most of the lay interviewees expressed enthusiasm for this latter approach:

Yes it could be interesting. Very interesting indeed. Probably the sort of thing which is worth you or somebody raising with [AAPEC] as a possible training for all the committees (L15).

The expert members, whilst not dismissive, were though distinctly less eager for the idea, and raised more caveats:

I suppose initially it is important that everyone knows why they are doing it, I mean you can't just join and pretend, be carried along by

everyone else... but the more regulation you have I think, the more life just gets complicated (E04).

[I]t depends what the syllabus was... [but] I think there is merit in [the idea] (E18).

I don't think it addresses any ethical issues but it does address a quality issue [...] training can be quite important...but I'm not keen on...multiple choice format. Some form of training where there was some sort of assessment at the end, but not multiple choice, would, I think, be quite useful (E20).

The evidence of these interviews also suggested that the topic of training had not been greatly discussed on committees:

[I]t would raise the standards ...[however] there might be a transition period when members of the committees felt it wasn't worth it and you might lose people who have quite long expertise in ethical review (E13).

Well, seems like a good idea but I get the impression that certainly new members tend to go on training whereas perhaps those who have been doing it for years, decades, tend to think that the training is not for them for whatever reason. Certainly fewer older ones go for training in my experience from my committee. They've largely

picked it up on the run which is what I did when I started. But I think there is some merit in the idea; it must be quite interesting for the lay members... I would have liked something like that when I first started especially if I was a lay member (E08, again suggesting that the role is perceived to be about science/ methodology rather than matters of wider ethical import.)

This member's proposal for an exchange of members in order to spread good practice caused the researcher to make a subsequent enquiry in which no one could recall such an idea ever having been operationalized in the three decades of IEC existence. This suggested, again, that training had been overshadowed by other, presumably more pressing, priorities:

In principle I have to agree because it's good. We should swap members or let members sit on other committees to observe and criticise and so ensure good practice becomes the norm (E02).

More than any other single topic discussed, the issue of training and certification generated a more engaged level of response, indicating that the matter was something that members had real feelings about, although these feelings may not have achieved full clarification in members' minds. That training was an issue that members had personally – if not collectively - thought about was indicative of role uncertainty.

I think education is an excellent idea and I think that this is the thing rather than, because within each particular committee you've no idea how new members are inducted in, about whether they have a mentor to help them through the first few protocols [...] so I think certainly education is an important thing however as you're no doubt aware is that we are a number of very small committees, and it's getting smaller each time around, the only thing that does worry me somewhat is that already on the courses going, a lot of it does not apply to, does not really pertain to us, a lot of the training is directed towards NHS committees particularly, and to involve and enthuse people really the training has to be directed, has to be targeted towards them... But I also have to say that I do believe that a standard training throughout all of the independent committees would be a good thing but I have to look at both sides to the coin there (E19).

If members believed that training was a potentially important issue, this did not exclude the possibility that some members understood that such training should address science and safety matters. Unless the training addressed 'research *ethics*' there thus remained a potential for each member of a committee to address the same points in review as the separate independent scientific assessment body arranged by the sponsor would do, and to the exclusion of a wider ethics agenda. The

following member was not alone in suspecting that training could result in a rather inflexible review process:

R: That's an interesting idea. I don't think it [training] would be a bad thing... The down-side, but I don't think it's a serious downside is that everyone will begin to think in the same way whether you like it or not but that can be overcome.

I: Another criticism might be that, well do volunteers want to do, sit an exam?

R: They might not want to but it might not be a bad thing. I know one or two members of our committee who come in, say nothing, pocket the money and then disappear, because I don't think they can make a contribution. And you think, that's not right is it? They are very pleasant people with, maybe very sincere, but just not there...The benefits far outweigh the downsides" (IEC member).

This latter quotation was telling in that the "*I don't think they can make a contribution*" indicated – again - that there was a perception that an ethics review in Phase I committees should be about the science.

If members were to take the view that the science and safety was in fact the responsibility of the MHRA and sponsor, the role of the ethics committee would need to shift to address something else. If this something else was to be a wider *ethics* agenda then there was no reason why such '*very pleasant...very sincere*' members cannot be 'there' for the

non-science and ethical aspects of research. Such a situation was perhaps how things were originally envisaged by those who advocated lay involvement in ethics review. (Many of the Nazi doctors' medical experiments were, after all, methodologically sound, but just simply ethically atrocious.)

It was possible that all the experts' comments (and several coming from lay members) about 'credentialing' (as it is termed in the States) can be read, in retrospect – regrettably not noticed during the interview phase - to have indicated, again, that it was an assessment of the science and safety that was the IEC's prime role. Lay members however appeared to perceive, albeit uncertainly, that there could be some scope for extending their role – if only they knew in what way it could be extended.

Thus, overall, the greater enthusiasm for the 'credentialing' approach amongst lay members compared to the expert members, and despite both groups' near-derision of the training days, can be accounted for (albeit speculatively) by the promise that it might grant the lay members credentialed (but not 'expert') status or at least a clear role.

8.3 Chapter Summary

In this chapter, together with the previous two, which collectively make up the findings chapters, several key discoveries have been made. Chief amongst these were that science and safety were the crucial issues determinative of 'ethical' acceptability in IEC reviews, notwithstanding the MHRA's role in more expertly assessing these very features of the

protocols. Another interesting finding was that members were neither very clear, nor did they appear particularly interested in, who amongst them had the expert or lay designation. Simultaneously however they were very supportive of a medical model approach towards review even to the detriment of wider ethics matters. Training and guidance were found to be regarded as essentially unnecessary because the relevant experience and knowledge, it was thought, could be gained by simply observing colleagues in committee and thereby picking up what needed to be attended to. However the current chapter has also indicated that if the training was authoritative, followed a syllabus and was 'credentialed', this could give definition to member roles in a supportive manner hitherto unattained.

In the next chapter the findings reported in this and the previous two chapters are explored further in a discussion which relates these findings both to the extant scholarly understanding of EC roles and procedures more broadly, and also to the literature on professions.

9. Discussion

Having presented the study's findings in the previous three chapters, it is the turn of this chapter to relate those findings to the existing relevant scholarly literature. In order to help ground the interpretation presented here, the sociological understanding of the professions is additionally recruited for its insights and upon which to fasten the emergent thesis.

The research reported here contributes to the scholarly study of RECs in two main ways. It is significant on one level because so little has been known about the workings of ethics committees in general (Citro, Ilgen and Marrett, 2003; De Vries and Forsberg, 2002; Hedgecoe, 2012a; Speers, 2008; Stark, 2012; van den Hoonaard, 2011) and this is the first detailed account of the workings of IECs. On another level the research identifies the prevalence of distinct uncertainty held by IEC members about several core areas of ethics review. Such uncertainty as to role has been observed in relation to other ethics committees (e.g. Dyer, 2004; EULABOR, 2005). The current research though broadens the range of matters where the uncertainty is seen to exist, extends it into IECs, and also offers an explanatory account for this uncertainty.

This explanatory account draws attention to the medical ('expert') dominance on IECs and argues that all the findings reported here are consequent upon this feature. As this feature shares much of its topography with Freidson's theory of professional dominance discussed

earlier (chapter 3.3 above) it is appropriate to compare the findings of the current research with that theory. Freidson's theory (1970) has been seen by some to have fallen into disuse due to the rise of other competing professions, with the inroads made by managerial impositions (such as evidenced based medicine, performance tables and targets) and with the access to wider knowledge permitted by both the internet and a more educated general populace. Dingwall (2008a) for example alludes to the theory being considered an obsolete one. However Dingwall was simultaneously able to revive it by suggesting the addition of a 'control function' feature. By this he drew attention to the medical profession still having a key role as a gatekeeper to other services, professions and resources. The doctor had to refer the patient, and so medical dominance was still extant.

What the research here shows is not the Dingwall-variation but the continued existence of the original Freidson theory of professional dominance in action. This may be accounted for by noting that the IECs (and indeed RECs) have existed in unreconstructed form since they were first created. They were modelled on committees that grew up in the 1960s (Hedgecoe, 2009) and so were part of the scene Freidson was then witnessing.

In IECs, practices were seen to have been shaped, not by the wide knowledge or experiential base of committee members as a whole, but just by the activities of a single profession. The expectations of the

medical model are thus seen to have become fundamental in ethics review. This finding supports the idea that professional dominance has survived in certain niches, if not more widely, and thus invites consideration that the theory is not 'obsolete' as Dingwall (2008a) has suggested it has sometimes been perceived to be. This finding also supports other research which has noted the fate of, for example, social science review succumbing to the disciplinary expectations of the medical profession rather than those of social sciences (Schrag, 2010, 2011; Van den Hoonaard, 2011). However this finding must be treated with caution as Hedgecoe (2008) has demonstrated that it is not all (even NHS) RECs which are anti-qualitative research.

Although specifically addressing the situation of IECs at a particular juncture in time, this research offers an approach for considering too the workings of other RECs. This is important because society relies on these committees to sanction human subject research and so such committees have an important role in shaping health research and the general scientific progress society makes.

Society reasonably expects that clear objectives should guide the committees, yet the evidence presented here is that this expectation is unmet.

9.1 The members' roles

The research sampled an equal number of expert and lay members. What became obvious and surprising very soon in the

interview process and data analysis stages was the proportion of members expressing their uncertainty not only about what their roles should entail, as Dyer (2004) and others had found, but also even about their role *designation* or that of colleagues, and often of both. Members were unsure whether they were expert or lay members. The literature review had not anticipated this finding.

NRES has agreed that a problem has been identified concerning member categorization and I have offered a potential solution which involves NRES no longer relying on asking for a would-be member's *curricula vitae* in order for an NRES member of staff to deduce the appropriate membership category. In future members are to be requested to complete a simple algorithm form to demonstrate their membership category (see draft at Appendix 4, and Humphreys, in press).

In part this finding about role designations can be accounted for by the fact that a non-medical clinician is regarded under NRES policy as an 'expert' until five years after giving up practice, and thus some interviewees could simply have been uncertain about where they were on this timeline. However, on pressing interviewees this proved not to be a significantly causal issue in the situation. As was seen in the findings, the issue of 'expert' and 'lay' hardly arose in the committees and so members were simply not obliged to consider the matter. No duty or role in relation to any specific aspect of the review was formally incumbent on members by virtue of their expert/lay position on their committee. Instead though it

was regarded as self-evident that members would generally address those issues they believed they were capable of addressing by virtue of their professional or life experiences: thus expert members would critique the science (method/methodology) implicit in the protocols.

All members could comment on the participant information sheet (PIS) simply because they could all read it for themselves and decide if they understood it. Lay members however could choose to pay special attention to it, and its clarity of expression. When asked about the main purpose of the ethics review the respondents unanimously cited the importance of the safety of the study. This was regarded as particularly a matter for those with a medical or allied background (e.g. pharmacy, toxicology). The medical model was thus seen to remain dominant in review, just as it always has been (Freidson, 1970; Nicholson, 1993).

When interviewees were asked to relate the role of their ethics committee to the role of the MHRA they universally acknowledged that the latter body had the legal responsibility, and the greater technical competence, to adjudicate on the science involved in the drug trial. Members however then struggled to explain the specific role of the ethics committee, or to justify the dominance of a scientific review within a committee established to address the ethical concerns that might underpin the proposed study, *given* that the MHRA was to concentrate on the scientific (methods, methodology, safety) aspects of the study. Although some commentators have recognised that the science of studies

has often been the main emphasis in ethics review, such findings (e.g. Cheung, 2007; EULABOR, 2005) were made in situations where there was no specific body (such as the MHRA) having a separate but specific involvement, or where the science had already been subject to an independent competent review. As such the findings of uncertainty of role *vis-à-vis* that of the MHRA (several years after its establishment with that role) represents an important new finding.

9.2 Medical professional dominance

To begin to account for this phenomenon of there being a conflation of science review with an ethics review, it is pertinent to note that so ubiquitous are medical members on the relevant ethics committees that the legislation does not even find it has to stipulate them as being necessary members. It has been almost unthinkable that they were not to be members of such committees. Indeed no NHS REC or IEC has operated without their presence amongst the membership, despite this being legally possible (Art. 2(k) Clinical Trial Directive requires only 'healthcare professionals' – these may be nurses or members of professions allied to medicine). In the case of IECs, medical members (as defined in sch.2, para.3(5) of the Clinical Trials Regulations, S.I. 2004/1031) comprised more than half of all expert members (see Appendix 2b) and as such could be described as the modal member. In NHS committees they also form the majority of expert members (see Appendix 2a) despite the ostensibly easier availability of other clinicians in the NHS setting. Even in situations where, for unusual (or simply sick-absence) reasons, no medical member has been available on a quorate

REC, the REC members left still adhere to the profession's medical model approach to the review – so the medical members retain a ghostly presence even in their physical absence. The medical profession thus keeps control of the ethics committees that adjudicate on the ethical appropriateness of all medical trials. And this medical control, via the medical model, extends beyond medical trials. According to Schrag “[i]n the United States, at least, committees [IRBs] treat the Belmont Report as a guide to all research ethics [and not just biomedical research]” (2011: 125). Such a situation can be explained by, and gives credence to, Jones’ (1993) claim that “[r]esistance to lay control ... [is] the cornerstone of [the profession of] medicine” (p.95).

Bond has accepted that, even in Britain, social science has been “unjustifiably mauled” (2012: 95) by RECs. He believed that such “[p]roblems are at their most acute when social scientists are reviewed by panels more used to biomedical research” (Bond, 2012: 111), thus implying that the lay members add little counterweight to the medical members on those RECs. Interestingly too he suspected that biomedical dominance may lead to both “conscious and subliminal influences in ethical reviews” (Bond, 2012: 98), indicating how pervasive the medical model had become. Again though, Hedgecoe (2012a) acknowledges this can happen, but reminds us that it is not every REC that operates in this way.

Abbott (1988) predicted defensive or even expansionary tactics being employed by the professions in attempts to secure an ever-tighter hold on any aspect of control over what their members could do. Indeed the broadening of ethics review beyond the field of biomedicine into social sciences and indeed anywhere where it is proposed to engage human subjects in research, demonstrates the success of the medical profession's strategy. That others have not formally drawn attention to Freidson's theory of professional dominance (1970) in this is surprising. However it is easily understood when one considers just how inaccessible the internal workings of RECs (and IECs especially) have proved to be over the years to the community of researchers.

This aspect of the ethics review process – that it has been dominated by the medical profession - is of significance. This chapter describes the evidence for this, and offers Freidson's theory of professional dominance (1970) and the concept of the professions (here the medical profession) seeking to take charge as providing an explanatory model for the workings of IECs (and thence other ECs).

This explanation also bears similarity in its structure, but not in its components, to a model recently introduced by Evans (2012). Evans' model argued for the existence of an influential 'bioethics profession' which exerts control over much of ethics review. He indicated that evidence for this included the number of university courses teaching the subject, its numerous journals and professional associations and,

especially, the widespread use of principalism. If his evidence was good in the USA where his focus admittedly was, it does not hold up so well in the UK where the evidence, for example, of awareness of principalism was noted to be almost non-existent amongst those involved in the research reported here. However his model need only be slightly adjusted (to recognise that the UK has not caught up with the US in terms of a bioethics profession) to note that the UK's medical profession has maintained control of the IECs (if not its RECs too). Also contrary to Evans' arguments for the existence of a powerful bioethics profession is that the research reported here noted a lack of training and education amongst members and it is also the case that few universities in the UK offer taught degrees in the subject. However both Evans', and a UK-adapted version of his model, share the imprint of the sociology of the professions, and especially the latter's notion that professions are about using abstract knowledge as a lever to control the content of debate.

Schrag (2010) has accounted for how members of the medical profession and their colleagues in the health departments of the US state government consistently and deliberately marginalized non-medical disciplinary concerns over ethics review, over decades, to establish the biomedical model of modern Western medicine as *the* model to follow in ethics review. This (US) model of ethics review as a biomedical model has been copied world-wide (Fitzgerald et al., 2006; Myser, 2011; Schrag, 2010). In this light then, it is thus unsurprising that qualitative research often encounters an (arguably) disproportionately rigorous review as its

methodologies are alien to those whose expertise lies securely in the quantitative research paradigm (on this see Boden et al., 2009; Bond, 2012; Dingwall, 2006, 2008b; Gunsalus et al., 2007; Hammersley, 2009; Murphy & Dingwall, 2007; Schrag, 2010, 2011 - and c.f. Hedgecoe, 2008, 2012a).

The medical member is always an expert member, yet the term 'expert' is problematic as the literature review indicated. It promotes a logical fallacy that suggests that because someone is an 'expert' then whenever they say something – especially concerning, *but not limited to*, their area of expertise – they must be correct: it is at least difficult for a non-medically qualified individual to dispute such an expert's abstract knowledge. By indicating a greater, almost unchallengeable, level of knowledge it marks those so designated as due a degree of deference which contrasts with those to whom the appellation is not applicable. Where discourse is controlled in this way (and professions were noted to be very concerned about 'control'), the experts' consensus wins out and marginalises other ('lesser') concerns. This was seen to occur so much so that interviewee L10 for example believed him/herself to be the only lay member on their committee because discussion was so dominated by matters scientific and medical. Such findings also support Stark's (2012) observations that professional warrants trump all other warrants.

In the nomenclature of ethics committees, 'expert' promotes the profession of medicine such that its concerns are accorded pre-eminence

and other, non-medical concerns such as the broader ethics debate to be had becomes marginal, an optional extra, to be accommodated if time and the inclination of the medical members permit.

Being considered an 'expert' enables one's pronouncements to be determinative. Hunter (2011) for example notes Confucius' belief that people react to descriptive titles. Thus the term 'expert', it could be argued, tends to inhibit the REC from acting ethically. As Black puts it:

“Defining an issue as one appropriate for pragmatic, technical discourse is at the same time a decision that deliberation should only occur between those who are competent to deliberate in a technical manner – it's a decision for 'experts'. Defining it as one appropriate for ethical or moral discourse broadens the range of deliberants” (Black, 2001: 45).

Someone who is accorded expert status is often accorded expertise in lateral aspects of their profession too – so a gynaecologist might well be assumed to have moral expertise in matters of fertility, abortion and even cloning. Indeed those so labelled are likely to come to regard themselves as experts and so perceive their knowledge as especially determinant in decision making. Thus the thinking is that as X, Y and Z are 'expert' members, what they say must be right, and as they are concerned with science/medicine/methods, that is what the IEC should be principally concerned with. Again this reprises another feature of professions - their concern not just about control but the allied notion of 'content'. Here the expert members are seen to privilege matters

scientific and especially medical as the appropriate content of debate in ECs, as distinct from ethical matters more broadly.

Indeed a lay member could succeed to para-‘expert’ status by talking knowledgeably about medicine/science – this is why the toxicologists were assumed to be in the expert category (and even though the legislation points to a lay classification for them). Other lay members could also demonstrate quasi-expertise if they could talk technically about medical and allied matters. Thus it does not actually matter on IECs who are the ‘experts’ - rather the *fact* that there *is* an expert group is enough as science and medical concerns code ‘expertise’ and such issues achieve pre-eminence in debate.

The findings of the current research thus indicate that Moreno (2005) was correct to suggest that it is the consensus *amongst the experts* on such committees that carries the decision and this even when they are not the majority grouping. Presumably if experts were significantly in the majority on a REC and the task seen as more administrative (e.g. deciding on the adequacy of the science or safety) rather than a distinctly ethical issue (such as whether to perform an abortion in particular circumstances) then voting might not upset the medical members’ sense of being part of a professional grouping, nor need it cause any lay members present to feel that there was any serious weakness in the structure of that profession). Thus, as Moreno

suggested, and as the research here finds, little can be *expected* to happen without the agreement of the medical members of the committee:

“Medicine is a consensus-driven system. That is, the practice of consultation among experts relies on a standard of intersubjective agreement, as is true of any practice that relies on scientific generalizations implicitly viewed as warranted. In an area like medicine, where objective information is often inconclusive regarding particular cases, consensus has an explicit role. But of all the committees in the healthcare institution only the ethics committee appears to be as consensus-oriented. One reason for this may be a widespread sense that it is unseemly to ‘settle’ ethical questions by a mere vote” (Moreno, 2005: 85).

If the experts on the committee are expected to come to a consensus (known as the expert opinion), then the lay members are at present automatically overwhelmed as it is the experts who form the majority in practice. For this reason – and the research here notes that the medical model’s advocates have formed the majority on IECs – there is again no requirement to refer to membership categories. The majority will inevitably succeed in their view, and so labels become redundant.

A proposal to split the committee such that there become specific roles for the ‘experts’ on the one hand and ‘lay’ members on the other can be seen to raise difficulties. Ethics committees function as a ‘committee’ and it is the consensus of the committee that produces the ethical opinion. To have a committee comprising of distinct roles or groups, with each grouping having its own objective can thus be seen as a potentially

unhelpful step, heralding fragmentation and limiting the opportunity to reach the necessary consensus. In such a scenario, a split decision could represent a blatant 'failure' for one side or the other to achieve their aims, and it would signal that the research was of dubious ethical merit.

Freidson's theory of professional dominance (1970) implied that in the dominance an imbalance in proper relationships resulted and led to the suppression of other views than those matters that the professionally dominant medical model would advocate.

Expert dominance is a problem where moral issues, as distinct from scientific issues, are at stake. For, whilst there may be medical experts, arguably (and see e.g. Steinkamp et al. (2008) for this debate) there can be no moral experts for there is nothing to be objective about with the notion of morality, and so no possibility of demonstrating that one approach is correct whereas another is incorrect. On IECs those members selected for their science/medical credentials are termed 'experts', and as experts their views predominate: they are deemed to be 'right' in virtually whatever they say, and permit. The term has power, owing much, as Hughes (1958) long ago observed, to the public relations successes of professions.

It thus follows that the terms 'expert' and 'expertise' are problematic in ethics review. 'Expert' indicates a distinct professional recognition of an individual's level of acquired knowledge in a given subject area. The

content of that knowledge constitutes the expert's expertise. Each term thus defines the other in a circular fashion. The conceptual linkage is made explicit by Freidson's (1970) professional dominance theory which notes that the knowledge-base which constitutes expertise is defined by the profession. The expert is someone who has a sufficiently high-level of expertise and this is typically 'objectively' evidenced by reference to particular sets of qualifications. Expertise is thus the property of the expert and so any notion of there being 'lay expertise' is rejected as oxymoronic under this model. However, if one can put aside the legitimacy of a professional dominance in a situation, one can reconceptualise expertise as being available to those individuals with mere access to knowledge rather than a professional background buttressed by a series of formal qualifications. 'Expert systems' or 'intelligent knowledge-based systems' provide examples. Such tools permit an 'expert answer' to follow from a given series of factual answers to a set of subsidiary component questions.

But such notions as expert and expertise, whether or not they include the 'lay' versions, tend to miss the point in ethics review if one can allow that an ethics review is separable from a scientific review. In ethics review the decision about what is morally the correct act does not require experts or expertise so much as mere humanity or sociality: competence as a socially-operating human is enough for such a decision-base.

The findings of the present research though confirm that it is still the science that is regarded as determinative, rendering other experiences marginal. In this the lay role on IECs is thus seen to have failed to achieve the expectations given by the Merrison Committee (1975) that lay involvement would “change the perspective of proceedings”, or by Hall (1991) that professional interests would be challenged, or even by Allsop and Mulcahy (1996) that more emphasis would be placed on deliberation about gains in knowledge versus potential risks to participants. The evidence here also confronts Hogg and Williamson’s (2001) view that there could be as many as three categories of lay person who might join a health committee as it finds only those of a single category - those supportive of the dominant interests. This must though be at least in part due to the controlling strategies used to select recruits and thence ‘capture’ the lay member. Indeed the notion of ‘capture’ can here be seen to have been either inadequately anticipated, if not cynically employed, by those who devised the REC constitutions as a tactic with which to confound the influence of lay members.

It is the influential nature of the very term ‘expert’, the concept of ‘expertise’, and that on IECs this expertise has been specifically animated by the model of medical science – as have been revealed in the current research – that opens up a new thesis which exposes the ethics review process as thereby potentially flawed because it is seen to be essentially a re-review of the science involved. The research has demonstrated the dominance of scientific considerations in ‘ethics review’ even though the

scientific, safety and methodology considerations are all the responsibility of another separate and decidedly expert body. An EC's emphasis on reviewing science which has already been reviewed is to ignore its own standard operating procedures and *GAfREC*, and is such as to marginalise lay considerations. In this the public are funding, but not obtaining, an 'ethics review' they may expect. The situation has arisen because of the medical professional dominance and that it is incumbent on these experts to perform according to their professional status (and when they are not instructed otherwise).

9.3 Recruitment

The way in which members were recruited has secured the experts' position. The research sample provided a consistent account of how individuals had been recruited on to their IEC: the recruitment approach was often initiated by an extant committee member ("I've also got two of my protégés on the committee" E02), and to this extent replicates Porter's (1986) findings. Although the data for this research had not been generated in anticipation of specifically seeking to establish which category of member acted as the recruiter, clearly potential members had to be acceptable to the committee as a whole and in this context it should be recalled that the medical members form the largest single professional group on the committee.

Neither the demography of the interview sample nor the general make-up of current committees suggests the operation of an extensive range of recruitment practices. Elsewhere I have noted the social

similarities (and consequent implications) of, on the one hand, members of IECs and, on the other, members of the research community (Humphreys, 2007c). Schuppli and Fraser (2007) noted that word-of-mouth recruitment is typical in the case of animal ethics committees too.

Membership of ECs is thus seen as representative of a rather narrow section of society, mirroring previous findings. Its dangers are illustrated by Fisk's (1980) argument that ethics are but class-created mechanisms for reinforcing extant social divisions. In this light, members of the medical profession are seen to be securing their dominance in the EC. An illustration of this occurring can be seen in the minutes of Welwyn Garden City's Queen Elizabeth II Hospital's medical staff committee of 9th July 1982:

"(5) Local Ethical Committee for Clinical Research:

[The Secretary]...asked the medical staff to reconsider their rejection of the proposed ethical committee. The medical staff agreed to accept the proposal with one alteration, that it should include three senior medical staff, i.e. medical, surgical and investigatory specialities."

Such evidence invites speculation that the medical staffs were to have considerable influence in what got approved in that committee and it is difficult to foresee lay concerns ever becoming paramount in any EC which has 'expert' designees.

In the current research, whether or not interviewees were in the 'expert' or 'lay' category, all had a professional background. All were (or had been whilst in employment and before retirement) eligible for membership of a professional body and, with the exception of the nurses, all had had a tertiary education. Not all members of an IEC necessarily have such a background, but the majority of them do, as they do in NHS RECs (Department of Health, 2005b). Earlier findings of REC memberships more generally (e.g. Department of Health, 2005b; Neuberger, 1992; Nicholson, 1986a; Porter, 1986) have noted the lack of ethnic variety amongst REC membership and although I did not specifically look for the ethnic category of my sample, my observations were not inconsistent with previous findings.

In this context, Groenhout's (2010) argument that European-Americans understand bioethics (ethics applied to matters of human biology within the Western tradition of medical practice) as essentially a reflective activity to be conducted in the comfort of one's home or office (i.e. private and mental) whereas for African-Americans it is something more appropriate to public settings is interesting. If there is indeed such an ethnic difference (and Bujo (2001) suggests there is), perhaps the latter would make for better members of ethics committees, but at present there is no empirical evidence in the UK for such a view. Similarly, no interviewee had an obvious disability (hearing aids excepted) although again this was not formally noted. The demographics of IEC membership therefore were seen to remain consistent with previous findings in both

the USA (Ghio, 1980) and the UK (Neuberger, 1992), where the higher level of education and the professional backgrounds of members of IRBs and NHS RECs respectively were noted. When one considers the manner of recruitment these findings are unsurprising: current IEC members have tended to be recruited by those they already know, and often from a time when British society was even more socially segregated than it is today. This all reinforces the position of the medical expert who can but find deference from the lay members.

It has been argued that such narrow demographic attributes increase the perceived distance of members from general society (Hinde, 2007). This restricts the range of issues that are likely to be discussed in committee (Humphreys, 2009 and 2010e), so favouring a more traditional view of society, which may not correspond with the groups which might like to participate in Phase I research (i.e. the lucrative trials). By representing such a narrow constituency, discriminatory practices can too easily be overlooked in ethics review (Humphreys, 2010c; see also Hunter, 2006). This too is a feature Freidson's theory of professional dominance (1970) predicted, for where professional dominance occurs other interests are easily pushed aside, and not necessarily in a manner obvious to those involved.

The consistency of membership has been a greater factor in IECs than amongst NHS RECs because in the latter the role has been linked to a member's career in a way that it was not on IECs. Whilst NHS staff were

regarded as 'at work' whilst sitting on their committees and so they have in effect been paid for their role, there has been no remuneration for retired members on NHS committees. Conversely IEC members were paid a stipend regardless of their employment status.

This payment may have contributed to the finding that interviewees had been on their committee for periods in excess of the ten year stated maximum time that NRES advises (*GAfREC* para. 4.3.2, Department of Health, 2011). Indeed, the present research found, just as Nicholson had, "[s]everal...long standing committee members...one of whom has been on a committee for nearly 30 years" (1997: 15). (When IECs closed in late 2011 some members had been on their IEC since its inception.)

Long-serving members emphasized their experience. Indeed, IEC members have approached reviews in a consistent manner over the years. Many acknowledged either never having had any training (other than 'observing' and then subsequently emulating what they saw the other members do) or but very little training, and then generally only in the technical aspects of Phase I protocols. In this they have not been required to keep up to date as their role has been perceived to be in 'steady state'. These findings can be interpreted to demonstrate another feature of the professions which was revealed in the literature and that is that they can be aggressive in developing their status against non-professionals, and also against other professions. An inter-professional hierarchy tends to arise, with doctors vying against all competitors for the

top position (Freidson, 1970). The medical profession has for example traditionally been seen to have tried to shape the nursing profession as having a professional duty of obedience to the orders of medical doctors (Burkhardt and Nathaniel, 2002; Small, 2010):

“The traditional nurse was expected to obey the physician, much as the wife was expected to obey her husband. Physicians demanded obedience, and nurses hesitated to disagree with physicians even if there was good reason to do so” (Burkhardt and Nathaniel, 2002: 166).

Although there was no evidence for such bullying, and none is suspected, it is nevertheless arguable that with the ‘expert’ status there is an expectation that medical concerns will find deference. This feature was seen to be of relevance in how the members under study were recruited onto their committees and again supports a view of medical professional dominance in review. After all, given that they are professionals, it is difficult to conceive of them wishing to dilute the very expertise that brought them to the committee by their then encouraging an alternative set of competencies and approaches to ethics review. This finding reflects Larson’s (1990) observation that the profession will have wished to keep its knowledge abstract and skill set intact and so emphasize ‘expertise’, and is further evidence of Freidson’s theory of professional dominance being in action in the IECs.

9.4 Safety first

The background chapter (chapter 2 above) explained the establishment of IECs as a consequence of the Declaration of Helsinki, the introduction of the Clinical Trials Directive as a harmonizing instrument within the European Union and the establishment of the MHRA as the competent authority established (1st April 2003) to consider the safety of proposed drug trials. That chapter also explored the model process of research ethics review and observed that a typical medical person's knowledge is most unlikely to be capable of adding anything to the science or safety of Phase I drug trials (Abadie, 2010; Hubbard, 2009; Petryna, 2009).

Despite all this, the findings of the research reported here demonstrated very plainly that members of IECs follow what has become known as the Georgetown mantra - that 'bad science means bad ethics' (Angell et al., 2008; Hunter, 2007b) - and insist they need to check the scientific adequacy of the proposed trial. Whilst it is undoubtedly true that bad science can mean that determinative results may not be obtained, and so resources expended on fruitless research will be wasted, which can be especially serious in Phase I studies where there is no prospect of benefit to a participant who is guaranteed only risk, this does not excuse the waste of time and opportunity created by an ethics review which emphasizes a re-review of the science at the expense of an ethics appraisal.

Dyer (2004) had noted that members of RECs are unclear about their role and suggested, whilst that remains the case, that it results in a waste of people's time and effort which in turn constitutes an unethical situation. The findings of the present study demonstrate that her findings persist.

The literature review demonstrated that the IEC could legitimately rely on the MHRA to adjudicate on the science and safety of the trial (e.g. Edwards, 2010a) and turn its attention to how the participants are to be treated, whether the insurance is at an appropriate level, whether certain groups of people are being unfairly prevented from participating in lucrative trials, whether the money on offer is too much (or inadequate), whether the information sheet is sufficiently comprehensive and clear, how incidental findings are to be dealt with, and so on. These are all more clearly ethical concerns yet are currently relatively under-emphasized in a research ethics review which, as the research reported here again demonstrates and reiterates, instead continues to concentrate on the science and safety of the trial – an adopted role which merely, if inadequately, attempts to imitate that of the more expert teams utilised by the MHRA.

Arguably such an approach represents a lower standard of ethics review and so constitutes a wasted opportunity which serves only to subject the sponsor to unnecessary delay and potentially further costs. Indeed it could be regarded as a situation of 'double jeopardy' which itself

might be regarded as unfair, wasteful and thus unethical. But it does perpetuate the experts' professional role, and as has been demonstrated in the literature review, professions are about maintaining position and status against competing interests.

Evidence was also found of lay members reporting that they had attempted to emulate the experts (attempting to assess the science and safety of the pharmaceutical protocols) and the experts wanted a say in assessing the participant information sheets. Such findings support EULABOR's own findings that "more than half...did not know the limits of their role" (2005: 6). It is unreasonable though to expect the professional to act unprofessionally and so if there is a problem with ethics review it may not be the fault of the experts, but of the system coupled with the nature of the professions as being (in part) about protecting members' interests. In the context of ethics committees, it is the dominance of the science, supported by the notion of 'experts', *where the science has been independently approved elsewhere*, that this research calls into question.

The professionalism of the expert – and most especially of the medical – members of the committees may be preventing an approach to ethics review that sees it as about ethical issues (as opposed to the science involved), as for that, what is required is debate, for:

"The Good ... is not a mere static thing, but a project – one that is undertaken, not by isolated individuals, but by social individuals, generally persons working together, even if often at odds... What

is...important is the quality of the deliberation... This underscores the fact that bioethics is a social activity” (Moreno, 2005: 60-61).

Evidence of expert/medical dominance was apparent throughout the interviews as no interviewee could conceive of not considering the science/medicine/safety of the IMP, despite all ultimately acknowledging that the MHRA both had specific responsibility for this and had more appropriately qualified staff and more information available to it. To recognise the MHRA’s ability in this matter would imply a concomitant recognition that the level of medical-model expertise in an IEC was excessive. This would be to betray the profession as a barrier against the entry of amateurs (such as influential lay members) on to the IEC.

As Caminiti et al. (2011) and others have also noted, technological and scientific progress is becoming increasingly complex such that any attempt to review it requires a level of knowledge and skill unlikely to be present on an EC. Thus several interviewees made reference to the Northwick Park incident as evidence that the MHRA was not perfect, but none could demonstrate that their IEC’s review would have been any better. Such findings indicated that it is at least arguable that EC review should no longer attempt to address scientific matters where the science is the known responsibility of another – better qualified, if not infallible – body. No special skills should be required for an ethics review which is to ensure the moral and social acceptability of the research proposed, yet – and ironically - training and certification could help demonstrate this, as will be discussed below.

9.5 Clarity or 'readability' of Participant Information Sheets

Whilst a focus of the literature on the ethics review process has concerned itself with the varying standards by which RECs 'improve' the grammar of the documentation presented to would-be subjects, the findings of the current study demonstrate that the process is not wholly a lay members' role. This finding was not apparent from the extant literature. That it is no one's specific role goes to explaining the varying quality of such revisionary activity. It is also further evidence for expert dominance. It is not the experts' obvious role to correct someone else's grammar and, in the model of expert-*scientist* dominance presented here, whether the task is performed, by whom and to what extent, becomes merely arbitrary. The only issue that really matters for the reviewers is the adjudication on the science. This is disappointing because it has been suggested that when the PIS are constructed, risks can be underplayed, attention distracted, inconveniences minimized and so forth (Lignou and Edwards, 2012; Menikoff, 2010).

The evidence of the data gathered in the present study indicates that the lay members believe their primary role – if they have one - is to ensure the documentation presented to potential participants by way of initiating 'informed consent' is likely to be understood by a typical volunteer (lay members cannot be expected to know if the PIS is accurate in its portrayal of the medical risks involved). However this role is always subordinate to the medical acceptability of the study. Neither do all IEC members have personal experience as clinical trial volunteers, nor do

their professional backgrounds suggest they have a greater ability to anticipate true volunteers' difficulties with comprehension than the expert members. The expert members are not however denied the opportunity to contribute to enhancing the clarity of the documentation (and it has been noted that distinctions in roles are rarely apparent on committees). Interviewees in this research were insistent that the safety of the trial was the sole determinative factor; anything else was thus effectively an optional luxury. Nor did the grammatical review ever extend beyond a subjective evaluation, despite the existence of objective tools to calculate 'readability' being freely available (Goldfarb, 2005).

By contrast, concerns about the science or safety can be referred to an external independent expert for an 'objective' opinion – even though the MHRA will also provide such an opinion. This route is now discouraged by the committee's standard operating procedures (SOPs), as seen above, and the facility is a relic from the time before the MHRA. Its continuance owes much to the fact that some applications coming before RECs (as distinct from IECs) may not necessarily have had an adequate independent scientific review (e.g. where the sponsor of a medical device is also its inventor and principal investigator (and see Humphreys, 2012a)). It is though also homage to the fact that ECs want the facility as it reinforces 'expertise' and the medical model, and they would use the mantra of 'bad science means bad ethics' to press for its continuance.

The contrast illustrated by the findings between the priority given to an (arguably) unnecessary science review and the consequent relative denigration of all other issues (such as 'readability') which thus effectively escape greater attention, illustrates the power of the committees. Whilst it is for ECs to decide what is ethical, when members take this duty beyond their remit (as given to them in *GAfREC*, their standard operating procedures, and their terms of appointment) they are, arguably, exploiting their power. Despite the presence of such guiding strictures, only members of an EC can know what is acceptable to it, and in this subjectivity their power becomes great indeed. They decide either to permit research to occur in a particular way, or prevent it altogether. Thus the findings of the present research would offer an alternative interpretation of the situation described by Juritzen et al. (2011).

Instead of the members' knowledge/power modality creating 'docile bodies' of researchers who go on to police themselves in accordance with what is created and legitimated by the committees as Juritzen et al. (2011) suggest, Dingwall (2010), Schrag (2010) and others have noted that researchers do not typically come to 'own' the ethics committee's stipulations. The findings from the present study suggest that it is not necessarily the *researchers* who are made into 'docile bodies', but rather it is the *lay members* on the committees who are made subject to the 'technologies of the self'. The lay members come to see the medical model of the experts as that which it is legitimate to model all research

and its ethical territory upon. Again the medical profession is seen in this analysis to have dominance.

9.6 Insurance

Although interviewees noted that their committees were in the position of waiting for guidelines on insurance which had been promised following the tragedy of Northwick Park, this did not answer the matter of how an IEC assesses insurance. IECs have been legally responsible (Art. 3, para 2(f) Clinical Trials Directive) for satisfying themselves about the adequacy of the insurance arrangements in place for clinical trials since before the events of 13 March 2006. Interviewees acknowledged that their committees have addressed this topic inadequately to date, with only luck preventing a situation of inadequate insurance materializing earlier than it did.

Clearly, insurance is not a 'medical' matter and because the committees have concentrated on the medicine or science, other matters – so the findings demonstrate - such as insurance have been overlooked, or treated in a cursory fashion because there was no guidance available to the IECs upon which to base any concerns. Again this finding that IECs have not known how to deal with insurance has escaped the attention of the literature but can be explained by the implications of the thesis that where there is a medical dominance other matters become marginalized (Freidson, 1970).

When the IECs were associated with a pharmaceutical company it may have been accepted by the IEC that the pharmaceutical concern's resources would be sufficient to cover any potential claims. Now, one may speculate, if IECs were lay - rather than expert-dominated, the question of checking the adequacy of the insurance would have occurred earlier in time because a lay-dominant membership would realise that the weight of ethical consideration was to be given to the participants' interests, and not to issues of scientific validity. Similarly if guidance had been available perhaps this would have steered committees towards concentrating their review towards issues other than the science and safety which are addressed by a more competent body. Again the dominance of the medical profession evidences itself. Interestingly too, when the guidance was finally published (ABPI/BIA/CCRA, 2012), the NRES guidance for REC members revealed that it had been "developed by the BioIndustry Association... *with observers* from NRES and the Department of Health" (emphasis added, NRES, 2012: 1). Again the advocates of the medical model are seen to be dominant in that relationship. In fact the guidance can be criticised as constraining RECs from voicing concerns, as it is easily envisaged that researchers or their sponsors might just point to the guidance as allowing the levels of insurance they obtain.

9.7 Guidelines

The literature on ethics committees often supposes that either one particular model of ethical reasoning is adopted by these committees or there exists a competitive "normative polyphony" (Shergold, 2008: vii) as

members vie to adopt their preferred choice from amongst the numerous normative guidelines that are available to the bioethics community. Eckstein (2003) indicated in excess of 350 guides as far back in time as a decade ago and Karlberg and Speers (2010) indicated that over 1100 laws, regulations and guidelines were extant to govern human participant research in some 96 countries.

Despite this, for many researchers it seems that when their protocol goes to an ethics committee it enters into a black-box of sorts, such that the outcome is unpredictable. The application process has even been described as akin to “a game...using a Ouija board... no one knows who answers or determines approval” (National Communications Association, 2005: 233). The four principles approach was intended to make the ethics review process clearer, even commensurate (Evans, 2000). It has also been claimed that principles-based reasoning (Beauchamp and Childress, 2009) is the model of ethical theorizing most widely used (e.g. Fox and Swazey, 1984; Macfarlane, 2009; Tranøy, 1990) and indeed that it has become the ‘lingua franca’ of bioethics (Grouenhout, 2010). Rawbone (2000) noted that ethics committees are obliged “to ensure research is conducted to acceptable ethical standards [a phrase apparently taken from paragraph 2.1 of *GAfREC* (Department of Health, 2001)] *using, for example, the application of the four principles of biomedical ethics*” (p.16, emphasis added).

Beauchamp and Childress's (2009) four-principles is a framework-approach for thinking about ethical issues in medicine and medical research. It suggests that virtually all ethical issues can be considered within the concepts of autonomy, beneficence, nonmaleficence and justice.

It was anticipated that interviewees might not necessarily favour the principlism approach (it being just one approach that might be taken), but that no interviewee was familiar with it was not predictable from the literature, and thus suggests that Evans' (2012) belief in the presence of a significant and powerful 'bioethics profession' is not supported by the evidence in the UK. Only three interviewees (two experts, one lay) indicated that they 'might' have heard of the component concepts when the researcher explained them, but none of them personally had used, or been aware of colleagues thinking in such terms in IECs.

The Declaration of Helsinki similarly is but one of the many ethics guidelines which are available to help ethics committees to do their work. The Declaration is referenced, as one of the interviewees phrased it, as part of the 'boiler-plate' seen in virtually every pharmaceutical-company sponsored protocol submitted for ethics review. As such members might have been thought to have read it and perhaps taken a view of ethics review from it. If they had studied it they might have recalled that it claims to be supreme of all ethics guidance (art 10) and all ethics reviews should be "in accordance with the principles of the declaration of Helsinki"

(Caminiti et al., 2011: 220). However the interviewees certainly had not read a recent version of it. Several interviewees believed it was no longer even published – probably being confused by the fact that it has been revised numerous times. Part of the confusion for some interviewees was that it is the 1996 version that is cited by the pharmaceutical industry. Again though, this represents a situation where ‘rules’ can blindly block members’ autonomous view of ethics (for another example in the pharmacy setting see Humphreys, 2012b). For many, ethics cannot be codified because, as discussed earlier (chapter 4.4 above), it is an inherently subjective notion. Despite this though the US Food and Drug Administration will only accept the 1996 version of the Declaration because it does not approve of the post-1996 versions, largely because these versions denounce the use of placebos in therapeutic trials. As two of the interviewees recognised though, the use of placebos in healthy volunteer (non-therapeutic) trials is not controversial.

The responses do suggest a significant proportion of IEC members would happily adopt the rules given to them by industry: they would be content simply for their ethics review to conform to industry ethics rather than represent a more socially nuanced moral stance. IEC members were content to rely on the industry-produced guide for ethics committees (Goggin, 2005) as instructive of what they should consider in an ethics review. There is irony in this reliance on the very industry to be checked itself instructing ‘independent’ ethics committees what it is they are to look for (Humphreys, 2007c). What the research here points to is that this

acceptance of such guidance is likely to be directly influenced by the reverence for, and be inculcated by, the expert members' interests and the concomitant status given to science.

This finding that guidelines are almost entirely ignored is interesting, and perhaps surprising. It can be accounted for though by realising that the IECs under study were still relics of the original IECs. They were bodies set up by members (but aided by the industry) to do what they thought best, and which eschewed much in the way of training and guidance, preferring to follow the professional interests of their dominant (medical) members. Instead they approached any ethics issues - or in reality all the issues they considered as it was difficult for them to decide what was an ethical issue and what was not – on the basis of instinct or gut-feeling. Such an instinctual response is really only suited for when “one has no time to think what to do, and so one relies on one’s immediate intuitive reactions; [although]...these give no guide for what critical thinking would prescribe if there were time for it” (Hare, 1981: 139). This instinctual response is also plausibly a factor accounting for applicant-researchers’ complaints that EC decisions are unpredictable.

A reliance on visceral, ‘gut’, responses rather than a stable, thought-through, moral framework and not even being aware of research ethics guidelines can be morally legitimate in that it can reflect honestly held, but possibly subconscious, attitudes. But it can also mean that decisions are likely to be capricious, and/or be prone to such a fall-back

position as is offered by the medical model which is ever present amongst the experts. Not being aware of such guidance on the one hand can suggest a lack of either commitment or engagement with one's role. Equally though such guidance can appear as largely superfluous if those present in meetings are content to rely on the medical model approach. The medical – or expert – approach to IEC review incorporates the Declaration of Helsinki within its medical ethics (it is authored by the World Medical Association) and thus the key requirements of informed voluntary consent are mandated with no further exploration of additional guidelines being considered necessary. In fact no explicit reference to Helsinki is required as its approach is taken for granted by the profession. Guidance beyond that offered integrally by the medical model is not perceived as necessary. This could explain Nicholson's (1986a) surprising finding that REC chairs were unaware of the guidance available to them, and their apparent continued avoidance of such 'external' assistance. It can also account for van den Hoonaard's (2011) observation that whilst REB conferences in Canada "proclaim the supreme validity of ethics codes" (2011: 98), individual members of such committees were rarely aware of a code's guidance and preferred to rely on disciplinary-inspired positions. Medical members by contrast can be expected to be well-versed in their medical ethics codes, as any failure to adhere to such codes can result in disciplinary sanctions.

9.8 Members' vague terms of reference

During the interview phase of the research it became apparent to the researcher that many of the interviewees had only a vague awareness

of the role prescribed to them by the mission statement of NRES. If they did not understand the terms of their mission statement, how could they articulate them in ethics review?

NRES's mission statement refers to the fact that RECs are to safeguard the rights, health, safety, dignity and welfare of participants. Such terms are known to be subject to misunderstandings (Seedhouse, 1998) – or at least different understandings will be held by different parties and individuals such that the terms cannot provide any real direction to those to whom such words are meant to give guidance.

Roy-Toole, a barrister and REC member, has argued that the duty to safeguard participants' rights requires the committees to protect the 'legal rights' of participants and he makes an eloquent case for this (Roy-Toole, 2008). However his view was declared "erroneous" in a joint letter of response to his article in the subsequent issue of the journal in which it appeared, when it was alleged that he had taken the term "out of context" (Taylor et al., 2008). The matter is however, for many, still shrouded in uncertainty – what, after all, is the relevant context?

Seedhouse (1998) is well-known for his exposition of the difficulties inherent in conceptualizing the term 'health', which, as he pointed out, had numerous meanings, so much so that it could be said to have no meaning other than the one agreed between those who choose to use the term.

'Safety' too is a subjective concept and, often under the heading of 'health and safety', has been used to put a stop to various traditional activities despite there having been no evidence of any harm ever having arisen from the activity in question. Children have been prevented from playing conkers in case the shattered seed damaged their eyes, and in the run up to the Diamond Jubilee of Queen Elizabeth II, local councils were reportedly refusing to put up bunting because it would necessitate 'stress-testing' the lamp-posts.

'Welfare' too is so unclear that, for example, despite being subject to a legal duty on all employers by virtue of the Health and Safety Act 1974 ("s.2(1) It shall be the duty of every employer to ensure, so far as is reasonably practicable, the... welfare at work of all his employees") – all the evidence points to a universal failure to understand what the legal duty might entail and it has never founded a successful prosecution (Humphreys, 2007a; 2007b). The term 'well-being' is increasingly used instead of 'welfare', but suffers from the same ambiguities.

Groenhout noted that such hard-to-define concepts as members of ethics committees are supposed to have regard for, require for "their definitions ... a variety of controversial assumptions about group membership, collective responsibility, and [even] the [very] existence of standards for defining [for example] well-being" (Groenhout, 2010: 224). Rawlinson (2010) went so far as to suggest that such abstract terms are in fact designed to deflect the attention of ethics committees from more

concrete duties. The findings reported here incline towards supporting these observations. Such distraction contrasts with the clarity of what the medical model advocates and so helps to suggest that as the model to concentrate on. The terms in the NRES mission-statement thus fail to provide an abstract-knowledge set capable of countervailing that provided by the medical model.

‘Dignity’ too is another abstract term which defies pinning-down (Harris, 1997; Humphreys, 2010d; Ida, 2004; Pellegrino et al., 2009). Several interviewees were asked about this term in particular and those who were asked tried to explain it in terms of a then current concern about mixed wards in NHS hospitals and the new government’s promise to eliminate the practice. The term had been chosen to ask interviewees about because it was felt to have potential to be particularly relevant to healthy volunteer trials if one took Kant’s view that dignity is so inherent to humanity that it precludes putting a price on any human’s worth. As such this could have afforded a discussion of how the IEC decided whether the financial inducement offered to the trial subjects was appropriate (and see Humphreys, 2010b, 2010f). On reflection, and from the experience of the interviews, the topic may have been either too advanced or optimistic a subject matter, or simply poorly managed. However it was clear that no interviewee was familiar with this philosophical notion. When asked about how they determine whether the payment on offer was appropriate interviewees all referred to the fact that their committee required the

sponsor to calculate payment on the basis of so much per procedure, per diem and so forth.

Another concept that 'dignity' could have conjured is the legal one of 'dignity harm' – the idea that one can be:

“wronged (even though not physically damaged) by having things done to them without their full understanding. If courts...adopt the dignity harm concept in the medical research arena, it would surely lead to a rapid increase in the number of lawsuits brought against researchers” (Menikoff, 2006: 194).

The limited data elicited in the present study though suggested that this notion had also not become a prevalent one amongst IEC members, and, with the emphasis on the medical model approach, this was unsurprising.

Despite the lack of clarity around these key terms, the out-going Chair of the Association of Research Ethics Committees was still able to claim that “[t]he main purpose of ethical scrutiny should be to achieve a balance between safeguarding the dignity and rights of the research participants...” (Anderson-Ford, 2010). He did not elaborate on the meaning of the terms, and the interview data reported here suggest that his audience, at best, would perceive such advice as vague – not wrong but not helpful either.

9.9 Ethicists

Just as Neuberger (1992) complained, some two decades ago, in her analysis of NHS RECs, no ethicists were members of IECs. Hunter (2007) has suggested that an ethicist is ideally suited to the lay role and Emmerich (2009) bemoaned their 'surprising absence'. One (lay) interviewee expressed surprise that formal ethics training was neither required nor particularly valued. Two (expert) interviewees however felt there was little scope for ethics in Phase I ethics review as both perceived the role of the IEC as being to do with science and safety – if the proposal passes those twin-criteria, for them, there would be no additional ethical problems to be addressed as everything else about the trials was perceived as 'standardised'. The other interviewees could only express uncertainty at best, which the researcher subsequently interpreted to indicate an absence of knowledge about the role of ethics. Hunter and Emmerich by contrast concur with the broader literature on bioethics which largely favours a place on such committees for sophisticated ethics consideration (e.g. Beauchamp and Childress, 2009; De Vries et al., 2009; Neuberger, 1992).

One problem that might occur with an official ethicist member on a committee has been pointed out by a feminist bioethicist who has suggested that where, as in some IRBs, bioethicists are involved in performing ethics reviews, they can replicate some of the errors they were to help prevent:

“Too many bioethicists have proudly assumed the same problematic role we have criticized in physicians. It is all too easy to present ourselves as neutral, objective experts on dilemmas that touch the very essence of the people experiencing them. According to conventional wisdom, the absence of a personal connection to these dilemmas is one of the bioethicist’s virtues, enabling her to consider all perspectives and interests with fairness and wisdom. But...this...too often leads the bioethicist simply to parrot accepted principles, pronounce an ideal resolution, and make a quick getaway...To a great extent, ‘Doctor knows best’ has been replaced by ‘Bioethicist knows best’” (Dresser, 1996: 156-7).

This situation again indicates that the ‘expert’ label is itself unhelpful. The term suggests the ‘expert’ is alone privileged with the requisite knowledge, and thus cannot be gainsaid: the experts’ pronouncements are those that matter. By suggesting there is one correct way, the expert view always wins out: morality though, as was argued earlier, is not about ‘expert’ matters but rather it is about wider social concerns.

Under this view one cannot have ‘expert’ ethicists, at least in terms of someone indicating that only one moral solution is possible, for:

“moral inquiry is an effort to develop plans for dealing with problematic situations that can evoke a shared social commitment, the determination of morally appropriate behaviour requires the contributions of other members of the moral community who participate in reflective moral inquiry. Thus the ethics consultant

cannot simply step in and announce that he or she has the ‘right answers’” (Moreno, 2005: 68).

Ethics is then always subjective and as there is nothing to be objective about, there can be no experts. To be moral is merely to have concern for others. Ethics theory, it is true, can provide some tools to engage with, but the nearest ‘ethics expertise’ gets is to a depth of relevant knowledge and a skilful application of the tools of theories of ethics – but this is not moral expertise. If there was such a thing as moral expertise of course there would be no need for a REC as currently constituted and determinations would be subject to an expert-only membership (albeit with a differently constituted expertise).

Another reason though for the ‘absent ethicist’, it could be argued, is that such a position could be perceived as a threat to, or at least inconsistent with, the medical professional perspective (Gesang, 2010). Medical experts were the least enthusiastic of all the interviewees about a training syllabus. Their scepticism about the value of such an approach would certainly be warranted as it would tend to undermine the indeterminacy of their professional skills, and result in a rather different – less medically oriented – research ethics review. As peer review by the sponsor team of the methodology of the protocol may be relied upon (Edwards, 2010a; Humphreys, 2008a, 2011) in combination with the separate, independent, review by the MHRA of both the methodology and safety aspects of the study, IEC review could have concentrated on other matters. The IEC members interviewed did not see matters quite as

clearly however. Nevertheless NRES, now under the umbrella of the Health Research Authority (HRA), has more recently proposed to “explore how closer working with funders *and the use of information* and standards *from funding decisions*, as part of the assessment for regulation and governance, *could avoid duplication of the review of scientific quality and study design [by RECs]*” (emphasis added, HRA, 2012: 7).

IECs or ethics committees generally, were not comprised of persons who were necessarily expert in the methodology or science of any particular study which they may have been asked to review (Collins and Evans, 2002). The interviewees in the study reported here acknowledged this fact, but so entrenched was their view of their role that they could not clearly foresee such a change in emphasis. Despite seeing the logic of it, they preferred the situation of ‘double checking’ to ensure the safety of participants and the very notion that they might leave the review of the science to the MHRA was not something members had seriously considered.

9.10 Training

Because IECs have operated as independent bodies for over three decades with little, if any, external interference until very recently, they have been able to decide what it was that they considered in their review and, as the evidence suggests, they had not perceived a particular requirement for continual updating or indeed for any initial formal training for their members. Rather, members were made aware of what was

expected of them by existing members in an 'apprentice model', and as IECs were established originally by medical professionals and pharmaceutical scientists it was the experts' biomedical model that was always followed. The existence of this apprentice model, and the degree to which training had been neglected, are again findings previously unnoticed by the scholarly literature.

As trained clinicians, the findings indicated that they perceived that they needed no additional training for their work on an IEC, and that they could explain to the lay members what was required. Within such a closed-circle of belief, alternative approaches would betray the certainty of the medical profession in its own abilities, competence and jurisdiction and could engender cognitive dissonance (Festinger, 1957). Their professional background may thus have framed their perspective and so precluded their seeing the situation any differently. Thus it is not that medical members are deliberately closing out others and alternative perspectives, but rather it is simply that their professional background urges them to act as the medical professionals they are.

Medical members give expression to their expertise and so to their expert role merely by being accepted as members of the profession. By discussing the medicine (IMP) at issue they, in a strong, indeed an 'expert' (and thus clearly 'right') sense, have defined what the issues were which should be discussed. If they did not bring in ethics theory this is because they did not see it as relevant in their expert-defined approach.

Their 'expert' role has thus shaped and delimited the scope of what might be discussed in the committees. This has obviated an ethics-focused agenda (in favour of a science review) which would be about what was the right thing to do so far as society thought it was the right thing to do, and expertise was not necessarily so paramount in such a discussion.

The 'expert' can thus prevent the full range of ethics issues being discussed by privileging certain topics for discussion in the limited time available. This has shackled the ethics from being aspirational, and instead limited it to a medical-model of acceptability. The fact that there were 'experts' on the committees indicates that it was these individuals' profession's (fixed) world-view that was to count. The medium was the message (McLuhan, 1967) which the lay members understood.

However this was not at all blatant or overt and it was for instance true that the designations of 'expert' and 'lay' have become largely irrelevant to the committees. As this NHS REC Chair put it "...such a distinction seems to be absent or irrelevant these days with the quality and quantity of training that is available together with the experience that accumulates over 10 years" (Chair, Northern and Yorkshire NHS REC, Annual Report 2009-10).

Yet the evidence from the current research qualified such a statement by noting that if the training made available could have such an effect, the fact that so few have had the training weakens the contention.

The evidence does show that members may not necessarily make the expert/lay distinction – with members not being clear who was and who was not in which category ‘without looking it up’. One lay member even thought him or herself to be the only lay member on their committee, so powerful was the capture of members to the biomedical agenda.

So long as the members were capable of performing the functions they have defined for themselves, such terms were unimportant, even alien. The committees saw themselves as in existence primarily to protect the safety of the participants and to ensure the trial was likely to produce the sorts of results expected of it. Yet such concerns were also the concerns of the trial sponsors who will have wished to ensure the trial is likely to produce a clear ‘go/no go’ outcome without risking the safety of participants, and for these reasons will have ensured that the protocol had already have been internally peer-reviewed. Taubel et al. (2011) even noted that the MHRA offer to hold pre-submission meetings with the pharmaceutical companies to discuss research before protocols are finalised. Moreno (2005) argued that the clinical researcher already typically focused on the science and expected to leave it to the ethics committee to straighten-out the moral aspects. If this is so then it becomes more urgent that the roles are thought through, agreed and understood widely to ensure sensible use of people’s time and efforts. This suggests that education may have a role in helping enable the change in existing practices that may be required.

9.11 Education

The findings strongly indicated a limited experience of training and education of members and that they have essentially learnt their role on an apprenticeship model without a clear syllabus (they simply attended meetings and replicated what they saw go on). As such they have stuck to the familiar precedents and have tended not to venture into new ways of looking at matters. No interviewee was found to have questioned, for example, issues of justice (the most recent addition – or afterthought – to the research ethics review process as mandated by US authorities) and the findings were that they were largely unaware of what this concept meant.

Despite this, when asked, lay members felt that they would be better enabled to define their role and have greater confidence *vis-à-vis* the expert members if they had access to education and training that adhered to an accepted syllabus. This approach was seen to be available in both the USA and Canada. In addition there are several university-based on-line ethics review courses that are freely accessible to anyone (Humphreys, 2008d; Ruyter, 2006; Schuklenk, 2005; ten Have, 2007). This approach could represent an appropriate way forward for members if the science review emphasis is to be thought in need of modification in favour of a broader ethics review.

Members of RECs have an obligation, under the terms of their appointment, to undertake both initial training and a “*minimum* of two

days' training a year" (Parliamentary Office of Science and Technology, 2005: 4, emphasis added) or "You will be required to attend a minimum of one training event per year" (letter of appointment) or, at the very least, "5.6 As a condition of appointment, a member must agree to take part in initial and continuing training and education appropriate to his or her role as an REC member" (*GAfREC*, Department of Health 2001 (para. 4.3.11 *GAfREC*, 2011); see also NRES's Terms of Appointment, 2011, para. 6). Whilst Hibbert (2008) gives potentially contradictory information about how much training IEC members have received (see her paras. 4.4.10; 5.5.2 and table 11), the data from the current research indicate that few of the interviewees had engaged in much by way of training. Nevertheless, any confusion about the exact 'requirement' becomes immaterial as that requirement is seen to flex over time and catch up with, rather than inform, practice. As it was, many interviewees did not regard training as necessary and several resented having to give up their time without being recompensed for it. The problem has been a contention of long-standing: "lay members are not paid, and may even lose income from their regular employment" (Nicholson, 1993: 14) and:

"...training. That's a real problem. Most members still have none. When we interviewed for a new member recently no candidates thought they even needed it!" (Saunders, 1995: 17).

The situation more than a decade later is that little has changed.

9.12 Summary and future directions for research

NRES SOPs and *GAfREC* are clear that a review of the scientific merits and design by ECs is inappropriate. ECs are instead to ensure that an adequate independent review of the science, methods and methodologies have been undertaken - yet despite such instructions the science remained the key focus of IEC review. If practice differs from policy (as expressed in *GAfREC* and the Standard Operating Procedures), the policy was clearly ineffective and the practice arguably unethical. This was a major lesson from this study of the IECs but the other findings are no less significant for the scholarly understanding of RECs, as much of the extant literature concerning them is now aged. Of particular interest was that ethics guidelines including the Declaration of Helsinki were unfamiliar to members of ethics committees. There was no engagement with formal ethics theory; training and education were deemed of limited importance, although perhaps more useful for lay members; and the expert and lay roles were essentially fictional and even unhelpful categories so far as ethics review practice was concerned. But above all the main lesson from the research was that the medical profession, at least via its medical model approach to ethics review, was still so dominant and shaped the nature of ethics review such that it could often more accurately be described as a scientific review – and this even where an independent and truly expert scientific review had already occurred. Rather than Freidson's theory of professional dominance having become obsolete (Dingwall, 2008a), the evidence of this research suggests that it has been alive and well and can account for the internal

workings of IECs and, although further research needs to confirm this, of RECs generally too. It is thus by appreciating the expert-dominance of the committees that an understanding of ECs can be best obtained.

No individual is an expert on how other groups should lead their lives or how society should respond to particular situations. If change is needed in RECs, as so often it will need to begin with education, but there will also be a need to reconsider member roles and for this reason it would be appropriate for research to extend the findings reported here, and to understand how the (trained) lay members who have either a majority, or at least equality in numbers, on their ECs - as is the case in New Zealand, Denmark and the Netherlands - operate and perceive their role. The experience of RECs in other countries too, where membership of the committees includes more disciplines than just professionals allied to medicine will also be of interest – not least under the prompting of Hedgecoe's (2012a) notion of isomorphism: clearly there are different ways of organizing RECs, and there is a need to better understand how these affect matters.

Quantitative research (not least to anticipate objections from those who disfavour qualitative approaches) to identify the extent of role-understandings of members in NHS and other RECs would also be of interest, and for example a survey-questionnaire to discover how familiar members are with their SOPs, *GAfREC*, relevant legislation, guidelines and so forth would be of particular interest. Research amongst members,

researchers and the general public would be of great assistance in clarifying where the science should be adjudicated upon in the approval process. An understanding of what motivates membership would also be of much interest.

Following Evans' (2012) recent contribution to suggest that there was a bioethics profession, it would also be appropriate for comparative research into the practices and experiences of members of NRES RECs and the numerically much larger body of IRBs. Although some NRES RECs are recognised by the US Federal government for the purposes of IRB review, it has anecdotally been reported (personal communication, 2011) that such RECs are not required to adhere to the federal legislation when they come to their decisions. If this is indeed so it is a very odd situation indeed and would form the basis of a small but interesting study in itself.

The present research has highlighted a concern that traditional practices not challenged by sufficient training and education to grant independence of thought, reinforced by labels such as 'expert' and 'lay', can occlude from ethics review a broader agenda and so perpetuate a professional dominance the committees were composed to tackle. Such findings also have relevance in other professional committee settings where a sprinkling of lay representation is intended to act as a mediating agent, for the findings have cast a concern over the effectiveness of

interposing a few lay members and then expecting the problems they were intended to tackle to be resolved.

It is also the case that both the methodology and theoretical perspective employed in this research were of particular kinds. Theoretical accounts of the professions supervening upon a phenomenologically-inspired methodological approach were used to gain important insights, and other methodologies and theoretical perspectives could have provided other interesting insights. Thus the research does not so much claim to have proven anything, but rather it has revealed a situation that has hitherto not been brought to the prominence it is suggested that is deserved. Part of this too has been in the showing that Freidson's theory of professional dominance (1970) still has relevance in contemporary society, even if it does not quite have the wider import it had when he first developed it.

It is hoped too that such concerns as this research has highlighted can now be aired for wider clarification and, the researcher hopes, the development of the ethics review system. Ethics review needs to consider the scientific and methodological aspects of studies – but only to the extent of confirming that such considerations have been given the specialist, independent, attention they need. For a REC to *again* review the science, is to do an injustice to the research process. This issue needs to be agreed upon if progress is to be made. One starting point

would be to consider specifying the duties of, or even the need for, expert members on a REC.

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Glossary

AIDS Acquired Immune Deficiency Syndrome

AAPEC Appointing Authority for Phase I (independent) Ethics Committees

AREC Association of Research Ethics Committees

Authorised REC able to provide an ethics review of non-CTIMP research involving NHS patients

COREC Central Office for Research Ethics Committees (predecessor to NRES)

CTIMPs Clinical trials of investigational medicinal products

Declaration of Helsinki Medical ethics guidance issued by the World Medical Association

FTIH First-time in human trials

GAfREC *Governance Arrangements for Research Ethics Committee* (see Department for Health (2001, 2011))

HRA Health Research Authority

IMP Investigational Medicinal Product

IEC Independent Ethics Committee

IRB Institutional Review Board (USA)

LREC Local [NHS] REC (term now replaced by committee types)

MHRA Medicines and Healthcare products Regulatory Agency

MREC Multi-centre [NHS] REC (term now replaced by committee types)

NRES National Research Ethics Service (successor body to COREC, managerially responsible for the organisation of NHS RECs)

Phase 0 The pre-clinical stage of drug testing in animals (in vivo), using human and/or animal cell-tissue (in vitro) and/or by computer simulation (in silico)

Phase I First clinical stage of a drug trial, involves humans (healthy volunteers) for whom there is no expectation of gaining any medical benefit from the trial. Aims to identify the safety and tolerability of the compound. Usually involves up to 100 volunteers, and lasts up to several months. Includes FTIH studies.

Phase I/II Sometimes used to describe a Phase I trial of an oncological (or other) preparation where toxicology is expected such that the IMP cannot be given to a healthy volunteer

Phase II The IMP is first tested in a patient group. Usually double-blinded and involving several hundred patient-volunteers. May last up to two years.

Phase III The IMP is tested in much larger groups of patients often involving thousands of patients in several sites and countries. May last several years. Provides the data required to decide if the medication can obtain a marketing authorization

Phase IV Post-marketing testing of a drug (usually in comparison with other marketed drugs)

PIS Participant Information Sheet(s)

REB Research Ethics Board (Canada)

REC Research Ethics Committee

Recognised REC able to provide an ethics review of CTIMP research

SOP Standard Operating Procedure

Type I REC able to provide an ethics review of CTIMP research in healthy volunteers

Type II REC able to provide an ethics review of CTIMP research involving NHS patients in a single (NHS) region

Type III REC able to provide an ethics review of CTIMP research involving NHS patients anywhere in the UK

USPHS United States Public Health Service

NHS REC Composition

Appendix 2a

REC	Number of members		
	Experts		Lay
	Medical	Other	
Derbyshire	4	3	5
IoW, Portsmouth & SE Hants	5	3	4
London (N) East 1	10	2	6
Essex 2	4	7	4
Newcastle & N Tyne 1	4	8	4
Sunderland	4	6	3
Oxford C	4	6	8
Kent	3	9	5
London (N) North 2	3	6	6
Bradford	6	4	4
Leeds East	4	5	5
Leeds West	9	0	5
Cambridgeshire 4	4	7	4
London (N) East 2	4	6	7
South West 1	3	5	2
London (S) SE5	5	4	6
North West 5	5	5	4
Leeds Central	4	4	5
Norfolk	2	6	5
North West 4	4	6	4
London (N) N.West 1	4	1	9
Cambridgeshire 1	3	8	6
Cambridgeshire 3	3	8	6
Lincoln, Northants, Rutland 1	6	3	4
Lincoln, Northants, Rutland 2	3	4	5
North West 3	6	2	6
West Mids	6	4	4
South West 2	5	4	4
London (S) SE4	3	6	8
Notts 1	4	3	5
North West 1	5	5	6
North West 2	4	6	6
North West 6	5	5	5
North West 7	5	4	5
North West 8	4	5	7
North West 9	5	2	7
North West 10	3	6	6
North West 12	4	5	6
Southampton & SW Hants 1	3	9	5
London (N) Central 4	8	2	6
Essex 1	4	3	9

Co. Durham & Tees Valley	6	4	7
North West 11	4	4	5
Berkshire	6	4	5
Oxford A	4	4	6
Oxford B	2	5	5
Southampton & SW Hants 2	6	2	6
Coventry & Warks	5	4	5
South West 4	4	2	5
South West 5	5	3	5
London (N) Central 2	4	4	6
London (N) North 1	3	6	7
London (N) North 3	2	6	8
London (N) N. West 2	5	5	5
London (N) West 1	5	4	6
London (N) West 3	7	4	6
London (S) SE2	6	4	4
London (S) SREc	7	3	7
London (S) SW1	4	5	4
London (S) SW3	3	4	8
Sheffield	6	5	5
S. Yorks	8	4	5
Cambridgeshire 2	7	4	5
Hertfordshire	5	4	7
Notts 2	5	4	4
Trent	6	5	5
Newcastle & N Tyne 2	6	3	4
Northern & Yorks	7	4	5
Brighton East	6	6	5
Brighton West	7	2	4
Surrey	6	3	5
B'ham, East, North & Solihull	5	4	6
Black Country	8	2	5
S. B'ham	7	4	3
South West 3	6	3	5
London (N) Central 1	5	4	7
London (N) Central 3	7	3	7
London (N) East Central	4	6	4
London (N) East 3	5	3	7
London (N) West 2	8	2	6
London (N) SE1	4	4	5
London (N) SE3	7	2	4
London (N) SW2	8	3	4
	<hr/>	<hr/>	<hr/>
	415	358	448
	33.99%	29.32%	36.69%
	<hr/>	<hr/>	<hr/>
	63.31%	36.69%	

Appendix 2b: Proportion of members by category in IECs

IEC	Medics	Other experts	All experts	Lay
Capenhurst 2008/9	4	3	7	6
Capenhurst 2009/10	4	3	7	6
Edinburgh 2008/9	8	3	11	7
Edinburgh 2009/10	7	3	10	7
Plymouth 2008/9	4	3	7	4
Plymouth 2009/10	2	3	5	6
Reading 2008/9	1	6	7	3
Reading 2009/10	1	6	7	5
Welwyn 2008/9	3	7	10	9
Welwyn 2009/10	4	7	11	9
Yorkshire 2008/9	4	3	7	5
Yorkshire 2009/10	4	4	8	4
Totals	46 (47.5%)	51 (52.5%)	97 (57.75%)	71 (42.25%)

Participant Information Sheet

1. Study title: Member role perception in independent Phase I research ethics committees

2. Invitation

You are invited to participate in a one-to-one interview to discuss your experience of being a member of an ethics committee which reviews Phase I studies involving healthy volunteers.

3. What is the purpose of the study?

This qualitative study seeks to understand the perceptions of members of Phase I ethics committees about various aspects of the review process and their involvement in it.

The research findings are intended to help shape the debate about member roles and may influence future recruitment and development strategies.

4. Why have I been chosen?

Committee co-ordinators have been asked to forward this information sheet to members of their committee. By obtaining a variety of members' views the researcher hopes to learn about member perceptions of the roles.

5. Do I have to take part?

No. It is entirely up to you. And you will be able to decline to answer any question(s) or withdraw at any time without having to justify yourself.

6. What will happen to me if I take part?

You will be invited to meet with the researcher at a time and place to suit you in order to engage in an informal interview about the lay and expert member role. The interview will be audiotape recorded (with your permission), you will not be identified in any research output, you will be paid any travelling expenses, and, in recognition of your time, £100 will be given to a registered charity of your choice.

7. What do I have to do?

Please contact the researcher by email (s.j.humphreys@herts.ac.uk) in the first instance to arrange an interview and/or to ask any questions you may have about the study. You may care to give a telephone number and indicate when you would like to be contacted.

8. What are the possible benefits of taking part?

By participating in this research, you will have an opportunity to reflect on your experience and contribute your knowledge towards a greater understanding of members' roles. The findings should help inform wider understanding of the roles and gain insight in to the views of current members.

9. What are the possible disadvantages and risks of taking part?

The researcher is not aware of any. Your confidentiality will be fully respected and no interviewee will be identifiable. If you do not wish to answer any question(s) you will not have to. You may retract any statements you make and these will not be included in the research. You will be able to ask questions of the interviewer.

10. What if there is a problem?

The researcher or his supervisors (Professors Martin r.martin@herts.ac.uk and Thomas h.a.thomas@herts.ac.uk) may be contacted as appropriate.

11. Will my taking part in the study be kept confidential?

Interviews will be transcribed either by the researcher or a secretary and your confidentiality will be maintained. Tapes will be erased after transcription and the anonymised transcripts themselves will be destroyed after seven years. Interviewees will not be identifiable in any resultant publication(s).

12. What will happen to the results of the study?

The research findings will be submitted for publication in peer-reviewed journals. A summary of findings will be provided to all interested participants.

13. Who is organizing and funding the research?

The study has been designed, and shall be conducted, by the researcher who is a doctoral student at the University of Hertfordshire. It is not externally funded. The university has insurance in place to cover approved student research.

14. Who has reviewed this study?

The University of Hertfordshire's Faculty of Health and Human Sciences' ethics committee has reviewed and approved this study under reference NMSCC/11/09/6/A.

I confirm that I have read and understand this information sheet, been given a copy of it, and have had the opportunity to consider the information. Any questions I may have had about my participation have been answered satisfactorily. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I consent to taking part in this study.

Name of Participant: _____

Signature: _____ Date: _____

Appendix 4

Algorithm for membership of NRES committees

Stage

1. Are you a current or retired member of the medical or dental profession?

Yes:
You are an **Expert** Member

No

2. Are you a current or former professional statistician?

Yes:
As a statistician did your role include a period advising on the statistics of clinical research?
Yes: You are an **Expert** Member

No

3. Are you (indicate) a current or former pharmacist, nurse, midwife, optician, osteopath, chiropractor, paramedic, physiotherapist, arts therapist, biomedical scientist, chiropodist, clinical scientist, dietitian, hearing aid dispenser, occupational therapist, operating department practitioner, orthoptist, orthotist, practitioner psychologist, podiatrist, prosthetist, radiographer, or speech and language therapist?

Yes
Are you still in practice or did you practise within the past 5 years?
Yes: You are an **Expert** Member

No

4. Are, or have you been (indicate) either (i) a provider of medical, dental or nursing care (ii) involved in the conduct of clinical research (other than as a subject of such research) or (indicate) (iii) a chairman, member, director, officer or employee of an NHS Trust, health authority or dental board?

Yes:
You are **lay** member

No

You are a **lay+** member

Having followed the above algorithm and having reached stage ____ I believe myself to be:

An **EXPERT** member

A **LAY** member

A **LAY+** member

Applicant: Name:

Signed:

Date:

For NRES use: