ESRC Research Ethics Framework

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Discussion Paper 4
Implementing the ESRC Research Ethics Framework:
The Case for Research Ethics Committees

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1. Introduction: The Research Ethics Framework and formal ethics review

1.1   In this Discussion Paper, we take as our starting point the view that, in developing a new ESRC Research Ethics Framework, consideration needs to be given not only to the normative expectations of what constitutes ethical research but also to the procedural mechanisms for implementing those norms. Particularly important in this context is the question of whether review by a properly constituted research ethics committee (REC) should be incorporated into the Framework as the primary mechanism for doing so. As previous papers have demonstrated, the context in which social science research is conducted is changing. Emphasis is increasingly placed on collaborative research that brings together researchers from a number of different disciplines and on research which crosses national boundaries, involving not only European nations but developing countries of the East and South. The ethical issues inherent in such research are complex, as are the cultural and disciplinary perspectives from which they are viewed and the expectations of appropriate processes for reviewing and regulating them (see Discussion Papers 1, 2 and 3). At the same time, a number of well-publicised 'scandals' in medical research and practice have undermined public trust in 'experts' and 'professionals' and fostered a more sceptical attitude to scientific endeavours. As public and political concerns for accountability and transparency in all sectors of public life have grown, the climate with regard to the regulation and governance of social science research has also changed.

1.2   In the UK, responsibility for the ethical conduct of research is currently left to individual researchers. Most professional organisations for social scientists and many Universities and research institutions have agreed codes of practice that set out the general principles that are intended to guide researchers in designing and conducting their research. Conformity to these principles is expected as an aspect of professional conduct. The Social Research Association (SRA) is an exception in including in their Ethical Guidelines 2002 the suggestion that 'serious consideration has to be given by researchers and by research organisations to the use of human subjects review committees (also known as Ethics Committees or Institutional Review Boards)' to provide a formal check and safeguard on their ethical practice (SRA 2003).

1.3   The reliance on self-regulation amongst social scientists contrasts with the situation for those involved in medical and health research where review by a properly constituted research ethics committee is incorporated into ethical guidelines themselves. Review by a REC has been expected practice amongst health and medical researchers in the UK and USA since the mid-1960s (Foster 2001) and is now the expected norm around the world. It is enshrined in the World Medical Association's Declaration of Helsinki (1964) and, as medical research has become ever more globalised, structures for independent ethical review – research ethics committees – have routinely been established as part of the extension of regulation and ethical oversight in developing countries (see Papers 2 & 3)

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[1] Authorship of REF Discussion Papers reflects lead pen

1.4   Review by some form of ethics committee is now also required for social science research in many countries, most notably the USA, Canada and Australia. In the USA, Institutional Review Boards (IRBs) were first established on a large scale in the mid 1960s, following the requirement that all institutions receiving federal grants take responsibility for ensuring the ethical review of all research involving human subjects, including social and behavioural research (Gray 1982); since the 1974 National Research Act, review by an IRB has been a legal requirement. In Canada, Research Ethics Boards (REBs) have operated in relation to medical research since 1977 and in relation to social science research since 1987. In 1998 the three government funding bodies (MRC, NSERC and SSHRC) together produced a single Tri-Council Policy Statement describing standards and procedures for governing the ethical conduct of all research involving human participants (TCPS, 2003). Government funding is available only to those institutions which sign up to this document which includes the requirement that research be reviewed and approved by a REB, in accordance with the standards set out in the Policy Statement, before it is started.

1.5   In the UK, however, it is only those social scientists who are involved in medical or health research who have been required to gain approval from a REC and in particular, from a REC recognised by the Department of Health (DoH). For some, contact with an NHS LREC or MREC has been a frustrating and unproductive experience and has fuelled calls to find alternative ways for social scientists to meet DoH requirements for ethical review. For others, it has raised questions about the adequacy of current means of ethical governance of social science research conducted outside the NHS and has given rise to calls for the establishment of research ethics committees to review all social science research (Freed-Taylor 1994; Kent et al 2002).

1.6   In considering such proposals, careful attention needs be given to both the *principle* of requiring review by a REC and to a range of *practical* issues around providing such review, including the membership of RECs, their remit, location and operating procedures. In the NHS, Local Research Ethics Committees were established in all District Health Authorities in the early 1990s (DoH 1991, 1994) with clear and detailed guidance provided on their operation and an additional tier of Multi-Centre Research Ethics Committees was added in the late 1990s (DoH 1997). However, within Universities, RECs are not so common, nor so well developed, although this situation is rapidly changing as a consequence of requirements of the DoH Research Governance Framework (RGF) (2001, 2003). Most Universities now have at least one Research Ethics Committee although there is considerable diversity in how they define their remit and responsibilities and in how they operate (SATSU 2002). Thus, while a basic infrastructure of RECs can now be found in the NHS and in most Universities, moves to extend the role of RECs in the governance of social science research would raise a number of questions, for example around their organisation and operation within Universities, the relationship of University RECs to those in the NHS and the expectations of funding bodies regarding the requirement for ethical review.

1.7   In the rest of this paper we will consider both general debates around appropriate mechanisms for ensuring high ethical standards in the conduct of research involving human participants as well as debates about specific aspects of RECs and the way they operate. We will begin by briefly considering the strengths and weaknesses of the most common mechanisms currently used for ethics review in the social sciences which might be candidates for implementing the new ESRC Research Ethics Framework. Of all of these mechanisms, scrutiny by a properly constituted research ethics committee seems the most appropriate. We will then turn to look at how RECs in Universities would operate in practice and raise a number of specific questions which would need to be addressed if the ESRC Research Ethics Framework were to incorporate the requirement for review by a REC. In considering how these questions could be answered, we will draw on the experience of Canada and the USA where similar committees (IRBs or REBs) are already well established and examine the issues raised for social scientists by the Department of Health's Research

Governance Framework (2003). We will conclude by setting the case for incorporating review by an independent REC into the new ESRC Research Ethics Framework in a broader context.

2. Current mechanisms of ethical regulation and governance in social science research

2.1   In this section, we consider the strengths and limitations of the main approaches currently used (or advocated) for ethical review of social science research[1].

2.2   Self-regulation on the basis of Professional Codes of Practice
2.2.1   In the UK, social scientists have traditionally been expected to regulate *themselves* in the way they conduct research on the basis of their professional codes of practice. Ashcroft (2003) suggests that reliance on a professional code of ethics can be seen as representing a 'moral' discourse of research ethics because it concentrates on individual agency and the personal responsibility of the researcher for his or her relationship with participants and their well-being. Most professional organisations for social scientists have their own codes of practice and many have revised and updated them recently in response to the changing environment of research governance (c.f. BPS, BSA, SRA). They vary in whether they are more educative (e.g. SRA) or prescriptive (e.g. BPS) in intent but generally provide a set of principles of good practice in relation to, for example, the need for informed consent, respect for privacy and confidentiality and the balance of risks and benefits. Researchers are expected to internalise these good practice principles and to act in a way which is consistent with them. They thus provide 'an aid to moral judgement rather than a constraint on action' (Ashcroft 2003: 47).

2.2.2   Professional codes of practice have been useful in raising researchers' awareness of key ethical issues and in providing a foundation for further training and debate. However, they are most appropriate in the context of a hierarchical profession which supports a stable professional culture with shared professional values and where each member is concerned about the good reputation of the discipline and their own standing in it (Ashcroft 2003). Within the social sciences, the relevance of professional codes of conduct in promoting ethical behaviour in research is increasingly questioned (Homan 1991, Ringheim 1995; Kent et al 2002). With some possible exceptions (e.g. BPS, Market Research Society), there is no requirement that social scientists join a professional organisation nor any means by which a professional organisation could discipline researchers who do not adhere to their code. A survey of researchers in the early 1990s found that few were familiar with the guidance provided by their codes of practice or even aware that such codes existed (Freed-Taylor 1994: VII). Nor is it clear what adherence to a code of practice would mean in practice: most guidelines are necessarily written in a way which requires a great deal of active interpretation on the part of researchers and leaves considerable scope for idiosyncrasies in the way they make sense of them in the context of their own study. Conflicts and contradictions between principles must also be resolved in practice. A consequence of this, as Truman (2003: 2.2) points out, is that 'most social scientists could justify any course of research as 'ethical' without necessarily providing effective protection for vulnerable groups in society.'

2.2.3   Others have also questioned whether such guidelines are, in themselves, sufficient to ensure that the interests of research participants are adequately protected (Robertson 1982; Ringheim 1995; Kent et al 2002)[2]. Freed-Taylor (1994 VII), for example, concluded that 'Given that it cannot be assumed that one set of principles is universally accepted by scholars and given human limitations and competing values and, further, given that researchers from different disciplines and from different countries will not be aware that their

standard practices or 'shared norms' are not, in fact, standard or shared, it cannot be assumed that we can rely upon all researcher to behave in consistently responsible ways.'

2.3   Review by peers in the funding process

2.3.1   A common claim amongst social scientists is that research which has received external funding has been through independent ethical review[3]. This view derives from the fact that a number of funding agencies have produced application forms which explicitly ask about ethical issues: if the applicants comments are not challenged in the course of the funding process, they may (not unreasonably) assume that they have provided an acceptable account of how ethical issues will be managed.

2.3.2   This, however, misrepresents the nature of peer review in the funding process[4] which concentrates largely on 'scientific' issues of theory, design and methodology as well as the significance of the research question. Good 'science' is fundamental to ethical research but 'scientific' review of a study is at a different level from that required in ethical review (Kent et al, 2002). Funding bodies do not generally ask researchers for details of how they will explain their study to participants, obtain and document consent, manage confidentiality and so on which are essential in considering the ethical conduct of research. Nor do applicants wish to develop their proposal in such detail before funding is agreed.

2.3.3   Peer review in the course of the funding process may be of value in flagging up studies which involve significant risks of harm to participants or which raise other complex ethical issues. However, it is not intended to provide independent ethical review: Kent et al (2002: 4.8), for example, note that the ESRC application form deals with ethical intent in an inadequate way and even implies that 'in some circumstances ethical issues will not arise'. In the USA, IRBs were initially established within institutions to provide independent ethical review of proposals as a parallel structure to the peer review committees within the funding organisation (NIH) which provided independent scientific review. The DH RGF now requires that research studies are peer reviewed to ensure the quality of their science *before* they are submitted for review by a research ethics committee. If ethical review were to become part of the funding or commissioning process, then a second stage of review would be needed, following the review of the proposed design and methods of the study, when the details of research instruments, information sheets and recruitment and consenting procedures could be reviewed in relation to the standards set out in the ESRC Research Ethics Framework.

2.4   Opportunistic review by University research committee, higher degree committees or Research Director

2.4.1   Social scientists also point to structures and procedures within their own institution which review research plans and proposals, for example in relation to registration for higher degrees or prior to submission to a funding body, which might also identify ethical issues. These include research supervisors and heads of department as well as university research or research degree committees (SATSU 2002). Their main concern, however, is generally in relation to matters such as registration, validation and quality control the 'science' of research and, as in the case of peer review, they are unlikely to be in a position to provide systematic review in relation to research ethics (Homans 1991: 22).

2.5   Accountability to Project Advisory Group

2.5.1   Advisory or Steering Groups, which bring together researchers as well as lay and professional 'users' to oversee and/or advise on a study, are an increasingly common feature of the research landscape. They provide an important forum for involving service users, who are likely to bring a different and valuable perspective to reviewing the research. Many now regard them, or similar groups, as making a key contribution to research governance

(Meerabeau et al 2003). For those involved in qualitative, participatory or action research where an 'ethics as process' model might be appropriate (Ramcharan and Cutculiffe 2001), they may provide a particularly valuable group with whom to reflect on and address ethical and other issues over the course of the study.

2.5.2 Project advisory groups clearly have the potential, at least in theory, to provide a forum for continuous debate and review of research ethics. Questions remain, however, as to whether such groups can *in practice* act as appropriate 'ethical reviewers' (Kent et al 2002: 4.13). They are generally difficult to implement and sustain over the longer term, may be regarded as too closely identified with the researchers (or the research aims) to provide independent review, and are of uncertain status with regard to formal responsibilities and accountably. They are also likely to lack specific training in ethics and may give idiosyncratic advice. Thus, while researchers may derive a great deal of benefit from them informally, advisory and steering groups are perhaps too fluid and informally constituted to take on primary responsibility for the implementation of the ESRC Research Ethics Framework.

2.6 Scrutiny by a Research Ethics Committee
2.6.1 Research Ethics Committees are intended to provide a systematic, informed and publicly accountable approach to ensuring that research meets expected ethical standards. In Ashcroft's terms, reliance on research ethics committees represents a 'regulatory' discourse of research ethics. 'RECs have many similar functions and stake-holders to classic regulatory agencies', providing confidential review 'with due diligence and process', independent evaluation against declared standards which represent a balance of interests of all parties and universal coverage (Aschcroft 2003: 51). Review by a REC generally entails submission of details of the proposed research to a broadly based committee which scrutinises it according to a number of criteria, most commonly the assessment of the risk of harm and benefits to participants and society and the methods proposed to ensure informed consent, protection of privacy and confidentiality. RECs may give or withhold approval of a proposed study – although in practice the most common response appears to be approval following specified modifications (Gray 1982) – and research can proceed only when approval has been given.

2.6.2 RECs located within the researchers' own institutions have many advantages, particularly in relation to research governance[5]. They can contribute to increasing the level of awareness of ethical issues within an institution or research community, stimulating informed debate, sharing good practice and creating an ethically more sophisticated research culture. They are also well placed to monitor adherence to standards and to provide continuing review over the course of a study. Their own performance can also be monitored and high standards of review can be maintained through training and regular audit and other quality assurance measures.[6]

2.6.3 Among social scientists in the UK, it has largely been psychologists who have sought advice and approval from a REC within their own institution for experiments involving human participants. (Most social scientists working in the health field have also routinely submitted their proposals to review by a REC in the NHS.) This contrasts with the situation in the USA, Canada and Australia where social scientists of all disciplines are expected to gain approval from an ethics committee, located within their own institution, for any research involving human participants. In the context of increasing political concern with research governance and of growing public expectations of greater accountability amongst researchers, the case has been made for considering a similar requirement for independent ethical review of social science research in the UK (Freed-Taylor 1994; Kent et al 2002)[7].

2.6.4 Such a requirement, however, is unlikely to be whole-heartedly welcomed. Some social scientists regard RECs, or any form of external review, as a threat to academic

freedom (Furedi 2002) and to the right and duty of researchers to define and conduct scientifically sound research as they see fit. In their view, the risks to society that interference with this right would entail would 'surpass the dangers to participants of unregulated research' (Pattullo 1982: 388)[8]. Others accept that RECs are valuable for medical research, where participants are vulnerable and in a dependent relationship with the medical profession and where risks may entail physical injury or death, but argue that they are not appropriate to social science research where relationships are more democratic and the risks entailed are of a different order. These risks, they suggest, are no more than those encountered in everyday life and are risks which we must all accept as the cost of life in a free society. Social scientists have generally adhered to a high standard of ethical practice, they argue, and participants, as free men and women, should also take some responsibility for their own protection (Pattullo 1982, Furedi 2002).

2.6.5   Two further concerns have been expressed about the growing importance of research ethics committees. Some point out that the expansion of RECs could be seen as a form of professional imperialism on the part of ethicists, particularly bio-ethicists. The mandatory requirement for ethical scrutiny, they suggest, may be of greater benefit to ethicists than to the participants in research studies. Others observe that RECs have been diverted from their main purpose of considering ethical issues and have become preoccupied with other matters such as legal requirements around researcher indemnity, data protection and health and safety of researchers. These issues, they argue, are matters of research governance rather than research ethics and would be more appropriately managed by a Research Governance Committee. If institutions supported high standards, clear guidelines and good training regarding the conduct of research (including, for example, what is entailed in getting informed consent and how to identify and address potential risks to participants), RECs could be left to discuss research which raised significant ethical issues about which there was considerable room for debate.

2.6.6   Do RECs entail an inappropriate 'medicalisation' of social science research? Those who advocate an increased role for RECs argue that the risks involved in social research are generally under-estimated and that while they are more likely to entail psychological distress, the invasion of privacy and social embarrassment than physical harm, their significance for individuals, their families and communities (and also for researchers themselves) should not be ignored (Nelkin 1982; Robertson 1982; Warwick 1982; Batchelor and Briggs 1994; Kent et al 2002). Much social science involves research on sensitive topics or with vulnerable individuals where the risk of harm is particularly high (Renzetti and Lee, 1993) but due recognition also needs to be given to the fact that taking part in research in *any* circumstance may impact on individuals 'not least within the research process itself' (Kent et al 2002: 5.13; see also Batchelor and Briggs 1994: 950). Proponents of RECs also argue that consideration of these risks and the steps taken to address them are too important to be left solely to researchers who may view them – and are likely to be seen by others to view them – in term of their own vested interests. RECs, they argue, bring a wider range of perspectives, knowledge and experience to the discussion, and greater independence from the researchers, and so are better able to identify the potential risks to participants and to judge the adequacy of the steps taken to deal with them.

2.6.7   Debates along these lines are concerned with whether or not RECs would provide an appropriate mechanism for implementing the ESRC Research Ethics Framework *in principle*. Just as important, however, is the way RECs would operate in *practice*. It is to this question that we now turn.

3.   Research Ethics Committees in Universities: How would they operate in practice?

3.1   A survey of UK Universities carried out in 2002 found that the majority now have both a formal ethics policy and a research ethics committee or committees (SATSU 2002). RECs within Universities, however, vary widely in the way they operate and hence in their potential ability to implement the ESRC Research Ethics Framework. At the time the survey was carried out, institutional procedures to identify research for ethical review were often unclear and many Universities continued to rely solely on researchers regulating themselves. The decision to seek review by a REC was commonly left to the discretion of individual researchers or expected only when studies had 'specific ethical dimensions', for example when they involved patients in the NHS. A consequence of this was that, in practice, social science research was rarely subject to independent ethical review. As one respondent reported:

> Social science researchers have tended to regard the Ethics Committee oversight as not generally relevant to their work (except in the health research area) and have not seen it as necessary to forward their proposals for review by that committee. . . . It is also the case that most are members of a professional association which lays down its own ethical principles. None of this is to say that things are sometimes done, or even quite often done, that do not strictly comply with legislation.' (SATSU 2002: 30)

3.2   Many Universities are in the process of reviewing and strengthening their systems of research governance in response to the more stringent requirements of the Department of Health and a number of funding organisations[9]. This may bring about a significant increase in the degree to which social science research is scrutinised by a properly constituted research ethics committee although this is unlikely to happen unless a clear case is made for both its necessity and desirability *in principle* and its workability *in practice*. In the context of a telephone consultation exercise in the Spring of 2004[10], all of those contacted, at twelve different universities, described an elaboration and greater formalisation of policies and procedures for ethical review in their institutions. What was striking, however, was the diversity amongst the institutions in the nature and level of ethical scrutiny they expected.

3.3   In the rest of this section we look at the practical issues which would need to be addressed if the ESRC Research Ethics Framework were to incorporate the requirement that research be reviewed by a REC. There are a variety of ways in which these questions could be answered and much debate about which answers are most appropriate. How they are actually answered will shape what review by a REC means both to researchers and to the institution in which they work. Two questions are also concerned with issues beyond the control of researchers and Universities and implicate the ESRC and other organisations: whether the ESRC (or RCUK) might set out its expectations for the way RECs should operate and recognise or accredit Universities accordingly and whether University RECs which operate according to these accepted standards might also be recognised by other organisations (for example, the DoH) and so be able to provide ethical review for social science research conducted within their jurisdiction. This is particularly important in relation to the Department of Health which has jurisdiction over research conducted within the NHS and to a lesser and changing extent over research conducted in Local Authorities with Social Services Responsibilities.

3.4   This discussion is premised on the assumption that RECs would be based within the University or research institution which employed the researchers carrying out the study rather than within funding or commissioning bodies (as suggested by the DoH (2003) in their implementation plan for social care) or at a national level (as in Norway (www.etikkon.no/Engelsk/about)). In our view these organisations are too distant from researchers, too cumbersome in their procedures and too centralised to be workable or

effective in scrutinising individual research studies or enhancing the 'culture of ethics' in which researchers work. (This is not to say that national ethics advisory committees, involving researchers, funders and professional organisations, are not potentially valuable in other ways – for example, in providing a focus for discussion, organising national and international conferences or producing reports, standards and guidelines on particular ethical issues.) We will return to the question of the possible relationship between funding agencies and Universities in relation to the ethical governance of research at the end of this section.

3.5   Practical questions regarding the operation of Research Ethics Committees

3.5.1   What constitutes 'research' requiring ethical review by a REC? The way in which this question is answered will determine whether most or little of the work of social scientists falls within the remit of a REC. However, attempts to define what constitutes 'research' have been problematic and attempts to distinguish which research requires ethical review have been contentious.

3.5.1.1 In the RGF, the DoH defines research as 'the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous method'. This is (presumably) intended to distinguish 'real' research which must be approved by an LREC from audit or routine evaluations which are part of good practice in the provision of services and do not require LREC approval. Such a definition, however, would exclude much social science research and points to the need for a definition which recognises the legitimacy of other paradigms of knowledge production (Truman 2003; TCPS, 2003).

3.5.1.2 In relation to social care, the DoH Implementation Plan for Social Care refers to 'forms of disciplined enquiry' rather than research and suggests an operational definition for RGF coverage in terms of who carries it out (those who are not employees of the local Council or its contracted agencies) rather than what it entails.

3.5.1.3 A more common approach has been to attempt to define research and then to specify those categories which are exempt from ethical review. For example, in the USA, the 1981 National Commission for the Protection of Human Subjects defined research as 'a systematic investigation designed to develop or contribute to generalisable knowledge' but excluded from the requirement for ethical review (1) research in educational settings on new or established instructional strategies and techniques, curricula or classroom management methods; (2) research involving the use of educational tests, if identifiers cannot be linked to the subject; (3) surveys and observational research in public places which do not entail collection of personal identifiers or address sensitive topics or illegal behaviour; (4) studies using existing data or documents in the public domain. In Canada, the TCPS defined research as 'systematic investigation to establish facts, principle or generalisable knowledge' (TCPS, 2003: 1.1) but excluded research involving public policy issues, the writing of modern history or literary or artistic criticism because they involve no interaction with the person who is the subject of the study. Quality assurance studies, performance reviews or testing within normal education requirements are also excluded.

3.5.1.4 In Australia, the NHMRC (1999: 6) identified 'the validity of its results' as its defining feature but acknowledged the difficulty of finding an agreed definition of research. Instead, it provided a (provisional and illustrative) list of examples, including (1) systematic prospective collection of information to test an hypothesis; (2) a planned study of existing practices with a view to changing/improving practice; and (3) the administration and analysis of data in response to surveys or questionnaires, interviews or opinion polling. It also discussed the distinction between therapeutic and non-therapeutic research, clinical and non-clinical research and 'pure' and 'applied' research, all of which it considered to fall within the purview of the National Statement on Ethical Conduct in Research Involving Humans.

3.5.1.5 A related question is what constitutes a 'human participant'. This is generally seen to include living human beings, human beings who have recently died (cadavers and human remains), embryos and foetuses, human tissue and bodily fluids, and human data and records (such as medical, financial, personnel or criminal records and test results or scholastic achievements). The Australian NHMRC, however, takes a broader view of participants and human involvement. Human involvement is regarded as including 'the use and/or collection of personal, collective or cultural data from participants or from their records, which may include their oral testimony or observed cultural activities, the testing of responsiveness to conditions devised by researchers or invasive testing of new therapies' (NHMRC 1999: 6). Participants are taken to include 'not only those humans who are the principal focus of the research endeavour but also those upon whom the research impacts, whether concurrently or retrospectively' (NHMRC 1999:7).

3.5.1.6 With regard to records, a distinction is sometimes made between records which exist in the public domain and those which do not, with research using the former not requiring ethical review. This would include, for example, the datasets which are available through the Office for National Statistics or the ESRC Data Archive where appropriate permissions have already been obtained and it is not possible to identify individuals from the information provided.

3.5.1.7 A final but important point is that exemption from ethical review does not mean exemption from ethical standards: it is generally expected that the same ethical principles will inform enquiries which are not subject to formal ethical review.

3.5.2. Who should review applications? The answer to this question is important for both the approach a REC is likely to take in reviewing research (challenging, probing, questioning – or either uncritically accepting or simply dismissive) and its credibility with the public. There is general agreement that RECs should be competent to review the applications they see, in terms of ethical reasoning as well as 'scientific' expertise (eg in research epistemology, methods of data collection and techniques of analysis). How this can be best achieved is more debatable. Traditionally, members of RECs have been expected to be of sound judgement, to have relevant experience and to seek specialist training and regular updating in relation to ethical and legal issues (eg around genetic or stem cell research, data protection, trial requirements). As these issues have become more complex, a case has been made for the creation of professional ethics committees – carefully constituted, properly trained, and developing expertise through dealing with large numbers of proposals on a weekly basis (c.f. AREC Newsletter December 2003). Whatever the professional status of RECs, however, it is essential that members receive proper and continuing training in research ethics, in relevant legislation and in research methods and epistemologies.

3.5.2.1 There is also debate over the appropriate composition of a REC with regard to the background of its members. Some social scientists have argued that review should be solely by peers from the same discipline who understand their position with regard to epistemology and methodology and are familiar with the professional code of practice which defines acceptable ethical conduct. Such committees, however, risk reflecting only the interests and perspectives of the researchers. It is more commonly argued that the membership of RECs should enable the views of 'the public(s)' as well as researchers to be considered and should ensure the committee's independence from both the researchers whose work they are reviewing and the institution or organisation they are advising: that is, that RECs should be multi-disciplinary committees and include lay members and individuals from the local community (Neuberger 1992; Ringheim 1995; DoH 2001b; TCPS 2003). A more broadly based membership is also more likely to have more credibility with participants and offer more public accountability. Where research is concerned with services – for example, health, education or social services – it is also important to involve services users at some

point in the review process since they are likely to bring a distinctive and valuable perspective.

3.5.2.2 Because the composition of a REC is crucial to the way it functions, it is important to recruit competent and respected individuals as members. However, at a time when Universities (and other public institutions) are over-stretched and under-resourced, there may be little interest or willingness amongst academics, users or lay people to sit on them. This is particularly likely to be the case amongst senior academics who would have most to contribute as members of a REC. Without adequate incentives and proper recognition of their efforts, the work of a REC is also likely to be regarded as a chore to be completed as quickly and easily as possible rather than a valued responsibility to be carried out with care and attention. Resources and recognition, as well as training, are fundamental to the success of any programme of research ethics review.

3.5.3   How can the independence of RECs be established and maintained? For the decisions and advice of a REC to be respected, they must be seen to be made impartially, free from bias and undue influence. That is, they need to be – and be seen to be – independent of both the researchers whose work they are reviewing and the institution in which they are based. The independence of RECs is generally regarded as founded on their membership, on strict rules regarding conflict of interests and on regular monitoring of and accountability for their decisions (Ashcroft and Pfeffer, 2001).

3.5.3.1 As noted above (3.5.2.1), it is generally accepted that the membership of a REC should reflect the interests and views of the lay public and potential research participants as well as of researchers and other academics. In order to maintain independence from the institution in which a REC is based, it is also accepted that at least two of its members should be recruited from outside the institution and should have no personal or financial interest in it.

3.5.3.2 Rules and procedures for identifying and dealing with potential conflicts of interest are also crucial to maintaining independence in the way a REC reviews applications. Potential conflicts of interest include, for example, conflicts between the interests of the University, or a part of the University, and the interests of a researcher making an application to the REC; conflicts between the private interests of a member of the Committee and the interests of a researcher making an application to the REC; and conflicts between the interests of the researcher and the interests of the research participants. Fundamental to dealing with each of these situations is the principle of prior disclosure of potential conflicts of interest and withdrawal from discussion and decision-making.

3.5.3.3 Ashcroft and Pfeffer (2001) suggest that 'increasing demands for mechanisms of governance or audit of the work of research ethics committees' will provide further means for monitoring and demonstrating the independence of RECs and the quality of the review they provide. On a very basic level, these might include the expectation that (like Parliamentary select committees) RECs meet in public and provide publicly accessible minutes of their deliberations.

3.5.3.4 These issues also have a bearing on where RECs might be located within an institutional structure. Department RECs are likely to comprise members from only one or a small number of closely related disciplines and are unlikely to include lay members or individuals independent of the University. They are generally regarded as appropriate for reviewing only undergraduate student projects. Faculty, School or Divisional RECs are likely to be multidisciplinary and could include individuals from outside the institution as well as those with the requisite skills and experience to evaluate more complex and ambitious research applications from post-graduates and academic staff. RECs at University level are also likely to be more broadly based, although these commonly leave the work of reviewing

applications to RECs in Schools or Departments and to concentrate on policy matters and oversight of the other RECs. The advantages and limitations of RECs at each of these levels are summarised in Appendix 1.

3.5.4. How can bureaucracy be kept to a minimum? One of the main concerns of researchers regarding ethical review is the level of bureaucracy (and consequent effort, money and delay) involved and it is likely to be accepted only if this is kept to a minimum (Alberti 2000, Lux et al 2000, Nicholl 2000, Tully et al 2000, Meerabeau et al 2003). This is the case both for those who apply for ethics approval and for those who are asked to sit on the Committees which review these applications. Research can make a real contribution to the welfare of individuals and groups as well as adding to the sum of human knowledge and understanding. In designing a system for ethical review, it will be important to ensure that the structures and processes do not obstruct research, or put off researchers, to the extent that potentially valuable studies are not undertaken.

3.5.4.1 A fundamental way to reduce unnecessary bureaucracy to adopt a system where the form and level of review are proportionate to the level of risk of harm involved. While the risks entailed in social research should not be underestimated, many studies address minimally sensitive topics, entail minimal intrusion or disruption and involve participants who would not be considered vulnerable in the context of the research. Full review of such studies would seem heavy handed, obstructive and a burden on the REC. However, this raises two further questions: How can the degree of risk be determined prior to ethical review? And what is 'proportionate' review?

3.5.4.2 With regard to the first question, the way the degree of risk is determined is likely to influence the proportion of social science research that receives closer scrutiny or a lighter touch. It has traditionally been left to researchers themselves to determine the degree of risk to participants and to voluntarily seek advice from a REC or similar source when they think it appropriate. How far they have done so in practice is unclear. While the growing literature on research ethics, particularly from qualitative researchers (eg Mauthner et al 2002), suggests that researchers are not unaware of ethical issues, there is little evidence that they have sought the advice of a research ethics committee in considering how to proceed. (This may, of course, be because research ethics committees with expertise in the social sciences have not commonly been available.) An alternative to this voluntary approach is the routine use of a checklist – completed by the researcher, supervisor or Departmental REC – to identify research which involves different levels of risk (SATSU 2002; DWP 2003). This is perhaps a more systematic approach and may facilitate greater consistency amongst researchers. (An example of a checklist is provided in Appendix 2.)

3.5.4.3 With regard to the second question, views differ as to what is 'proportionate' and in particular as to how 'light' a lighter touch should be. The Canadian Tri-Council Policy Statement (TCPS) (2003: 1.7), for example, specifies three levels of review, 'each linked to the other through formal authorisation by the institution, as well as by accountability through the REB to the institution's authorities'. These are full review by the REB, expedited review by the Chair or sub-group of the REB and, for undergraduate projects only, review at Departmental level.

3.5.4.4 The use of expedited review is an important option in ethical review as it adds a degree of flexibility to procedures. Chair's Action is perhaps the most common form of expedited review although it is controversial as it concentrates considerable power (and responsibility) into the hands of one or two individuals. Unless restricted to particular circumstances, Chair's Action defeats the purpose of having a Committee at all (Neuberger 1992). These circumstance are nonetheless important to researchers and might include, for example, dealing with responses to specific questions or requests from the REC, agreeing

minor revisions to research instruments or research design or approving new studies which are close variants on previous studies which the REC had already approved.

3.5.4.5 Other forms of expedited review include review by sub-committees of a REC and review by a 'virtual' committee. Sub-committees of a REC can each look in detail at a proportion of the applications received and report their decisions and advice to the full Committee for ratification (or discussion and revision if required). Virtual committees provide a similar function but conduct their review electronically (via a web site or email). Both approaches have the advantages of drawing on a wider range of individuals to take part in ethical review and of facilitating swifter review. This may also help 'demystify' research ethics review and develop a more sophisticated understanding of the issues amongst those who take part in it. There is a risk, however, that if appropriate training in research ethics is not also provided, it may simply confirm assumptions that social research is ethically unproblematic and result in a ritualised 'rubber-stamping' of applications.

3.5.4.6 Research by students can also be considered a special case requiring a different approach to ethical review. Student research is primarily intended as a training in research methods rather than to produce 'generalisable knowledge' and the case has been made that the 'science' of such studies (though not the 'ethics') should be evaluated in these terms. Student projects can be particularly difficult for RECs to deal with, however, as they come in large numbers, start at the same time and have a very short timescale for completion. RECs specifically for student projects (SPECs) are under consideration by a working party of COREC to accommodate student projects carried out in the NHS (Working Group on Ethical Review of Student Research in the NHS, 2004). They would be based in the University providing the training and established 'as a joint endeavour between the Department of Health and the University/Higher Education sector' (WGERSRNHS 2004: 7). Membership of SPECs would also need to conform to the requirements of GAfREC (2001).

3.5.4.7 A flow diagram showing the different levels of ethical review is provided in Appendix 3. What is important to note here is that *all* research involving human participants enters the system of ethical review though much of it is dealt with quickly and simply by Departmental RECs or expedited review at School, Faculty or Divisional level.

3.5.4.8 Another key way of addressing bureaucracy and the delays it brings is by adjusting the timing and frequency with which RECs meet. This is important in relation to researchers' timetables and the demands on them to produce timely results. Delays to research caused by lengthy waits for LREC approval has been a common complaint amongst medical and social science researchers alike (Alberti 2000, Lux et al 2000, Nicholl 2000, Tully et al 2000, Meerabeau et al 2003). University RECs have traditionally met infrequently – in some cases, once or twice a year – which may also have discouraged individuals from seeking their approval.

3.5.4.9 The question of how often RECs should meet is perhaps best answered in terms of local needs and resources, although regular and frequent meetings are important in developing and maintaining expertise. The proposal for 'professional' ethics committees in the NHS entails a smaller number of committees meeting once a week. In Universities, RECs could meet both on a regular monthly basis and on a more ad hoc basis 'as required'. SPECs would be expected to arrange their meetings in accordance with their knowledge of course timetables in their institution.

3.5.4.10 Whatever the system adopted to provide timely and proportionate review, research ethics review remain the responsibility of the University Research Ethics Committee (or the main REC within another institution) which in turn is accountable to the appropriate University authority, for example, the University Research Committee or Academic Board. Responsibility for reviewing applications can be delegated to RECs at other levels which

would in turn be accountable to the University REC for the decisions they made. Some form of annual monitoring and periodic audit of the activities, procedures and decisions made at all levels would also be helpful in maintaining high standards and combating any tendency towards routinisation or 'streamlining' of procedures to get through a heavy workload quickly.

3.5.5. What (and whose) criteria should be used in reviewing applications? This question addresses an issue which is at the heart of the difficulties recently described by social science researchers seeking approval from NHS LRECs – the review of research conceived within one paradigm in terms of the criteria determined by another paradigm. The appropriateness of doing so has long been questioned (Gray 1982; Tropp 1982; Robertson 1982; Ringheim 1995, Ramcharan and Cutcliffe 2001) and the recent moves to tighten requirements for ethical review in both Canada and the UK have served to draw attention to it once again.

3.5.5.1 One aspect of this question concerns the review of the 'scientific' merit of research proposals. While a poorly designed study may not be ethical, a REC – however experienced the members are in their own research traditions – may not be in the best position to judge the science of all the proposals that come before it.[11] Scientific review and ethical review are related but distinct and both are important. In recognition of this, the revised DoH RGF requires that applicants provide evidence of independent peer review of the science of their research proposal prior to review by an LREC or MREC which will then focus exclusively on ethical issues. Alternative approaches to obtaining appropriate review of a proposal in terms of both 'science' and 'ethics' would include ensuring that the REC includes members who have relevant research expertise or requiring it to draw on external advisors with relevant research expertise to review the science of each proposal.

3.5.5.2 The other aspect of this question concerns the knowledge and expectations which RECs bring to the ethical review of research proposals. In the UK, researchers (particularly those using qualitative methods) have complained that it is often impossible or undesirable to meet the standard requirements for LREC approval – for example, signed consent forms from each participant – and that the focus of LREC scrutiny often completely misses what they and their participants regard as significant ethical concerns (Kent et al 2002; Truman 2003; Meerabeau 2003). They have also pointed to a gap between theoretical prescriptions and the realities of fieldwork, particularly – though not exclusively – in relation to qualitative research which involves maintaining a relationship with participants over a substantial period (Oakley 1981, Batchelor and Briggs 1994, Ramcharan and Cutcliffe 2001). The process of ethical review is perceived to distort the collaborative relationship between those conducting and participating in research and to frustrate the general 'thrust and purpose ' of the research (Kent 2002; Truman 2003; van den Hoonaard 2001).

3.5.5.3 This points to the need for RECs to be familiar with and willing to use a variety of ethical and epistemological frameworks in reviewing research proposals (which in turn points to the importance of proper training programmes). In Canada, for example, the TCPS (2003) explicitly recognises that there are a variety of philosophical approaches to ethical issues and that ethical principles should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline. 'Some approaches are traditional, but others, such as feminist analysis, are centred on context, relationships of power and allocations of privilege that perpetuate disadvantage and inequality' (TCPS 2003: i.9) Debate between these approaches is encouraged, both to inform ethical decisions and to ensure an evolving context for ethical considerations.

3.5.5.4 Such flexibility is not easily achieved within a bureaucratic process which strives for universal coverage. In Canada, for example, despite the good intentions of the TCPS, the Social Sciences and Humanities Research Ethics Special Working Committee has

questioned the core assumptions and paradigms of research which underpin the framework used in reviewing their research (PRE 2003). Others have also pointed out that the use of standard forms for all research proposals submitted for ethical review forces those researchers who do not use the dominant paradigm into a defensive position in having to argue the case for 'doing things differently'. If a RECs are to consider research proposals from a number of different paradigms, then the forms on which they are set out will also need to reflect these different paradigms as will the procedures the RECs use.

3.5.5.5 In the UK, Ramcharan and Cutcliffe (2001) suggest an 'ethics as process' model which might serve as an example of how ethics committees could manage the protection of the rights, dignity and wellbeing of participants in qualitative research. They suggest that RECs make the prior assumption that the research under consideration would be conducted in a way that would not undermine participants emotionally, socially or physically; would take care to manage the researcher-participant relationship and the researcher's withdrawal from the field; would make clear (repeatedly) to participants the balance between their personal contributions and the benefits of the work to them and more widely; would enable participants to review how they were presented in fieldnotes and publications; and would create an 'audit trail' as a record of their work (Ramcharan and Cutcliffe 2001: 364). Rather than expecting applicants to specify their research design and the potential risks to participants in advance, RECs would accept that the research design was emergent and that not all risks could be anticipated and would monitor the risks and benefits (and the ratio between them) as they became apparent over the course of the study.

3.5.6. When should research first be reviewed and (how) should review continue?
This question is related to the previous one insofar as the times when significant ethical issues are likely to arise or be recognised are likely to vary according to the paradigm in which the research was conceived and designed. The way in which it is answered will have implications for the way RECs operate and the resources they require.

3.5.6.1 The question of when research should first be reviewed is relevant to all studies. While there is a clear expectation that research should be reviewed before it is started, there is some debate about the particular point at which this should first occur. The requirement that research be approved before an application is *submitted* for research funding seems inappropriate and wasteful as the majority of applications are not funded. It is less clear at which of the other points prior to the main stage of data collection review by a REC might be most appropriate: prior to a pilot study so that participants interests are protected (DoH 2001a); prior to seeking the agreement of potential research sites and gatekeepers so they can be assured of its good standing; or prior to the main data collection when research instruments have been tested and access to participants agreed.

3.5.6.2 Continuing research may require continuing review but for qualitative research this may be particularly important (Neuberger 1992; DoH 2001b; TCPS 2003). The question for RECs is whether they should attempt to provide this review themselves – which could become burdensome and entail too close a relationship with researchers – or liase with other another group such as a project advisory group or department REC which may be better placed to support continuous reflection and debate (Batchelor and Briggs 1994; Truman 2003).

3.5.7. What about sanctions? For RECs to be effective, they need 'teeth' (Neuberger 1992; Freed-Taylor 1994). What sanctions are available to RECs when their decisions are ignored? In the USA, the requirement for IRB review is supported by legislation. In the NHS it is a disciplinary offence to conduct research on human participants without first obtaining approval of a recognised REC (hence the requirement that non-NHS researchers obtain

honorary contracts). Other possible sanctions include censure, reprimand and ostracism by professional bodies, withdrawal of research funding and refusal of co-operation in research undertakings (Freed-Taylor 1994)

3.5.7.1 Sanctions are also important at the institutional level, with regard to ensuring that Universities and research institutions agree appropriate standards of ethical review and put into place appropriate structures and procedures to implement them. In the USA, Canada and Australia, government funding is available to institutions only if they agree to ensure that all research involving human participants is reviewed by a recognised REC. The Canadian Tri-Council Policy Statement on Research Ethics (2003) makes it clear that this includes all research conducted by or within the institution, regardless of the source of funding (see TCPS (2003) Appendix 1). In the USA, the system of regulation has sanctions and penalties which can affect the whole University as well as any single study.

3.5.7.2 If review by a REC is incorporated into the REF as the preferred mechanism for implementing it, then clarification would be needed on whether this was a hope, an expectation or a requirement; if it were a requirement, it would need to be backed up by a statement that funding would be restricted to Universities and institutions which signed up to the ESRC Research Ethics Framework and demonstrated that they were able to provide (or secure) ethical review by an appropriate REC. (The ESRC already takes a similar position with regard to research training: Universities which do not meet the specified requirements for training research students in research methods are excluded from applying for studentships for their post-graduate students.) It would also be appropriate to ask other organisations, agencies and government departments to endorse the ESRC REF and support its implementation. This is in effect what a number of other funding bodies, such as the Wellcome Trust, have done in response to the requirements of the DoH's Research Governance Framework.

3.5.8. Who bears the costs?
Reviewing research proposals takes considerable time and resources on the part of REC members; resources are also needed to provide appropriate training to members and administrative support for their activities (DoH 2001b; TCPS 2003). The ability of Universities and other institutions to provide these resources will depend on who is expected to bear part or all of the costs. For example, a case could be made for support to be provided by HEFCE as part of quality assurance measures or by funding bodies in recognition of the increased costs of conducting research.

3.5.9. What should be the relationship between RECs?
The principles of accountability require that each University be responsible for research carried out under its auspices and under its jurisdiction. This means that each University is responsible for research carried out by those employed by the institution and for research carried out by researchers external to it who wish to recruit participants through the institution. Where research is carried out by a team of researchers from different institutions, each institution is, in principle, individually responsible for the research carried out by its employees. How easily these complexities in responsibility are managed will depend on whether acceptable arrangements can be made between RECs in different Universities and institutions (or more accurately, the REC with primary responsibility in each institution) to communicate their views and concerns to each other and/or to accept each other's reviews and decisions.

3.5.9.1 In the past, researchers who have attempted to recruit participants from a number of NHS sites have identified the need to gain formal approval from each LREC as a major hurdle in conducting research. The process itself was time-consuming and, as each LREC

was independent, it was not uncommon for researchers to receive inconsistent and contradictory comments from different committees, which could create significant difficulties for the design of a study. MRECs (Multi-Centre Research Ethics Committees) were established in an effort to address this problem, although MREC approval does not preclude the need for site-specific assessment by an LREC as well. Much has improved, however, since the establishment of the Central Office for Research Ethics Committees (COREC) to co-ordinate the development of operations systems for LRECs and MRECs on behalf of the NHS.

3.5.9.2 Within academia, communication between RECs would be facilitated by the use of common forms and approaches for reviewing applications. Mutual recognition by RECs would be aided by the establishment of a common policy for reviewing applications – including common standards, structures and procedures and appropriate training – which could be agreed and monitored along the lines of the ESRC research training recognition. Universities could then authorise their own REC to accept the review carried out by another REC recognised by this procedure.

3.5.10 Should University RECs be accredited, recognised, registered or certified by or with an appropriate organisation, for example the ESRC or RCUK? As noted above, if Universities or other institutions were to be asked to accept the decisions of RECs in other Universities or institutions, a common policy (including common standards, structures and procedures and appropriate training) would need to be agreed amongst them and some mechanism of quality control (along the lines of the ESRC research training recognition exercise) put in place. This could be the basis for registration, accreditation or certification, with formal adoption of detailed governance arrangements such as those set out by the Department of Health (2001b)[12].

3.5.10.1 Such an approach would be similar to other systems of ethical governance, including those instituted by the DoH for research conducted in the NHS and those operating in Canada and the USA. For example, both the American approach and that adopted by the DoH require that the institution responsible for a research study (in practice, usually the employing institution) formally sign up to accepting responsibility for ensuring that the research is carried out to a high ethical standard (*FWA* in the USA and the *sponsor* role for the DoH) and both require review by a research ethics committee which is properly constituted and which is *registered* (as an IRB in the USA) or *accredited* (by the DoH). (In the UK, some research will need to be reviewed by a 'recognised' REC. Recognition involves more demanding requirements including specific scientific expertise such as statistics and pharmacy and is a consequence of the new EU clinical trials directive. All MRECs and some LRECs will be required to be recognised.)

3.5.10.2 As an incentive to meet these standards, it could be made clear that funding would be available only to those institutions which signed up to the new ESRC REF and provided (or secured) ethical review of research involving human participants by a properly constituted REC. This would be similar to the ESRC's approach to raising standards in research methods training, where research studentships are available only to institutions which meet the detailed requirements it sets out.

3.5.10.3 Is there a case for taking such measures? The case made in this paper has been a general one: that in the context of the changing research environment, ethics review in the social sciences needs to be more rigorous, transparent and accountable, and that a properly constituted research ethics committee is the most appropriate mechanism for providing this.

3.5.10.4 A more specific case can be made in relation to the issues raised for social science researchers by the Department of Health's (2001a) Research Governance Framework. This requires that all research on human participants carried out within the NHS be approved by a REC that it accredits or recognises. As noted in earlier sections, this requirement has created many difficulties for qualitative social scientists involved in health research, and given rise to calls for RECs which are specifically for social science research. The DoH also makes it clear in both the Research Governance Framework (2001a) and the Implementation Plans for Social Care (2003) that research which involves participants recruited through social care services for which it has responsibility will also eventually require review by a properly constituted REC[13]. Since much research within social care is conducted within a social science paradigm, this is likely to have significant implications for social researchers.

3.5.10.5 Would the DoH or other government departments, agencies or organisations accept review by a REC accredited, registered or recognised by the ESRC or RCUK, as adequate reassurance of the ethical standards of the conduct of research? The DoH has already acknowledged that the NHS system of LRECs is probably not the most appropriate way of reviewing research in social care and has asked whether review by RECs within researchers' own institutions might be a better solution (DoH 2003). The COREC working party on student research has also proposed a joint endeavour between the Department of Health and the University/Higher Education sector in establishing SPECs within Universities providing training to students in health, medicine and social care (WGERSRNHS 2004: 7). If RECs were established to an appropriate standard (c.f. DoH 2001b) within Universities, they could provide a solution to the challenges faced by both social researchers and the DoH – or whatever government department(s) take on responsibilities for social care services – in reviewing research within social care. If these RECs were regarded by the DoH as equivalent to LRECs within the NHS, they could also provide ethical review for research involving patients, carers or staff within the NHS where this was agreed as appropriate. Similarly, as other government departments consider the need for closer ethical scrutiny of research they conduct or fund, Universities would be in a position to provide any ethical review that was required as a condition of government funding.

3.5.10.6 Such a solution would be in keeping with common practice elsewhere. In Canada, for example, institutions are accountable for the research carried out under their jurisdiction but can authorise their RECs to accept the decisions of other RECs 'constituted under the Tri-Council Policy Statement' if it wishes (TCPS 2003: 1.3). In the USA, Government funding is available only to institutions (anywhere in the world) which have provided, and had approved, written assurance that they will comply with the Federal Policy for the Protection of Human Research Subjects (DHHS 2001) and which have a registered IRB (or have an agreement with an institution which has a registered IRB) to review all research involving human participants (regardless of the source of funding). But a properly constituted REC in any institution can apply to be registered as an IRB and any institution which has an IRB (or has an authorised agreement with an institution which has a registered IRB) can apply (to the Office for Human Research Protections) for approval of its policies and procedures in relation to the protection of human subjects (OHRP 2002).

4. Concluding Comments

4.1   In this paper we have considered mechanisms which might be appropriate for implementing the ESRC Research Ethics Framework, particularly review by a properly constituted Research Ethics Committee. It is important, however, to put this into a broader context.

4.2   Review by a REC is only one of a number of elements which underpin ethical conduct in research. RECs contribute by considering ethical issues from perspectives additional to

those of the researchers and by providing advice and guidance on how particular ethical issues could be addressed. This can help researchers to avoid breaches of professional conduct and to protect the well being of participants, researchers and the wider community. But responsibility for ethical conduct lies ultimately with researchers themselves and 'positively ethical' research is the product of their day to day actions and decisions in carrying out their work.

4.3   Fundamental to ethical research are the values and attitudes, knowledge and skills of researchers and it is through education, debate and reflection that these are formed. The ESRC Research Ethics Framework, like other professional codes of practice, can play an important part in setting out the principles which should guide researchers. RECs provide a forum for discussing the way these principles are interpreted and put into practice in individual studies. Their role should be seen as more 'educative' than 'policing' and their main functions as stimulating informed discussion, sharing good practice, and creating an ethically more informed research culture within an institution.

4.4   RECs entail cost to both researchers and their institutions and these can only be justified if ethical review is accepted and taken seriously by all concerned. To facilitate this, ethical review will need to build on and take forward the systems and structures which Universities and other institutions are developing as part of their measures for research governance. It will also need to avoid involving researchers in unnecessary bureaucracy by ensuring that the level and form of ethical scrutiny is proportionate to the level and nature of risk of harm entailed and that review procedures are sufficiently flexible to address ethical issues in a practical timescale. Finally, it will also need to demonstrate 'added value' for all involved, for example in terms of a research culture which is more aware of and sensitive to ethical issues and the variety of ethical (and epistemological) perspectives for considering them, greater confidence in the ethical conduct of research on the part of participants and their communities and the organisations (for example, the DoH) through whom they are recruited; and the ethical conduct of researchers in their daily work.

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Endnotes:
1. See also the DWP document for their list of options available within government to put into place suitable and observable compliance arrangements. These include individual discretion, additional training for social researchers on ethical issues, ethical checklist, team checking, inter-term reviews, inter-governmental reviewing, external academic reviewing and medical ethics style committees.

2. Lessons of the past suggest that they are not. Perhaps the most famous code of ethics is the Nuremberg Code, drawn up at the end of the second world war in response to the atrocities of Nazi experiments on human beings. In the absence of any external process of ethics review, however, it was largely ignored in the 1950s by doctors in the UK and elsewhere who regarded themselves as professionals bound by a strict code of practice but

who nonetheless conducted clinical research which routinely violated the rights and interests of their patients (Foster 2001; cf Pappworth 1969; Beecher 1966).

3. This is also implied in the Social Care Implementation Plan p 4 1.11

4. See Kent et al 2002 – personal communication with the ESRC

5. Ashcroft argues that the inclusion of research ethics committees in the Department of Health's Research Governance Framework represents the culmination of the regulatory model of research ethics. 'Placing RECs in the governance framework effects the completion of a conceptual transformation of RECs from peer-led 'ethical committees' close in spirit if distant in form to the professional-oriented model, to management and institution-oriented quality management systems' (Ashcroft 2003: 52-53). Furedi (2004) also sees RECs as part of the ethos of managerialism and the culture of administrative functions that have been introduced into University life over the last 15 years. '[W]hen you look at the working of ethics committees in universities you will find that they are primarily in the business of dealing with issues like risk management which, in a different setting, would be dealt with by risk managers with no claims to ethical knowledge or expertise' (Furedi 2004: 4).

6. While RECs have the potential to monitor research conducted with their institutions and are accessible to audit and quality assurance measures themselves, there is little evidence that this happens in practice.

7. Following a review of ethical considerations in European cross-national research, for example, Freed-Taylor (1994: VII) proposed 'a combination of a self-regulatory code, an ethics review committee and recourse to legislative sanctions in the case of serious breaches' as the way forward for the social sciences.

8. Those who reject this position counter that academic freedom brings academic responsibility including that of a more general accountability to society (TCPS 2003: i.8). 'The premise that scientific freedom overrides other social values would place scientists beyond the judgement of the larger social system' (Nelkin 1982: 164).

9. In autumn 2003, the Nuffield Foundation funded a survey of 115 UK Universities (Tinker, 2004). The findings of this study were not available to the authors at the time this paper was written.

10. In Spring 2004, MB consulted senior researchers from 12 institutions – in the fields of anthropology, economics, epidemiology, geography, health economics, health psychology, medical sociology, politics, public health, social policy, sociology – regarding current practices of ethical review in their disciplines and in their own institutions. An Assistant Director in Researcher Governance and a senior administrator for three NHS Research Ethics Committees were also consulted. All the researchers reported that they now had to submit their research involving human participants to formal ethical review in their institutions. However, the mechanisms of review varied widely and included self certification, peer review by email, and mandatory review by a Divisional or University REC. It also became clear that, regardless of their particular discipline, the social scientists who had routinely to submit their research to an NHS REC found the process valuable and reassuring even if they also complained of the additional effort and delay involved.

11. Qualitative social science researchers are not alone in finding that RECs to not understand their research methods: medical scientists have also reported what they regard as inappropriate responses to their applications based on poor understanding of the science. See, for example, Pearson 2000.

12. In Canada, the Tri-Council Panel on Research Ethics has been consulting with the research community on similar questions: 'Should research ethics boards be accredited or certified? Should the ethics of human research be governed by specific federal legislation?' (PRE position paper April 2002).

13. The relationship between the Department of Health and social services is changing, as the Social Services Inspectorate which used to be located within the DoH is replaced by the National Care Standards Commission and as children's services move from the DoH to the new Children's Trusts where the DfES is taking the lead. It remains to be seen whether the requirement for research ethics review as envisaged by the DoH will be accepted or adapted by those who have responsibility for social care services in the future.

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Contact details:
ESRC Research Ethics Framework project
Email: ref@york.ac.uk Project website: http://www.york.ac.uk/res/ref/

Appendix 1: Advantages and Limitations of RECs at different positions in a University

Site of REC in University	Advantages	Disadvantages
Department or Discipline (eg Psychology REC)	• Well versed in appropriate professional code of practice & able to cater for particular requirements of discipline • Likely to have Methodological Specialists (eg in qualitative research, experimental design) • Close to researchers and able to identify new studies at appropriate time • Able to respond quickly to applications for review (eg *ad hoc* meetings, limited workload) • Able to provide continuing support & advice to researchers	• Can become too closely identified with the needs, interests & values of researchers (rather than the public) and hence lose the confidence of potential participants • Can become insular or ghettoised and hence lose the confidence of researchers from other disciplines/departments • Can lead to a proliferation of RECs and duplication of bureaucracy within the institution • Can become intrusive & a burden to researchers if providing on-going support & advice
Division or School (e.g. Health Care REC, Business School REC)	• More multi-disciplinary and independent of individual researchers • Good balance between specialist knowledge (eg of methodology, codes of practice) and alternative paradigms (eg of above) which may help constructive debate • Able to respond relatively quickly (eg manageable workload, administrative support) • More efficient use of time (fewer individuals involved in RECs across the institution)	• Can lead to inconsistency in expectations & approach amongst RECs in an institution (which undermines confidence of researchers in the process of formal ethics scrutiny – cf comments on inconsistency in comments from NHS LRECs) • Not appropriate in Divisions where little research involves human participants which can leave some researchers without support or REC for formal review
University (University Research Ethics Committee)	• Multi-disciplinary, drawing together a wide range of experience & expertise • Can include lay members, reflecting views/concerns of potential participants & enhancing independence from researchers • Can foster good practice across the institution	• Perceived by researchers as remote bureaucracy • Potentially unmanageable workload • Slower response time

Appendix 2: An example of a checklist to determine the level of risk of harm entailed in a study

Oxford Brookes University

School of Social Sciences and Law

Research Ethics Review Checklist for Undergraduate and MA students

This checklist should be completed for every research project which involves human participants. It is used to identify whether a full application for ethics approval needs to be submitted. If a full application is required, a form E2/SS&L should be used.

Before completing this form, please refer to the University Code of Practice on Ethical Standards for Research Involving Human Participants. The principal investigator or, where the principal investigator is a student, the supervisor, is responsible for exercising appropriate professional judgement in this review.

This checklist must be completed before potential participants are approached to take part in any research.

Section I: Project Details

1. Project Title:	
2. Participants (number & characteristics):	
3. Methods of data collection (brief description):	

Section II: Applicant Details

4. Name of Researcher (applicant):	
5. Status (please click to select):	Undergraduate Student
6. Email Address or other contact address :	
6a. Telephone Number:	

Section III:

7. Module name and number or MA/MPhil course and department:	
8. Supervisor's or module leader's name and email address:	

☐	The student has read the University's Code of Practice
☐	The topic merits further research
☐	The student has the skills to carry out the research
☐	The participant information sheet or leaflet is attached and is appropriate
☐	The procedures for recruitment and obtaining informed consent are appropriate and the consent form is attached

Comments from supervisor:

Section IV: Research Checklist

Please answer each question by ticking the appropriate box:

	YES	NO
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position? (e.g. children, people with learning disabilities, your own students)	☐	☐
2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g. students at school, residents of nursing home, members of a tribe)	☐	☐
3. Will participants be asked to take part in the study without their knowledge/consent at the time or will deception of any sort be involved? (e.g. covert observation of people in non-public places)	☐	☐
4. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, death, religious beliefs, illegal activities)?	☐	☐
5. Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?	☐	☐
6. Will blood or tissue samples be obtained from participants?	☐	☐
7. Is pain or more than mild discomfort likely to result from the study?	☐	☐
8. Could the study induce psychological stress or anxiety, or produce humiliation, or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☐
9. Will the study involve prolonged or repeated testing?	☐	☐
10. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?	☐	☐

11. Will the study involve recruitment of patients or their carers through the NHS?	☐	☐
12. Will the study place the researcher at any risk greater than that encountered in his or her daily life (eg involve interviewing alone or in dangerous circumstances, involve data collection outside the UK)?	☐	☐

If you have answered 'no' to all questions, **send the completed and signed form E1/SS&L to your Department's representative on the School Research and Consultancy Committee, together with your participant information sheet and consent form, for their records. Retain a copy of the form and submit it with your research report or dissertation** (bound in at the beginning). Work which is submitted without the appropriate ethics form will be returned unassessed.

If you have answered 'yes' to *any* of the questions in Section IV, you will need to describe more fully how you plan to deal with the ethical issues raised by your research. **This does not mean that you cannot do the research, only that your proposal will need to be approved by the School Research Ethics Committee.** You will need to submit your plans for addressing the ethical issues raised by your proposal using the ethics approval application form E2/SS&L, which should be sent to the School Research Ethics Officer. Form E2/SS&L can be obtained from the School web site.

If you answered 'yes' to *question 11*, you will *also* have to submit an application to the appropriate external health authority ethics committee, *after* you have received approval from the School Research Ethics Officer. Further information is available on the University Ethics web site.

Please note that it is your responsibility to follow the University's Code of Practice on Ethical Standards and any relevant academic or professional guidelines in the conduct of your study. **This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data.** Any significant change in the question, design or conduct over the course of the research should be notified to the School Research Ethics Officer and may require a new application for ethics approval.

Signed: . . . . Principal Investigator

Signed: . . . . Supervisor

Date: . . . .

Appendix 3: Flow chart of proportionate review

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┌─────────────────────────────────┐
│ Is this 'research'?             │
├────────────────┬────────────────┤          ┌──────────────────────────┐
│ Yes            │ NO             │─────────▶│ Professional code of     │
└────────────────┴────────────────┘          │ practice still applies   │
         │                                    └──────────────────────────┘
         ▼
┌─────────────────────────────────┐
│ Is this Undergraduate           │
│ research?                       │
├────────────────┬────────────────┤          ┌──────────────────────────┐
│ No             │ Yes            │─────────▶│ Review by Department     │
└────────────────┴────────────────┘          │ REC (or SPEC if NHS)     │
         │                                    └──────────────────────────┘
         ▼
┌─────────────────────────────────┐
│ Does it entail                  │
│ recruitment via NHS             │
│ (or social services)?           │
├────────────────┬────────────────┤          ┌──────────────────────────┐
│ No             │ Yes            │─────────▶│ Review by Divisional REC │
└────────────────┴────────────────┘          │ and referral to          │
         │                                    │ appropriate LREC         │
         ▼                                    └──────────────────────────┘
┌─────────────────────────────────┐
│ Does it entail more than        │
│ minimal risk? (ie 1+            │
│ boxes ticked)                   │
├────────────────┬────────────────┤          ┌──────────────────────────┐
│ Yes            │ No             │─────────▶│ Expedited review by Sub- │
└────────────────┴────────────────┘          │ group of Divisional REC  │
         │                                    │ or Chair's Action        │
         ▼                                    └──────────────────────────┘
┌─────────────────────────────────┐
│ Does it entail:                 │
│ Major ethical issues?           │
│ Conflict of interests?          │
│ Appeal?                         │
├────────────────┬────────────────┤          ┌──────────────────────────┐
│ Yes            │ NO             │─────────▶│ Full review by           │
└────────────────┴────────────────┘          │ Divisional/School/Faculty│
         │                                    │ REC                      │
         ▼                                    └──────────────────────────┘
┌─────────────────────────────────┐
│ Review by University            │
│ Research Ethics                 │
│ Committee                       │
└─────────────────────────────────┘
```