Research Ethics Framework

ESRC Research Ethics Framework

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Discussion Paper 1
Crossing boundaries: social science, health and bioscience
research and the process of ethics review

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**Crossing boundaries: social science, health and bioscience research
and the process of ethics review.**

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1. Introduction

1.1   This paper, the first of four commissioned by the ESRC as background material informing the new *Research Ethics Framework*, explores an increasingly common feature of contemporary research and the implications this has for ethical review. There is a growing interest in sponsoring collaborative research that explores a particular set of issues or problems from a number of different disciplinary perspectives, often linked to work commissioned to address a particular policy objective. There are a number of drivers encouraging this trend, most notably the desire among research funding agencies to support interdisciplinary research, especially across the bio/natural and social science boundaries in regards to developing a better understanding of the science/society relationship.

The following discussion of this question is organised in four parts:
- a set of illustrative cases and the problems they throw up for ethics review;
- a number of general implications we can derive from this;
- a consideration of the implementation of the Department of Health's Research Governance Framework and its relation to social science research;
- a series of general conclusions we can draw about ethics in the context of cross-boundary research.

1.1.2 Today, social science is more likely to be working alongside other disciplines than was the case in the past: witness the rapid increase in the number of projects that explore the implications of science and technology developments in areas such as health, multi-media, transport and the environment. This trend is also reflected in the number of research centres and programmes funded by the ESRC itself that foster this type of work – such as the *Science in Society*, *Innovative Health Technologies*, *Virtual Society*, and *Sustainable Development* programmes and the new network of *Genomics Centres*. Moreover, OST policy is to bring the principal research councils closer together (as in RCUK) such that this research pattern will become more commonplace.

1.1.3 At the same time, however, many methodological difficulties are associated with this multidisciplinary work: questions arise such as what is the status of, and relationship between, different types of data, what assumptions are held by different research teams about the core issues under scrutiny, how are different assumptions to be translated across teams, and what ultimately is the 'problem' to be 'solved'? In regard to the ethics that should inform this work, some might argue that, unlike the need to negotiate and secure a consensus about the research problem, at least there is available a stable and universally agreed set of principles and a process of ethical scrutiny to which all can agree.

1.2 Indeed, this might well be the case, especially if ethics is defined in terms of the four core principles (derived from biomedical research) of beneficence, non-malfeasance, autonomy, and justice. Moreover, notions of consent and confidentiality and more general research governance issues such as honesty with participants and professional integrity seem to be well-understood. This model of a universal ethics is so strong precisely because it is presented as context-free: the broad principle at work might be summed up as one where good research governance prioritises avoiding risk and harm over

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achieving benefits. When research practices, assumptions, and relations to 'the researched' are considered, however, the way in which the model is implemented may be less clear-cut. Where multidisciplinary research is being undertaken, the core principles and the process of review might be interpreted in quite different ways. A few brief (and quite typical though entirely fictitious) illustrations will help clarify this point.

1.3 In the first example, a group of researchers from a university and a government department are funded by a number of different agencies (e.g. the Home Office [HO], ESRC and a charity) to undertake collaborative research on the relationship between patterns of crime and substance (drugs) abuse among young people. The team is made up of sociologists, criminologists, biochemists and social psychologists. To secure the necessary primary data the research involves recruiting young people, possibly through social services and so may be seen to fall under the aegis of the Department of Health's (DH) new Research Governance Framework (DH 2003) even though the work intended is not directly related to the physical or mental health of the respondents, and is certainly not within the context of NHS care or provision of care (a key RGF issue). However, it might also be the case that the proposal be deemed appropriate for review by a university research ethics committee and an HO Approvals Board. The sponsoring charity and ESRC may be happy to devolve to the research team responsibility for determining the most sensible route to take for ethics approval. However, taking one route, rather than another, may mean that the principle of avoiding risk and harm is defined differently: for example, an LREC (via the DH route) might seek further information about the biomedical aspects of the work and any clinical implications it might have, while the HO Board might focus attention on the risk to offenders through loss of anonymity via recruitment and publication of the results. These need not be mutually exclusive demands, but the primacy given to one rather than another would shape the approval process, and quite possibly the sort of research that is eventually done. Strengthening the interdisciplinarity of the REC would clearly make sense in order to deal with these complex cases., while taking a number of ethics approval routes (which is often the case in practice) may well compound the problem further.

Moreover, the research involves securing data on the drug use/crime pattern, but this is to be approached by different team members in different ways: the criminologist might be especially interested in deriving data to determine causal, in contrast to the sociologist who seeks interpretive accounts of the pattern. The relationship between researcher and researched is likely to be quite different across the team members as is the view about the possible harm/benefit to the subject (and wider society) that different findings might suggest. Furthermore, the issue of access to data by all team members when respondents give it on different terms to different members of the team could raise problems about confidentiality and trust.

1.3.1 In this example, we can see that there are potentially competing definitions of the research problem and risk (and benefit) before, during and in the concluding stage of the research that are not easily resolved by an appeal to universal ethical principles. Nor is there an 'obvious' ethics review process through which such a project might go, while it is open to question whether the DH route would be one that would be required.

1.4 A second example involves social science researchers working with clinicians and biomedical researchers to explore the use of IVF and user/practitioner relations, especially patients' perspectives on IVF as a treatment for infertility. In this case an action research approach is proposed whereby the researcher/researched relationship is less sharply drawn at the start as the issues are to emerge through developing a close working/researching relationship with all involved. Even so, there appears to be a more direct relationship here between the research and the health of the subjects and so a conventional LREC route for ethics approval would seem appropriate. Confidentiality and consent for all those individuals involved – clinicians and patients (and their partners) - is crucial in such research, and this will be a point that will need to be properly addressed in the submission for ethics approval. Yet action research is by definition iterative, and so may be unable to identify in advance the risks and harms that could form the basis of informed consent. Moreover, this type of research presumes some sense of partnership between researcher and the subjects of research, and thereby, as co-researchers, a pre-

sumption that they too will accept a degree of ethical responsibility for the work. A different route would be to secure respondents who had had IVF treatment in the past, though this would lose one of the key aspects that a real-time, action research approach would be able to track. And, as the research develops, issues might well arise that would require new consent to be secured, where, for example, information came to light that would need cross-checking with third parties involved in resourcing IVF.

1.4.1 In this example, confidentiality and consent and the review process could only be handled properly where the interpretation of the four principles of the biomedical model were seen as a benchmark for, but not sole basis of, approval. The qualitative, action research model also points to a review process that can only partly be managed via the traditional regime of ethical scrutiny. The case also points to the ways in which ethics scrutiny needs to be able to handle rights and obligations at both an individual and wider collective level. In regard to the risk/benefit of this type of work, we have to see these in both more nuanced ways but also perhaps more limited too: Gomm (2004) has argued that, 'participatory research is usually research which is designed to bring a direct benefit to a small group of people, and only secondarily to generate knowledge for use by others' (p 317). This is arguable of course, and does not do justice to the ways in which such work *has* been of wider use, but it is important that this case be made quite explicitly in social science research. There are also wider questions about qualitative research methodology that have been discussed by Lee-Treweek and Linkogle (2000).

1.5 A third example involves researchers working in the sociology of science examining the development of new information systems in health care that are used to create and manage patient-based records. Here the focus is to be on the social relationships – organisational, professional, socio-technical, regulatory – that shape the development and use of the system. Access to the system requires approval from managers of a local health Trust. The objectives of the research are to determine the utility of the system for practitioners: if this were defined as a 'management review' it would be regarded as an 'audit' rather than piece of research, and, at least formally, require no ethical scrutiny. However, the research team is well-aware that such a definition – though practically convenient - would limit both their analysis and the implications they could derive from their work. A crucial question in judging this research is whether it would require access to raw material in the form of (paper and electronic) clinical records, or whether these simply provide the backdrop against which broader organisational and delivery issues can be explored with users of the system. While this would still require ethics committee approval precisely in order to answer this question properly, bounded as such, it would be debatable whether this would necessarily require LREC approval *per se*, even given the need to access users of the system.

1.5.1 Here the determination of risk and benefit of the research is likely to involve negotiation over the strategic rather than directly clinical implications of the work, whether the work would compromise the autonomy and authority of professionals (since information about the system might reveal unenthusiastic users) and broader organisational questions about the social determination of 'efficacy' and 'efficiency'. How Trust managers respond to these claims to a set of social science priorities that do not require LREC approval is likely to determine whether this type of research could go ahead.

1.6 A final example involves health economists, epidemiologists, sociologists and public health geneticists in accessing data held in the newly established Biobanks (such as that in the UK located in Manchester). They are particularly keen to collaborate on a project that examines in detail the link between the socio-economic and health-related information for a cohort. Secondary use of the Bank's data in this way that link (perhaps in a decade from now) genetic and lifestyle information on deposited samples raises many new ethical problems, especially in regards to so-called 'stacked consent' whereby depositors are deemed to permit subsequent research on samples from their initial consent. Collaborative research that brings together social and other scientists (as above) will be likely to be regarded as central to deriving the full value of the Banks. However, research teams will face powerful ethical and regulatory hurdles placed by Banks themselves, outside of normal ethics review procedures, which will require clarification about and restriction on the use of material. Within social sci-

ence itself, of course, there are parallel research governance requirements made by the ONS in regards to use of its data sources, for example, in relation to census data.

1.6.1 This example has been included here to illustrate one of the features of contemporary large scale ('Big Science') research – the establishing of large national datasets that bring together scientific, clinical and social information in new ways. The novelty of such developments lies in the scale and characteristics of their data that thereby require new *institutionalised* ethical and governance provisions that underpin and in a sense precede any specific ethics approval process and are not reducible to the four principles. In light of this, it is a moot point whether a conventional LREC process would be appropriate here since conventional notions of risk and harm may be inadequate measures of the possible affects of the research, especially in the medium to longer term.

1.7 These four different examples of collaborative research crossing the social science, health and bioscience boundaries have been sketched out to draw attention to some of the problems that will become increasingly commonplace for UK researchers responding to more complex even if exciting research opportunities. They also suggest that the implementation of a set of ethical principles as a context-free model is likely to miss as much as it catches in minimising risk and harm to the subjects, researchers and sponsors of collaborative work. In section 4 below, a number of suggestions are made to help manage the research process where cross-disciplinary teams are involved. First, though, these introductory remarks and exemplars lead to some broad observations, as follows.

2. General observations on cross-boundary research

2.1 In light of the above, it seems important to distinguish between three distinct even if necessarily related domains in which ethics play a central role. First, there are what might be regarded as generic ethics, those principles and processes that should inform all good research practice (whether single or multidisciplinary): these are the *ethical duties* associated with a moral regard for the subject(s) of research. Second, there is the wider domain of *research governance* that concerns questions of accountability, legal liability, and the management and reduction of research risk. Finally, *organisational and professional procedures* need to be in place to oversee these two domains. The first of these may be seen as anchored in a universal set of principles of good practice, that all research should respect and reflect while the second and third might encompass a more diverse range of practices, reflecting distinct disciplinary, institutional or professional requirements and demands.

2.1.1 That there may be some variation in research governance and organisational/ professional procedures presumes a degree of local autonomy across different constituencies in the research universe. However, this picture becomes more complicated where interdisciplinarity is involved, where boundaries of responsibility in jointly-funded research are blurred, and where legal and regulatory provisions covering specific types and areas of work are introduced at either a national or international level (as in the Biobank example), with limited room for translation into localised settings.

2.1.2   These issues have been given greater prominence by the Department of Health's Research Governance Framework (RGF), prescriptions driven by a duty of care to patients especially in regard to their safety. The proposals affect not merely those working formally within the health arena but also social care researchers, or social scientists more widely who may seek to undertake research involving respondents who are secured via the NHS, are patients or who work within the NHS. It is debatable whether this also applies to those not under clinical supervision but who have indirect links to the health service - such as members of Patient Associations, or where a respondent may be researched in their professional role within the NHS. Here questions about the locus of oversight of different research agendas, accountability to distinct professional codes of research and practical questions relating to research approval (possibly to a multiplicity of agencies) have been thrown into sharp relief. We return to this key issue in section 3 below.

2.2 Different fields of research might be characterised as distinct domains within which one finds rather different cultural expectations about the ethical dimensions of research and the relation between

the researcher and human (or animal) subject(s). There are strong epistemological differences here that can lead to a misunderstanding of each other's frame of reference. Moreover, in some fields, such as the natural and physical sciences, scientists may only rarely encounter human subjects and are unfamiliar with the ethical issues associated with this kind of research. The move towards multidisciplinarity will make such encounters much more commonplace.

2.3 In short, one might argue for an approach that, beyond a *generic* code, seeks to identify ethical issues that have particular saliency for a field or *discipline*, an approach based on the recognition of diversity, a point often stressed by professional bodies. Some subject areas – such as medicine and psychology – might be regarded as more closely linked than others. At the same time, moves towards greater linkage would not necessarily mean greater uniformity. Indeed, growing interdisciplinarity would work against any methodological reductionism. Rather, dialogue between the fields could lead to a shared learning and mutual extension of existing, discrete, field-based ethical practice. So the ethical framework informing medical research (based on the four principles noted above) could be usefully broadened and strengthened via social science. For example, their operationalisation could be enhanced by a greater reflexivity on the part of the researcher, a deeper awareness of the context of research and an acknowledgement of the wider socio-political setting in which it takes place. This would be a move towards a form of *interdisciplinary ethics* in the years ahead, the introduction of special procedures for interdisciplinary research that might be beneficial inasmuch as this would make different approaches and expectations both more transparent and perhaps resolvable. It is not self-evident that the practice of recruiting members from different disciplines for research ethics committees would in itself secure this objective.

2.3.1 Ultimately, perhaps, it is not a question of the articulation between generic, disciplinary or interdisciplinary ethics that is central, but whether and if so how human subjects are involved in research and how best to protect their interests.

2.4 While the various issues of cross-field collaboration are seen to pose new problems that need addressing, the issue of *genetics-related* research is worthy of specific comment (not least in view of the huge investment in this area across most if not all funding agencies). As noted above in the Biobank example, the most significant development taking place at the moment is the drive to develop genetic databases, and to give these greater utility by linking them with socio-economic data about lifestyles, occupation etc. It could be argued that in future linkage data should be subject to special review, especially with regard to the way material collected for one purpose is then used for another later on, particularly through the mobilisation of linked information systems across researchers (whether public or private). It should be noted that there are also methodological problems in linking data inappropriately.

Ethics-related questions will also need to be considered in light of the legal and insurance-related implications created by linked-data. Such questions are, in part, addressed by the provisions of the Data Protection Act and more recent Human Rights legislation (both 1998). However, though both might be seen to encompass linked-data issues, the 'volatility' of genetics research suggests a more codified approach based on interdisciplinary dialogue and peer review will be needed to refresh and update provisions in this area. The UK government is, of course, exploring this question through new government committees charged with the review of existing policies and practices (see HGC, 2002).

2.4.1 This suggests the need for a framework for linkage data that goes beyond the immediate confines of the strictly 'ethical' domain of moral rights and obligations to the wider demands of research governance, especially where this might involve the combination of very large datasets shared electronically across multiple research partners. How might informed consent be secured and be presumed across multi- or inter-disciplinary research and what is the relation between the sources of funding and researchers' control over databases shaping the ownership and subsequent use of research data?

2.5 This question of cross-boundary research, especially that relating to social science and health, is one that is rarely discussed in the policy documents provided by UK professional associations or funding agencies. The latest Social Research Association ethics code of practice (December 2003) does, however, provide some advice about how to handle interdisciplinary research (SRA, 2003). It says,

'Social inquiries are frequently collaborative efforts among colleagues of different levels of seniority and from different disciplines. The reputation and careers of all contributors need to be taken into account. The social researcher should also attempt to ensure that social inquiries are conducted within an agreed ethical framework, perhaps incorporating principles or conventions from other disciplines, and that each contributor's role is sufficiently well defined. The World Medical Association's Declaration of Helsinki (1975), for instance, gives excellent guidance to researchers working in the field of medicine' (p. 23).

While this assumes an intellectually diverse division of labour can nevertheless be encompassed by a consensus on ethics, the SRA text does go on to observe that diversity might be a recipe for misunderstanding and so misplaced ethics review:

Medical or health service ethics committees may not fully understand the checks and balances of social research. To illustrate, there may be a difference over what precisely constitutes informed consent. Medical models can be inappropriate in social settings and *vice versa*. For example, allowing an interviewer to attempt to persuade people to take part in a study is regarded as coercion in social research and, therefore, not regarded as informed consent. In clinical trials, however, such persuasion is a common feature of subject recruitment. (p 24)

2.5.1 Here variation in expectations about proper ethical principle and practice will be bound to affect the process of ethics scrutiny itself and the judgements that are made about research governance more generally. Elsewhere, there is fairly limited, aspirational commentary on the role that a professional dialogue and discussion can play in managing ethics in research that is collaborative and interdisciplinary. For example, the BSA's current code of practice (BSA, 2003) notes that:

Members should ensure that sponsors and/or funders appreciate the obligations that sociologists have not only to them, but also to society at large, research participants and professional colleagues and the sociological community. The relationship between sponsors or funders and social researchers should be such as to enable social inquiry to be undertaken professionally. In research projects involving multiple funders or inter-disciplinary teams, members should consider circulating this Statement to colleagues as an aid to the discussion and negotiation of ethical practice.

2.5.2 Beyond this type of comment, all professional codes address their own disciplinary or immediate professional membership (such as the Market Research Society see http://www.mrs.org.uk/standards/codeconduct.htm) and tend to presume single-discipline research as the target for their guidance. In the previous national review on ethics that the ESRC commissioned (ESRC, 2002) in collaboration with the Strategic Forum for the Social Sciences, it was noted that respondents readily acknowledged paradigmatic differences between social and biomedical/clinical research. These differences have been discussed in earlier academic literature (such as Erwin, 1994; Weisstub, 1999; and Romm, 2000) with particular attention being drawn to the different forms of accountability and research tradition found in the two arenas. At the same time, some writers have advocated much greater exchange and dialogue between the two. One of the more recent (and extremely valuable) commentaries here has been provided by Kent et al. (2002), though their focus was mainly on the process of ethics review (see also Truman, 2003). In discussing this, however, they draw particular attention to the very different notions of 'risk' that underpin the review process, a point which casts light on the boundaries between social and biomedical research. As they suggest, where social science works within the field of health it should be subject to the process of ethics scrutiny, but a process that acknowledges a more complex sense of 'risk':

'Given the diversity in research design and methodologies within health research the location of social science research within a continuum of research and risk assessment is not such a novel idea but points to the need for an ethical review process which is designed to take account of different methodologies and diverse risks'

2.5.3 Kent et al (2002) go on to make a case for the establishing of new procedures for social science ethics review. These should – among the full spectrum of research that social science pursues – be constructed such that they are able to handle social science health related work which, they believe, is

poorly dealt with through the traditional LREC route (see also Tod et al., 2002; Dolan 1999; Ramcharan and Cutliffe (2001). This begs the question, of course, of whether the new RGF, in making new demands on all health based researchers, has implications for social science. It has, of course, and it is to this issue that we now turn.

3. The Research Governance Framework and its relation to social science research

3.1 The Department of Health's Research Governance Framework (RGF) identifies the responsibilities and quality checks for researchers, employers of researchers, NHS care providers, funders and the 'sponsors' of research. In terms of procedures and practice, the terms of the RGF are presented as key to improving the management of 'public health' and 'social care' research, especially in regard to the prevention of 'poor performance, adverse incidents, research misconduct and fraud' (DH, p 4), and the clarification of rights and responsibilities in research. However, the DH document also says, that the framework should act as 'a model for the governance of research in other areas' especially if these 'impact on the health or well-being of the public'. The boundaries of this last phrase are exceedingly broad and could cover a vast range of research disciplines and fields of inquiry, including economics, politics, psychology and many other areas.

3.1.1 It is the potential breadth of coverage that has raised concern among social science researchers, who believe that the scope of the RGF is much too broad, especially in regard to research they might hope to carry out in health settings. There has also been ongoing debate among the social care community about the terms and procedures introduced by the RGF, and in this regard there has been willingness on the part of the DH to review how the framework should be implemented in social care research (see Pahl 2003), since as its preface acknowledges 'there are also important differences between the two contexts'. In addition, there has been some concern expressed among those within the health delivery system itself that the new RGF is difficult to implement, costly and in need of much greater resource, especially in regard to training for ethics review. Some of the key points made by those working in social science, social care and health research itself are discussed below.

3.2 There are various ways in which the RGF raises issues that need to be addressed through dialogue across the DH/social science communities. Based on both the earlier ESRC review and recent papers published elsewhere, these may be summarised as follows:

- One of its primary purposes is to cover research that is, subject to various legal and statutory provisions set by the Secretary of State, principally about the management of, and accountability for, potential risk. However, risks to respondents in regard to clinical interventions are typically very different from those participating in a social science project, and the form and level of vigilance properly required for medical risk management will be inappropriate here (as Kent, 2002, observes above).

- The notion of informed consent is typically based on a medical model of research that is quite distinct from that pursued within social sciences and, indeed, might well be contrary to the interests of those participating in social science research. A one-off securing of informed consent is unlikely to encompass the diverse and complicated path taken by much social services and social science research where consent might well need to be revisited along the way, especially in qualitative, participatory or action-oriented types of research. Many researchers would seek some form of iterative support from a research ethics committee beyond initial formal review. LRECs do, of course, allow for changes in a research project beyond Stage 1, and requires that researchers report back any changes for further approval.

- The RGF states that research funders supporting work that 'requires collaboration with the NHS or social care services in England', must be 'willing and able to discharge the responsibilities of research sponsor or collaborate with another organisation which is prepared and

able to do so' (para 3.7.2). This will create major problems for social science funders – especially the small research charities – if they have to oversee social science research according to the provisions of the RGF: it seems more appropriate – as the second clause implies - that researchers' employing organisations be asked to take up this responsibility

Even so, while funders do not have the resources or mechanisms in place to take on an oversight role, it is also the case that some universities still need to build local competences in ethics review procedures and culture before they could discharge this responsibility properly.

- Finally, at a much more practical level, the RGF provisions would have an effect on social science postgraduate projects, especially those undertaking health services based projects as part of their training. Such research might well become impossible in the future as dissertation proposal dates would have to be brought forward to allow sufficient time for LREC approval, something that is likely to be impractical, say, in the time constraints of a Masters thesis. The move towards a specific Student-based ethics review process that COREC has instituted is a welcome development inasmuch as it will help to address this issue.

3.3 The implementation of the RGF raises a number of questions in particular. One relates to the extension of ethical approval to Health Service personnel, inasmuch as one might argue that 'personnel' and 'patients' are extremely distinct populations of research subject whose vulnerabilities to the risks of research need to treated differently. Clearly, LRECs may well be able to approach this question in a flexible way. However, there is some uncertainty over how the RGF provisions might handle research proposals that are intended to investigate questions relating to health service management, organisational efficiencies or institutional culture. Here, 'research ethics' may well become a means of protecting local institutional credibility rather than a mechanism for protecting research subjects from harm.

3.3.1 Other questions arise in regards to the likely effects of a much more formal and administratively intensive research environment, arising from widespread compliance with the forthcoming framework. The bureaucratisation of governance and ethics could be potentially anti-innovative (see para 3.4.1 below) where research applicants might be dissuaded from undertaking research that might in any way involve patients, NHS staff or services. Moreover, the framework might well inspire much more administratively burdensome ethical review structures beyond health care itself. Additionally, bureaucratisation may well undermine the informal sense of personal duty and care that many social scientists see as inherent in their research culture.

3.3.2 Despite these concerns and reservations, there are clearly arguments for the strengthening of ethics review and understanding in sound structures of formal governance. The framework is in this sense an opportunity to review existing procedures in order to identify and correct evident weaknesses, especially in work involving the NHS. However, given the remarks above, it is important to recognise where and when it is most appropriate to implement the RGF governance provisions and where these need to be flexibly interpreted, and where their boundaries lie. But beyond their boundaries, it is as important to build as robust a research ethics framework for social science. Improving ethics review procedures across social science departments and faculties would clearly resolve some of the current anomalies and inconsistencies that tend to characterise the research ethics terrain.

3.4 Those working in health related social care research are statutorily required to meet the terms of the RGF, though as noted above, some negotiation over their application in the context of social care research has occurred (see Pahl, 2003). The initial consultation document explored the particular needs of this sector and how the wider, more clinically focused RGF might best translate to the social research setting, especially in regard to research within or commissioned by Social Services organisations at local, regional and national levels.

3.4.1 A recent paper (Meerabeau et al., 2003) reports on social care researchers' understanding and experience of the RGF in regard to their current or anticipated research in the primary care area. The

RGF was seen to herald the arrival of a more formal and administratively demanding research environment. While most acknowledged the importance and necessity of the RGF, there were a number of barriers they thought it created in regard to pursuing health based social research. Three in particular were noted: more bureaucratic delay and overlap; a lack of understanding of qualitative research methods; and ethics review procedures that were geared only to high risk biomedical research.

Most of the academics believed that the RGF would inevitably increase the bureaucratic burden on research, but, more importantly, that there might thereby be an increasing reluctance to actually undertake work in this area: as Meerabeau et al. observe the bureaucratisation of governance and ethics was thought to be potentially anti-innovative where research applicants might be dissuaded from undertaking research that might in any way involve patients, NHS staff or services. Finally, on a practical point, the RGF requires researchers working with/in NHS establishments to obtain an Honorary NHS contract to ensure they comply with the Services duty of care to patients. This can create difficulties on multi-site projects, though these may be overcome through a single contract with one site being mutually recognised by the other research venues. Alternatively, Meerabeau offer the notion of an institutional Letter of Agreement between the researcher's employing organisation and the NHS Trust such that individual contracts need not be sought for each research project.

3.5 Another recent review (Boddy and Warman, 2002) of the introduction of the RGF into work sponsored by local Councils' Social Services Departments in the UK, found that there was much that would be need to be done in terms of training and resources to ensure the Departments could take its provisions on board. For example, their survey found that 30% of all research activity had no ethics review, while 'none of the case study Councils had any formal governance systems in place for the approval of research' (p. 45). They argue that a successful implementation of the RGF guidelines will depend on Councils receiving '…clear guidance in order to determine what counts as research: which research-like activities necessitate independent scrutiny of ethical standards and scientific research quality, and which do not?' (p. 7). Social scientists working with Social Services Departments will need to determine whether formal systems are in place and if so, how they are best deployed in collaborative research informed by a social science ethics framework.

3.5.1 Finally, there has been some comment on the RGF from those directly involved in clinical research and practice. Kerrison et al. (2003), who are all based at the University College London Hospitals NHS Trust and responsible for research management and governance, discuss the impact the RGF will be likely to have on the management of research in Trusts. They point out that given the extensive number of collaborations the UCL Trust has with other groups the implementation process '…is not entirely within the NHS's control and is complex for trusts with large research portfolios' (p. 554), such that 'negotiations and written framework agreements are needed to establish responsibilities for governance and its funding between many different research partners' (p 556). They point out too that the move towards research governance 'means a change of emphasis from professional codes of conduct to legal rules' (p. 556). Given this, it is somewhat paradoxical that they claim that '…without clear lines of accountability the new structures for research and current proposals for foundation trusts could fragment research governance arrangements and weaken accountability to parliament' . (ibid.)

3.5.2 Beyond the social science arena, there are then practical and resource related issues for Trusts and those working in social care/services research raised by the RGF. The development of a new Social Sciences Research Ethics Framework should help to address these questions where it can, and, in its own terms, be able to articulate with the RGF as problems of implementation are resolved.

4. General conclusions: implications for ethics review in cross-boundary social science research

4.1 This paper has discussed a range of issues that need to be considered in dealing with the question of cross-boundary research ethics, particularly interdisciplinary social science and social research that investigate health. As has been argued, there are various drivers at work that will mean that multidisciplinarity and cross-boundary research will become more commonplace. It is then a question whether the process of ethics scrutiny in regard to this work can be encompassed by the standard operating

procedures of an LREC. While such procedures can and must in some circumstances be deployed and used to evaluate health-oriented research, other considerations must be taken into account, to do with the definition of risk and benefit, the distinct epistemological and problem focus of the social sciences, and the methodological implications this may have.

The new Research Ethics Framework introduced by the ESRC in collaboration with the wider Strategic Forum for the Social Sciences sets out the core principles and procedures for managing cross-boundary as well as single subject social science research.

4.1.1 Where social scientists work within the field of health – or indeed elsewhere - they should always be subject to the process of ethics scrutiny, but a process that acknowledges a more complex sense of 'risk', and thereby criteria for evaluation. Moreover, as noted in para 1.4 above, research subjects may be active participants in social research in such a way that the outcomes and so control on the research agenda cannot be determined fully *in advance*. A genuinely cross-boundary research governance perspective needs to recognise the distinctions between research domains and seek to enable rather than restrict diversity and innovation.

4.1.2 This issue has been very effectively and recently addressed by perhaps one of the best known interdisciplinary codes, that developed by the TriCouncil of Canadian research funding agencies (2002). The TriCouncil is made up of agencies covering three areas: the natural sciences, medicine and the social sciences/humanities. In regard to risk, while primacy for minimising risk or harm to subjects is a shared priority, the TriCouncil recognises that in some social science research, the goals and objectives of this work might legitimately suggest otherwise. As the TriCouncil says:

'…researchers and REBs [Ethics Committees] should also be aware that some research may be deliberately and legitimately opposed to the interests of the research subjects. This is particularly true of research in the social sciences and the humanities that may be critical of public personalities or organizations. Such research should, of course, be carried out according to professional standards, but it should not be blocked through the use of harms/benefits analysis or because it may not involve collaboration with the research subjects' (p.)

Furthermore, in relation to qualitative, participatory research, the TriCouncil argues that:

'Research subjects contribute enormously to the progress and promise of research in advancing the human condition. In many areas of research, subjects are participants in the development of a research project and collaboration between them and the researcher in such circumstances is vital and requires nurturing. Such collaboration entails an active involvement by research subjects, and ensures both that their interests are central to the project or study, and that they will not be treated simply as objects. Especially in certain areas of the humanities and social sciences this collaborative approach is essential, and the research could not be conducted in any other way.' (Ibid.)

4.1.3 This is an excellent example of different research paradigms accepting the need for mutual recognition of different approaches to research within a broad ethics research framework without one seeking to impose itself on the others. It might well be the case in the UK that the preference is for a discrete set of frameworks for the main domains of research – for clinical/health research, for (a version of this relating to) social care and for the social sciences, that are mutually supportive yet acknowledge the different contexts, paradigms and problematics of research. The latter speaks particularly to distinct notions of risk, that though related, operate at quite different levels. This has been advocated by Kastenberg et al. (2003) who have called for an ethics framework '…aimed at expanding risk management from employing just a set of universal rules and principles (e.g. risk based or quantitative safety goals and criteria) to one that is contextual or situational (commensurate with the degree of uncertainty and ambiguity)' (p. 1)

This position is one that we have also advocated in this paper, and in this spirit, we conclude with a number of observations that should be of use to researchers and agencies dealing with cross-boundary research, and which inform the ESRC's Research Ethics Framework. We believe that it is important to

- recognise the need to interpret the four benchmark ethical principles in terms that make sense across the principal domains of research, and accept the need for dialogue relating to the determination of 'risk' and benefit' of the research
- ensure that the process through which propsoals are submitted for ethics scrunity be managed by the principal, lead disciplines *initiating* the research and defined according to the core issues that the research seeks to address: this is especially important for cross boundary, collaborative research where clarity of the proposal needs to match its complexity. Otherwise there might be a regulatory inflation of review involving many different organsations seeking further information about the proposed work: the intention of the research, how it proposes to engage with human subjects and how it will use data should point to the most appropriate basis on which the proposal is framed for ethics review
- foster dialogue between fields that could lead to a shared *learning* and mutual extension of existing, discrete, field-based ethical practice, and in the medium term, an ethics framework that is genuinely rooted in interdisciplinarity: the TriCouncil of Canada points, perhaps, to how this might be achieved at a policy level
- adopt a position where the researcher's employing organisation carries the primary responsibility for ethics scrutiny of research whether this falls within or across different domains
- recognise that researchers external to the health services but seeking to undertake health based research that depends on access to patients, NHS staff or data therefrom, should ensure that the proposals are subject to independent ethics review (not necessarily by an LREC) to meet ethical standards (this is in accordance with the RGF itself: see RGF footnote 2.2.8)
- acknowledge the need for a framework for linkage data that goes beyond the immediate confines of the strictly 'ethical' domain of moral rights and obligations to the wider demands of research governance.
- finally, to acknowledge that, despite uneven capacity at present, most if not all universities already have in place ethical and governance provisions relating to a 'Code of Practice for Ethical Standards of Research involving Human Participants', and wider issues relating to secondary data analysis and the proper administration of research data. Such a Code might well be enhanced and extended both to acknowledge and enforce the RGF requirements where appropriate, but also to articulate more clearly the diverse research contexts where human participants are involved. The social sciences and research funders could encourage this move to ensure that a plurality of research is facilitated, while ensuring that a global quality of governance exists. ALSSS might act as a forum through which this might be reviewed and updated on a regular basis, in liaison with the funding agencies that are members of the Strategic Forum for the Social Sciences. The new ESRC Research Ethics Framework offers a robust parallel framework that could be drawn on for such a review, while providing a key basis for ethics scrutiny in universities (see paper 4 of the REF).

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