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A Review of Ethics and Social Science Research for the Strategic Forum for the Social Sciences

Commissioned by the ESRC

Summary of the Review

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1. Introduction

1. The Review, which was commissioned by the ESRC in the autumn of 2002 on behalf of the Strategic Forum for the Social Sciences (SFSS), examines existing ethical review procedures, and any changes underway, with regard to social science research involving human participants, across a range of institutions and organisations, including research funders, universities, professional bodies, and other organisations.

2. The Review was prompted by a number of discrete but broadly related developments within the research, policy and regulatory arenas, including changes in research methods; changes in the context of research, and in government policy (both national and international); and changes in public perceptions and apparent demands for increased accountability and transparency.

3. In addition to these ‘external’ drivers, there is concern within the social science community that the imposition of practice developed in other disciplinary areas may unintentionally restrict the conduct of important, high quality, social science research.

4. The results of the Review are based on data collected by a variety of means from a range of organisations and institutions and interested individuals, including research funders, universities, professional bodies and various other relevant organisations.

5. This document provides a summary of the Review: the full document contains material and confidential information that has prevents its full publication. This summary provides a commentary on the main points that emerged from the analysis and indicates the range of issues that are to be explored in much greater depth via the ESRC commissioned project on developing a ‘Framework for the Evaluation of Social Science Research Ethics’. This new activity will be carried out by Webster, Lewis and Brown of SATSU, University of York, and Boulton of the School of Law and Social Sciences, Oxford Brookes University, between 1 September 2003 and 30 April 2004.

2. Summary of the Review

2. 1 Introduction

Our review of a wide range of constituencies across academic and non-academic sectors indicated how far virtually all our respondents thought that the ‘ethics environment’ is changing. As a result, we were not surprised to discover that some two thirds of organisations have recently been, or are currently, undertaking systematic reviews of their local ethics provisions and guidance. The drivers for these changes are quite diverse, and are summarised below.

2.2 Summary of changes and key drivers in the research ethics environment

Most of the key changes taking place, and the impetus for such changes, with reference to social science and ethics are summarised below. These relate motivation for change, institutional and disciplinary changes, changes in the level of formality and scope of ethical scrutiny and wider changes related to information held on databases.

2.2.1 The motivation for change: general drivers

- Increasing tendency to turn aspirational or informal principles into more binding/prescriptive measures.
- The contested status of expertise associated with an increased public / patient and political advocacy.
- The cumulative effect of a whole series of malpractice incidents mainly though not exclusively within clinical research.
- An increasing tendency for disparities between institutions to be more evident than before – leading to a process of standardisation that some might regard as 'ethical inflation'.
- A higher sensitivity to legal exposure and the costs of litigation.

2.2.2 The motivation for change: specific drivers

- DoH Research Governance Framework due for implementation in two stages between Oct 2002 and April 2003. Extension of ethical remit beyond patients to staff/employees and NHS premises.
- The request, by DoH, that funding agencies act as 'research sponsors' to the framework – highlighting fiscal issues attached to implementation.
- The Wellcome Trust report on research governance.
- Increased sensitivity to the terms of the Data Protection Act.
- Section 60 of the Health and Social Care Act in relation to patient identifiable research data.

2.2.3 Institutional change

- Most universities, for the reasons cited above, described their institutions as currently undergoing some level of change in relation to ethical procedures.
- As the primary employer of research staff, universities are increasingly coming to recognise themselves as one of the central locations for overseeing and approving research practice.
- Institutional parity: some universities have begun to implement highly formalised structures whereas others remain less developed. However, improved communications between institutions has made their comparability more transparent. This has tended to force universities to be much more structured in their approach to the management of research ethics.
- Some universities are now in the process of adopting software-based research management systems that, in addition to monitoring administrative aspects of research, include reference to ethical review procedures.

2.2.4 Disciplinary Change

- Since most research now involves some form of interdisciplinary element, researchers are increasingly exposed to standards of ethical practice that may once have lain outside their own disciplinary framework. This has meant that, in addition to

methodological or epistemological points of comparison, ethical points of comparison have come to the fore in collaborative work.
- Whilst it is clear that many researchers are concerned that qualitative work may be poorly understood by LRECs, DoH ethics committees are themselves undergoing change, becoming more interdisciplinary in their composition and expertise. However, little is known of how this process of ‘re-tooling’ is working out in practical terms.

2.2.5 Changes in the level of formalisation

- Clearly, the general tendency observable throughout this report is towards an increased level of formalisation and bureaucratisation in review procedures. In many cases this is recognised as a positive development, removing potentially onerous reliance on ad hoc personal or local ethical review practices.
- Training clearly pays a key role in the process of raising awareness. However, much of the institutional effort put into providing taught courses and workshops is disproportionately directed at students and not research staff. Clearly, it is easier to add ethical research components to student curricula than it is to initiate mandatory ethical courses as part of personnel training.
- Training for LREC and MREC members was outwith the remit of this Review. However, the voluntary status of LRECs has potentially serious implications for the ability and willingness of members to participate in training initiatives.
- A number of universities have initiated formal discussions with regional NHS ethics committees in an attempt to anticipate potential problems and improve understanding.

2.2.6 Changes in ethical remit

- The expansion of the DoH RGF to include employees and NHS property is of some concern to social science research communities. In particular, the use of LRECs to licence research involving senior personnel may seem excessive. Additionally, there is some concern that ethical review procedures may inadvertently operate to work against potentially critical research.
- The broad category of ‘patient’ within the RGF is a particular concern, where research subjects cross a number of services, but where the research itself may be more directed at social care services rather than NHS treatment.
- Another source of change relates to the way in which research ethics and research governance are being differently institutionalised. On the whole, change tends to be in the direction of considering both ethical and governance issues together, again broadening the mandate of ethics committees.

2.2.7 The changing character of information and data interfaces

- New capabilities around the interface of otherwise separate data sets raises new concerns for researchers – particularly, where medical and genetic information can be cross-referenced against public health (demographic, lifestyle, occupation) information. On the whole, both the potential and inherent risks in this kind of information utilisation clearly require reform of hitherto more ad hoc ethical arrangements.

2.3 It is important to note that there is no single approach being adopted in response to these broad changes summarised above and the increasing demands they make on research agencies and researchers. In the university sector, many institutions appear to recognise that much greater responsibility is likely to be carried by them. As a result they are typically broadening their governance base locally to foster both organisational learning and practical burden-spreading. Many are moving towards a two-tier approach, comprising a broad institutional framework supplemented by departmental or school based procedures according to disciplinary characteristics and requirements

2.4 In examining the formal documentation relating to ethics procedures it was clear that across the range of universities, professional associations, and funding agencies there is wide diversity of two kinds: in how well developed such systems are, and over the specific details of research governance mechanisms. In part this reflects the legacy of the past where ethics provisions reflected an era where there was less interdisciplinary work, where demands were at least perceived to be less complex, and where the new governance requirements in terms of managing the ever increasing researcher/researched risks (for example to do with genetics-related) research were yet to be embodied in the extant guidance. In part, it also reflects what many respondents in social science thought was a strong belief in the autonomy of the researcher to deploy her or his good professional judgement, albeit guided by the broad guidelines set by the researcher's discipline.

2.5 In terms of training, the Review found that efforts in universities are focused more on students than staff, suggesting that staff are assumed to be already familiar with the subject. This Review suggests that there might be a need for greater coherence in ethics training provision, especially for staff. However, funders and other organisations must also recognise that improved ethical oversight procedures will require additional resources and will take time to be put in place.

Overall, the Review found that the burden of responsibility falls on either the individual, research funder or host institution. There are moves underway in several universities to improve the profile of the review process, and to reduce institutional reliance on individual researchers.

2.6 How this last point works out in practice is, however, complicated by the fact that there appears to be a strong contrast between those ethical procedures that seek to embed ethical considerations in a researcher's everyday work, with clear lines of accountability, and those that are much more overly prescriptive. A number of the professional bodies surveyed reported that they adopt a more facilitative than overly directive guidance to their members. No doubt, this might simply be a result of the constraints of trying to implement a strongly prescriptive regime on members, something that would be practically impossible. Even so, this divide between 'facilitative' and 'impositional' approaches marks a key philosophical and organising difference between competing principles and procedural frameworks.

2.7 In regard to the core issue of informed consent, most of our respondents reported specific procedures for obtaining informed consent, although it was unexpected to find that a considerable number reported the absence of such procedures. In practice, we found that consent procedures often differ in detail, according to the type of research being undertaken. For medically-based research, the procedures follow the requirements of the LREC/MREC system. In other cases, obtaining consent is often governed according to advice contained in professional codes of practice; or alternatively, an institution may have its own internal procedures. In broader terms, highly formalised or bureaucratic ways of securing consent were seen by many respondents to be marginal to fostering relationships in which a process of *ongoing* ethical regard for participants could be sustained.

2.8 In relation to another specific issue raised via the questionnaire, there is some difference of opinion about how to respond to the more complex ethical demands thrown up by interdisciplinary research, increasingly common as funding bodies encourage more of this type of work. Some see these demands as being happily managed via a single ethics route while others do not; yet for the latter, there is still some concern over what multiple approval processes might create in terms of differing assumptions and requirements.

For many, obtaining ethical approval for interdisciplinary research highlights the practical problems inherent in what we have termed the impositional model of research ethics, as conflicting ideas of what constitutes good (necessary, relevant) practice collide.

Considerable confusion, delay, and lack of transparency was reported by respondents who are required to seek approval from more than one ethics committee.

2.9 Respondents were very concerned about making sure that ethical vigilance is proportionate to the risks borne by research participants. In many circumstances, low risk research projects are directed at relatively non-vulnerable populations. Methods for protecting participants need therefore to be able to acknowledge the common obligations to protect participants from harm, whilst also distinguishing between these differing degrees of potential harmfulness. And yet, ethical measures designed for the protection of the vulnerable from high-risk research are still applied. On occasions, this level of vigilance can appear excessive.

2.10 There were various points raised by Review respondents in relation to the specificity of qualitative research. Many social scientists are anxious that qualitatively oriented work is not recognised as methodologically sound and often, as a consequence, fails to find approval, at least at first submission to an LREC. The new provisions and much more detailed guidelines introduced nationally across all LRECs in October 2002 should help deal with this concern, since qualitative methods are given much greater attention.

On the other hand, even this might not go far enough as for some social science researchers in the context of highly qualitative or participatory research, since, as noted above, consent to participate is seen as an ongoing and open-ended process.

This finding has important implications for any new framework for social science research, and connects with our earlier discussion on the divide between ‘facilitative’ and impositional’ approaches to ethical oversight and risk management. Acceptance of a ‘dynamic’ view of consent also has resource implications, for it implies both some form of on-going monitoring and increased awareness levels and training, linked to the active encouragement of a ‘culture of care’ within the social science community.

2.11 The DoH Research Governance Framework

The DoH Research Governance Framework (RGF) was a key issue examined through the Review. There were significant variations in formal policy documents and guidelines, arising from different approaches to establishing an ethical framework for social science research.

Thus, it appears that the research culture evident in the professional academic bodies’ documentation and questionnaire responses, may in some cases differ from that espoused by the RGF. The approach of the RGF is much more prescriptive and less aspirational.

Moreover, there appears to be some way for universities to go before they can play the role of research sponsors as defined by the RGF. Finally, the differences between research funders’ expectations about who is responsible for ensuring that the research they fund is ethical reflects an important issue that will have to be addressed if social science research is to be properly governed: this is where, between the various ‘players’ involved in the course of a piece of research, does the (relative) burden of responsibility for ethical clearance lie?

Respondents were very concerned that the RGF framework should be able to distinguish between different gradations of risk borne by research respondents and adjust the level of vigilance accordingly.

In regard to the RGF, there were concerns about the extension of its provisions to all health service staff. These concerns were partly based on the premise that ‘personnel’ and ‘patients’ are extremely distinct populations of research subject whose vulnerabilities to the risks of research need to treated differently. Perhaps more importantly, respondents were concerned about the potential conflict of interests that might arise where research proposals are intended to investigate questions relating to health service management, organisational efficiencies or institutional culture.

Given the importance of the RGF in relation to the objectives of this Review, the implications of the RGF for social science, and for the ESRC and Strategic Forum for Science Social in particular, are summarised in the next, concluding, section.

2.12 The implications of the RGF for social science and the ESRC and the Strategic Forum for the Social Sciences (SFSS)

This Review raises a number of implications of the DoH’s framework for the social sciences in general and the ESRC (and other social science funders) in particular.

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’ (DoH, p 4), and the clarification of rights and responsibilities in research. However, the DoH 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. It is the potential breadth of coverage that has raised concern among social science researchers, who, though prepared to meet the terms of the RGF where required in regard to research that involves collaboration with clinicians, patients or others under differing forms of medical supervision, believed that the scope of the RGF may be drawn too widely.

There were various issues raised by respondents to the Review relating to the RGF:

- 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 very different from those participating in a social science interview, and the form and level of vigilance properly required for medical risk management will be inappropriate here.

- The RGF notion of informed consent is based primarily on a medical model of research that might well be contrary to the interests of those participating in social science research. The 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 to address these without a further return to the approving research ethics committee.

- 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).

However, the Review suggested that institutional mechanisms are yet to be put in place such that funders could take on this role, and respondents to the survey stressed that universities still needed to build local competence before they could be invited to act in this way.

- Where a research project involves collaboration that is based on both interdisciplinarity and co-funding, it would make most sense for the DoH to accept that certain elements of a project – to be determined clearly and comprehensively in advance - were subject to professional, organisational or funding council oversight that complemented, but which was not secondary to, the DoH RGF.

- 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'. 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.

- Finally, at a much more practical level, the RGF provisions could, perhaps, have an unintentionally damaging 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.

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