Research Ethics FRAMEWORK

ESRC Developing a Framework for Social Science Research Ethics

Project Update

Produced by
ESRC Research Ethics Framework project team
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1. Introduction

This paper provides a brief update on the ESRC-commissioned project to develop a Research Ethics Framework (REF) for social science research in the UK, which was undertaken by the Science and Technology Studies Unit (SATSU), University of York and the School of Social Sciences and Law, Oxford Brookes University, over an eight month period from September 2003 to April 2004.

The proposed REF and an accompanying Report to the ESRC that details how the project was conducted, was submitted to the ESRC in April 2004. We should make clear at the outset that the proposed REF and accompanying Report are the property of the commissioning body, the ESRC, and are not available for public distribution (apart from the four Discussion Papers included in the Report, which are available online – see below). This update has been produced by the project team in order to outline the issues raised during the project and provide feedback to the many individuals who participated in one way or another, and to indicate what is likely to happen now that the draft REF proposal has been delivered to the ESRC. We emphasise that the contents of this Project Update do not necessarily reflect the ideas or intentions of the ESRC.

2. The REF project

The project's principal objective was to prepare a set of research ethics guidelines that will have value to the ESRC and, hopefully, to a much broader range of stakeholders supporting social science research as well. In order to build a framework that codifies ESRC requirements and one that would be welcomed and subscribed to by other social science constituencies, the project adopted a consultative dialogue with different groups throughout the duration of the work.

This consultative process consisted of a series of initial interviews with key stakeholders, followed by regional consultation meetings in Newcastle, Edinburgh, Manchester and London, and then lengthy interviews with a number of senior social science researchers and research administrators in UK universities. The project also exchanged ideas with the Central Office for Research Ethics Committees (COREC), several government departments including the Department of Health (DH) and the Home Office, as well as the Cabinet Office and ONS.

The implementation of the DH Research Governance Framework (RGF) is a key feature of the current research ethics landscape, and the project liaised closely

with Professor Jan Pahl and colleagues, who were commissioned by the DH to develop the RGF in the context of social care. A number of other initiatives informed the project, including the Government Social Research guidelines, the recent Department of Work and Pensions (DWP) guidelines, recent revisions to professional codes of conduct and ethics guidelines such as those undertaken by the Social Research Association (SRA) and the British Psychological Society (BPS), and at the European level, the EU-funded RESPECT project. The Nuffield Foundation has also recently funded a project to map university ethics practice, which connects with earlier SATSU work for the ESRC in 2002[1] and interview data collected during the present work. Although the proposed REF relates specifically to UK social science research, we also had useful discussions with staff at the Programme on Research Ethics (PRE), a Canadian initiative that has addressed similar issues.

The project website at www.york.ac.uk/res/ref/ (which will remain available at least until the end of 2004) provided a focus for all this activity, as well as access to a range of other ethics resources, and we advise anyone new to the project to visit the site. For those familiar with the project, it will provide a means to keep in touch with developments. A detailed summary of this activity, including issues raised by participants and interviewees, was included in our Report to the ESRC.

Although reservations were expressed by many about the degree to which the proposed REF might increase the burden of review for researchers and research organisation, most acknowledged the need for a more robust and more standard set of procedures for ethics scrutiny than currently exist. Two points in particular are worth drawing attention to: on the one hand, all felt that it is important to focus efforts on reviewing research that raises 'real' ethical issues and keep review of the rest to a minimum. On the other, it was generally recognised that researchers need much more training in developing their 'ethics literacy', and that the focus should be on institutions building an 'ethics culture' as much as responding to the proper demands of a future REF.

The Report to the ESRC provides a thorough review of UK social science ethics and the current range of concerns, practices and likely responses to the proposed REF. The Report also includes revised versions of the four Discussion Papers on cross-boundary research, international regulatory dimensions, research in developing countries, and the mechanisms for research review in research organisations referred to above. These Papers were received for the most part very positively and were revised in the light of comments received.

Although one can anticipate some reluctance to the introduction of a more formal and transparent process of ethics review that any proposed new framework is likely to involve, it is also clear that many research organisations are already putting new provisions in place, and as such there is already a move towards greater transparency and formalisation of review procedures.

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[1] SATSU (2002) *A Review of Ethics and Social Science Research.* Commissioned by the ESRC on behalf of the Strategic Forum for the Social Sciences. SATSU, University of York. (Summary available at: http://www.york.ac.uk/res/ref/documents.htm).

3.   What has happened since the regional consultation meetings?

Following the four regional consultation meetings in Newcastle, Edinburgh, Manchester and London held in February 2004, which were attended by more than one hundred people, the project team prepared the draft proposed REF ready for submission to the ESRC, and the Report to accompany this. The four Discussion Papers produced by the project team, which form an integral part of the project, were revised in light of comments received at the regional consultation meetings and feedback received via the project website. We also asked specific individuals to comment on the Papers to provide a degree of external review. We are extremely grateful for their contribution. The revised versions are available at:
www.york.ac.uk/res/ref/documents.htm

4.   What we expect to happen over the next few months

As noted above, the draft proposed REF was submitted to the ERSC in May 2004, accompanied by a Report detailing activities during the project. The submission marks the formal ending of work commissioned by the ESRC. As regards the project team's remaining obligations, we have recently made presentations to the three ESRC Boards, and to a session on 'ESRC strategic directions' at the ESRC Research Methods Festival in Oxford in early July. But essentially our work is completed.

We understand that the ESRC Boards are presently examining the draft proposed REF and the accompanying Report. The ESRC may also consult with other social science funding agencies through the Strategic Forum for the Social Sciences (SFSS). As we are not party to current ESRC discussions, we are unable to provide any information as regards ESRC plans for the proposed REF, or the likely timetable for implementation, or what form implementation may take, *if* it occurs. However, we expect the ESRC to announce steps towards implementation of the proposed REF in some form or other sometime later this year subject to its formal approval by the Council of the ESRC, perhaps by means of a "launch event" in autumn 2004, although we emphasise again that this expectation is entirely that of the project team and **not** a representation of ESRC views.

5.   Feedback from regional consultation meetings

The project held four regional consultation meetings during February 2004 in Newcastle, Edinburgh, Manchester and London, with delegates attending from a wide range of universities and other research organisations, government departments and other bodies, such as COREC, research charities and other research councils. Presentations made to the meetings are available at www.york.ac.uk/res/ref Attendance was by "open invitation" and the following section draws on notes made by the project team at the meetings. The subsequent section does the same with respect to data collected through telephone interviews conducted with selected senior researchers and research administrators.

A number of common themes are apparent, but the two sections also demonstrate the varying views expressed at the meetings and in interviews. It is hoped that reproduction here provides a flavour of the issues discussed and concerns raised, and in this way helps inform the debate over the proposed Framework. The notes were

prepared by the project team and *do not represent in any way the views or intentions of the ESRC, nor necessarily the views of the project team*.

5.1 *Appropriate scrutiny and mutual recognition of ethics frameworks*

Much of the debate focused on the requirement for ethical review of research. In many cases, what is regarded as appropriate scrutiny, and the location of this scrutiny, will be straightforward: a particular project will require Local Research Ethics Committees (LREC) approval under the terms of the Department of Health's RGF. However, in a number of instances a different form of scrutiny may be more appropriate, such as one based on the proposed REF.

There was a feeling that some form of mutual recognition between DH LRECs and RECs constituted under the ESRC REF would be appropriate in order to accommodate the requirements of the RGF and the differences between biomedical and social science research. Once in place, these parallel procedures should be recognised as having equal weight within their respective domains. However, mutual recognition of parallel procedures by all relevant parties may not be straightforward. Some observers argue that the social science community must first "put its own house in order" and demonstrate its commitment to a more robust approach to ethics scrutiny (which, of course, is what the REF seeks to accomplish) before seeking mutual recognition of its own, separate but equivalent, scrutiny processes, such as the proposed REF. There was a strong feeling that the ESRC REF should be complementary to, and not additional to, existing frameworks such as the DH RGF. As noted below, some go much further and question the basis on which the ESRC REF is proposed.

5.1.1 Some social science researchers take issue with what they see as the untested assumption that LRECs are incapable of scrutinising social science research (SSR) in a fair and appropriate manner. Such a view implicitly questions the need for a separate procedure for non-NHS related SSR. Whilst there are accounts of what was seen as unfair treatment at the hands of LRECs, others speak of positive LREC experiences and argue that such experiences are not necessarily representative of LRECs in general.

In similar vein, some delegates felt that the RGF is a more useful framework than it is often given credit for, and believe it is often misunderstood and misinterpreted. Some believe medical researchers confront similar problems as those faced by social science researchers with regard to the RGF, and suggest that the RGF should be re-drafted to take account of SSR concerns.

5.1.2 Individual experiences with LRECs are likely to depend on a variety of factors. LRECs may differ in their understanding of SSR and in their capacity to assess such research. A typical complaint is that LRECs do not understand SSR methods and frame their decision-making according to a biomedical model of ethics. On the other hand, as already noted, others argue that social scientists often appear reluctant to submit their research to ethics scrutiny and that SSR should be subject to the same process as biomedical research. As regards LREC members' expertise and capacity to scrutinise SSR, COREC is taking steps to ensure all RECs have members with knowledge of SSR, and believes this will answer the points raised by critics.

Researchers will also be asked to provide evidence of peer review of the 'science' of the study which will relieve LRECs of responsibility for reviewing it themselves.

5.1.3 Whatever approach is adopted towards different scrutiny mechanisms, it is likely that any arrangement for mutual recognition will take a number of years to be put in place. However, the position taken by the different parties (ESRC, other research councils, COREC etc.) will obviously affect the speed with which mutual recognition develops.

Any new review system must be seen to be independent (thereby meeting one of COREC's demands). However, delegates asked how this would be achieved. The typical methods for ensuring independence, such as 'lay membership', 'transparency' and 'multidisciplinary representation' are often not easy to implement in practice. The REF would need to clarify this.

5.2   *Meaning of informed consent and its place in different research fields*
The issue of informed consent was raised on several occasions – what does it mean, and is there more than one definition possible, depending on whether one is referring to medical research or SSR? Informed consent is a wide-ranging topic in itself, and requires special consideration within the proposed REF.

Whilst there was an understandable reluctance to define SSR, the prospect of a paradigmatic statement in the REF describing the types of research that fall under 'social science research' was welcomed, with recognition of different methodologies.

5.3   *Place of the REF and wider responsibilities*
It was argued that the respective roles of funding body and Research Organisation (RO) should be spelt out clearly, particularly given the expectation that the latter will be responsible for REF implementation as the employing organisation. Duties and responsibilities should be delineated in an unambiguous manner, with clear direction as to who is responsible for what within any new review system.

Relating to this, guidance and commentary in the REF is necessary in a number of other areas, especially clarification of the difference between 'ethics' and 'research governance'. There is concern about fundamental definitions and the apparent blurring of meanings such as these.

5.3.1 At one meeting in particular, a series of concerns were expressed around the need for a REF, and about possible retrospective application of the Framework. Was it designed to foster good practice - or make good former mistakes? What problem was it trying to resolve? What evidence is there that things have been done inappropriately in the past? In response, it was suggested that many universities still need to develop more robust processes to ensure appropriate scrutiny.

Some delegates argued that there was a 'protectionist culture' at the moment, with efforts directed at protecting institutions.

5.3.2 Many delegates felt that any new system such as the REF had to allow time for discussion of ethics issues, and provision of additional resources from funders

or through the new full economic cost provisions to do this, both prior to commencement and during the research itself.

5.4 *Training in and resources for ethics review*
Training remains a key issue. The SATSU 2002 Review highlighted the fact that many institutions provide some form of ethics training. However, this was found to be patchy, and where it did exist, often directed at post-graduate students rather than everyone engaged in the research process. The assumption appears to be that since supervisors and researchers were once students, they have received adequate ethics training. This is a flawed assumption for two reasons: it cannot be assumed that all such individuals have received ethics training; and secondly, the ethics and governance environment is a dynamic one and subject to on-going change.

Training also connects with research governance and ensuring procedures are indeed being implemented within research organisations. Training also has major resource implications for funders and ROs.

There was general support for a system of web-based resources that give researchers a guide to interrogate their proposal, and advice on handling specific issues, and on when to take them to a REC/LREC. Such resources might be linked to others provided by professional associations, and to any future ESRC/RCUK or similar national online resource.

5.5 *Wider scope of the REF*
The issue of research on children may require specific attention within the REF, and recent guidelines from the DWP and DfES are relevant here, as well as expertise within organisations such as Barnardo's. Similar attention should be paid to other vulnerable groups, such as older persons and people in care situations.

Another area requiring attention is what might be described as 'marginal cases', such as situations where market researchers ask individuals about health. On the other hand, some observers doubt the ability to distinguish between health research and health-related research on the grounds that questionnaires and interviews are interventions according to the RGF. This is an area that requires careful consideration.

5.5.1 There was also a plea not to constrain SSR in areas where data is available in the public domain and available to others (such as, for example, journalists in court situations) through the imposition of rules that apply to SS researchers but not to others. Accordingly, it was important that the REF offers a 'minimalist compliance' regime, rather than a 'maximalist' one with jurisdiction restricted to SFSS members.

5.5.2 It was argued that the REF needs a section on legal issues (DPA, FOI, observation of adverse events, disclosure of criminal activities, child abuse etc.) that makes clear to participants what would happen in such circumstances. It should be noted that this raises issues as regards the position of the researcher, as well as the researched.

5.5.3 It remains unclear whether legal differences and statutory obligations in different parts of the UK may impact on the REF and its implementation. Clearly, the REF must reflect differences in structures and powers in different regions of the UK, where these are relevant. This is an area that requires further study and advice in order to determine the position accurately and the implications, if any, on the REF.

5.5.4 The REF must recognise particular differences and sensitivities that may influence ethics review in developing countries, and the way in which such differences may impact on research undertaken in these countries. The concept of rights may, for example, be communal rather than individually based, and there are likely to be other issues when research is undertaken in developing countries by researchers based in the UK. There is a need to develop mechanisms for dialogue with collaborating countries, with special attention to communication and the basis of concepts like 'informed consent' in this context.

6.   Feedback from interview data

Telephone consultations with senior researchers working across the range of social science disciplines and in a variety of university contexts were conducted after the regional consultation meetings to explore further the issues raised in relation to review of research by research ethics committees (RECs). This section summarises the range of issues they raised in the course of these discussions.

6.1   Most but not all of those consulted were aware that their University was instituting, elaborating or formalising procedures for research ethics review. In line with our earlier work, there was considerable diversity in the policies, structures and procedures for ethical review that they described.

6.2   Some, particularly those in a university with an established medical school, indicated that their institution required all research involving human participants to be reviewed by a REC. Others indicated that their university was more selective, for example, making it a formal requirement for student but not staff research. Most indicated that their institution had some sort of 'fast tracking' procedures for reviewing 'routine' or 'low risk' research. Some reported that their institutions were already revising policies and procedures instituted within the previous two or three years because the workload had proved unmanageable for the REC: this typically involved establishing RECs at Faculty or Institute level and devolving review from the University REC to these RECs.

6.3   Many of the academics consulted had themselves submitted research proposals to a REC for approval, and some had served on RECs in their own institution or in the NHS. Those who had done so had generally found the review provided by RECs a positive and worthwhile experience, though one recounted a story of the difficulties a colleague had encountered. The general view was that RECs could delay the start of research by raising questions about the proposal but that this usually proved valuable in improving the quality of the research. None had ever been turned down by a REC though some had had to put in place additional procedures, checks and supports to protect the welfare of participants.

6.4   All those who conducted research primarily with patients or professionals in the NHS and who had become accustomed to submitting their research proposals for ethical review by a REC said they found it reassuring and felt more comfortable about conducting their research when it had been critically reviewed by an independent committee. REC approval gave them confidence that what they were doing was regarded as worthwhile and the way they proposed to conduct it as taking due regard of the potential risks. Several volunteered that they would not want to conduct research without prior ethical review and approval.

6.5   Those who worked in areas where ethical review was not routinely expected (i.e. outside the field of health and medicine) or used methods which did not involve direct contact with people (e.g. secondary analysis of existing data sets, or large anonymous postal surveys) regarded it as a 'necessary evil' in some circumstances, particularly where the research involved risk to participants. However, most felt that it was not usually relevant to the kind of research they did. Most also indicated that, amongst their colleagues, there was a general resistance to and disquiet about the increasing regulation of research by RECs.

6.6   Those who worked in areas where review by a REC was not common practice also pointed out that their work raised issues which might be considered 'ethical issues' but which were not normally considered by RECs. These included issues around how research findings were used (eg in making policy decisions) and issues around maintaining confidentiality in situations which were commercially sensitive.

6.7   Those who had become accustomed to submitting their research for review by a REC felt that it would be appropriate for social scientists more generally to do so, particularly if they were receiving public funds to carry out their research, and that review by a REC should be regarded as standard good practice for all research involving human participants.

6.8   Overall, those consulted gave a range of views on the strengths and limitations of REC review.

Positive comments can be summarised as follows:
• Review by a REC raises awareness of ethical issues that would not otherwise happen. The requirement to make an application forces researchers to think about the issues in a structured way in advance of starting the study. This is important in protecting the well being of participants.
• REC review engenders and reinforces amongst researchers a value system around good practice and quality control and, as well as protecting the interests and well-being of participants, helps protect the university from embarrassment (when research is done badly) and litigation (when things go wrong).

Areas of concern can be summarised as follows:
• Ethical review procedures create more work for researchers, are time consuming and can cause delays. They can become a hurdle which prevents people from conducting good research or puts them off even attempting empirical studies.

- The comments that RECs make on the 'science' of a study are sometimes naïve and inappropriate. Research paradigms and the values and belief systems associated with them may also be so different that discussion and debate between researcher and REC is futile. This can undermine the researcher's confidence in the process of ethical review and create considerable hostility.
- The comments RECs make on ethical issues are also sometimes trivial and show little insight into the real ethical issues a study may raise. Where researchers are required to submit their proposals to more than one REC, they may receive inconsistent or contradictory comments. Such experiences can again undermine confidence in the process of ethical review.
- RECs in universities are perceived to be engaged in tedious administrative work and are regarded as having little real power or status. More senior and experienced researchers are perceived to be reluctant to serve on RECs with the result that RECs are seen to be composed of individuals with limited knowledge and of low status. This can undermine the authority of a REC, make recruitment of senior researchers more difficult and discourage members as well as applicants from taking review seriously.
- RECs are at risk of becoming inappropriately conservative and of preventing important research which they think might be embarrassing to the institution.
- Researchers who work overseas could be put in an impossible position if they are expected to get approval for any changes they make in their research design once they arrive at their research site.

6.9   Interviewees also made a number of observations about the way RECs and ethical review should be organised:

- The membership of a REC should be selected from amongst those who are experienced and held in high regard by researchers and the wider community.
- Training of REC members is vital and the ESRC could make a valuable contribution by funding proper education and training for them. A better-trained, more experienced committee generally gives a better, swifter and more proportionate review of research.
- RECs should have an educational rather than a solely regulatory remit. They should concentrate on raising awareness of research ethics, debating ethical issues and providing education and training to researchers. Detailed feedback to applicants on their proposals is particularly valuable in this context.
- Expedited review procedures such as Chair's Action for revisions in proposals or documents are essential.
- Institutions should consider rolling costings, health and safety issues, research ethics and other more general research governance into the same set of procedures and review committee.
- Research paradigms differ between disciplines and a 'one size fits all' approach may be inappropriate. Application forms and procedures should be kept as brief as possible and could be tailored to each discipline.
- While ethical review helps researchers think through and be prepared for potential problems or negative effects on participants, review should not be driven by the 'worst case scenario' nor should researchers be expected to put inordinate effort into preparing for potential problems which are extremely unlikely to arise.

- Review should focus on research that raises 'real' ethical issues and review of other studies should be kept to a minimum.

6.10   Several of those consulted made suggestions as to how they thought high ethical standards could be maintained without recourse to routine review by RECs. Underpinning these comments was the view that what was needed was a mechanism that would encourage researchers to think through ethical issues rather than concentrating on ways of getting through an ethics committee.

- Good, continuing training of researchers in research ethics plus regular audit of research studies (while they are going on and after completion) might be a more effective way of encouraging research of high ethical standards than ethical review prior to conducting the research.
- Greater emphasis should be put on convincing people that ethics is integral to their work and not an 'add on' or a hurdle to overcome. It is perhaps better to include ethics as a substantive issue integral to the normal research process than leave it to an external event at the beginning of data collection.

7.   Conclusion

To conclude, at the time of writing we have no information as regards a possible timetable for REF implementation, or even whether it will in fact be introduced. We recommend that interested individuals and institutions keep in touch with developments through the REF project website at www.york.ac.uk/res/ref which will be maintained at least through 2004. Finally, we remind readers that the four Discussion Papers are available at www.york.ac.uk/res/ref/documents.htm

We believe the proposed ESRC Research Ethics Framework is an important initiative, and would like to thank everyone who participated in some way or another, and for the support and encouragement received from numerous individuals during the course of the project.

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