

ESRC Framework for Research Ethics (FRE) 2010

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Introduction

The Economic and Social Research Council (ESRC), in facilitating innovative and high quality research, requires that the research it supports will be carried out to a high ethical standard. The Framework for Research Ethics (FRE) is based on the Research Ethics Framework published in 2005¹. The ESRC committed then to a process of regular review to ensure the framework was kept up to date to reflect changing scientific agendas and policy developments. This revised Framework responds to new developments and an extensive consultation with the research community and stakeholders. A summary of the changes is provided at Appendix E.

In a fast moving research environment, new situations arise and new forms of research emerge which cannot all be covered within this document. We encourage the research community to share their guidance, experience and solutions to ethical dilemmas to facilitate innovative research. Research Ethics Committees in institutions have an important role in facilitating ethical research by sharing their expertise.

The principal aim of the ethics review is, as far as possible, to protect all groups involved in research: participants, institutions, funders and researchers throughout the lifetime of the research and into the dissemination process. Research integrity is closely linked. An example checklist on research integrity is given in the appendix and it is suggested that such a list is used alongside ethics review².

This document outlines the ESRC's approach, aims and methods for maintaining high ethical standards in research in light of the new developments, while further clarifying issues that were unclear in the original framework. The original principles, procedures and minimum standards have been retained. The Framework for Research Ethics sets out what the ESRC requires by way of ethics approval for the research it is asked to support, and sees as good practice for all social science research. Whilst it is **mandatory** for ESRC-funded research, it is also recommended for use by other funders.

Principles, procedures and minimum requirements of the Framework for Research Ethics (FRE)

There are six key principles of ethical research that the ESRC expects to be addressed whenever applicable:

1. Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.
2. Research staff and participants must normally be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific research contexts for which detailed guidance is provided in Section 2.

¹ The name has been changed to Framework for Research Ethics so that it is not confused with the new HEFCE Research Excellence Framework (REF)

² Example checklist at Appendix A has been provided by the UK Research Integrity Office

3. The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.
4. Research participants must take part voluntarily, free from any coercion.
5. Harm to research participants and researchers must be avoided in all instances.
6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

To implement these principles:

- The responsibility for conduct of the research in line with relevant principles rests with the principal investigator and the research / employing organisation.
- The responsibility for ensuring that research is subject to appropriate ethics review, approval and monitoring lies with the research organisation seeking or holding an award with the ESRC and which employs the researchers performing it, or some of the researchers when the Research Organisation is acting as the co-ordinator for collaborative research involving more than one organisation. This responsibility also applies to research organisations hosting ESRC students and visiting researchers.
- Research organisations should have clear, transparent, appropriate and effective procedures in place for ethics review, approval and governance whenever it is necessary.
- Risks should be minimised.
- Research should be designed in a way that the dignity and autonomy of research participants is protected and respected at all times.
- Ethics review should always be proportionate to the potential risk, whether this involves primary or secondary data.
- Whilst the secondary use of some datasets may be relatively uncontroversial, and require only light touch ethics review, novel use of existing data and especially data linkage, as well as some uses of administrative and secure data will raise issues of ethics.
- Research involving primary data collection will always raise issues of ethics that must be addressed.

Breaches of good ethics practice in ESRC funded research will be treated as a serious matter. Where these occur, the institution, researchers and principal investigator will be called to account by the ESRC and sanctions may apply depending on the severity of the breach. These could result in the immediate suspension of the individual project and other projects based at or under the co-ordination of the contracting institution, and a halt to the consideration of further applications from that institution.

ESRC rules state that:

- The ESRC will only fund institutions that have processes in place that comply with the Council's minimum expectations as set out in this Framework. However, the ESRC does not seek to impose a particular model for achieving these expectations. The ESRC will ensure that its peer review of proposals addresses ethics issues, and it will also engage in ad hoc testing of institutions to check that commitments to ethics review have indeed been followed through by institutions.
- The ESRC does not require that ethics approval should be secured prior to submission of a research proposal. A proposal must state what the applicant considers to be the ethics approval that will be required for their proposed research, and if so how it will be obtained.
- The applicant should factor in the time required for the necessary ethics approval of the project to be obtained.
- The administering authority in submitting the proposal will be confirming that it concurs with that judgement and is prepared to administer any resulting award on that basis. If a research organisation does not have arrangements to ensure that its research complies with this Framework it will not be permitted to undertake ESRC-funded research.
- During peer review, referees and assessors will be asked to comment specifically on whether they agree with the ethics assessment in the proposal.
- If referees or assessors disagree with the proposed approach to ethics within the application, this will either be grounds for rejection of a proposal where it calls into question researcher competence or the feasibility or validity of their proposal, or for a conditional award requiring further review or feedback to be taken into account.
- Before the start of a project, funds will not be released until the administering institution provides written confirmation that the required ethics approval has been received. This notification should precede or accompany the starting certificate. If an ethics review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC (see Section I 'On-going review' for further information). At a minimum we expect that ethics approval will be received prior to the stage in the project that the research will be undertaken.
- The ESRC's guidance on postgraduate training will identify any specific requirements in relation to research ethics.

Summary of the ESRC's minimum requirements

(See Section I for more detailed guidance)

The ESRC does not seek to impose a detailed model for ethics evaluation and conduct, but the following requirements will constitute the minimum standard for a research proposal to

be eligible for ESRC funding, including studentships. Further details of the procedures are given under the guidelines in Section 2.

1. **Ethics issues must always be addressed in the proposal.** Research Ethics Committees (RECs) must consider all proposals that have been recommended for award by the ESRC before the research starts.
2. **All ESRC-funded research must be subject to at least a light touch review** (see Section 1 'Types of Review'). Where the potential risk of 'substantive' harm to participants and others affected by the proposed research is minimal, this may be all that is necessary (for a list of possible risk groups see 'Types of Review' below). Light touch reviews can be handled by a REC sub-committee who monitor all proposals including those of students. They may use an initial check list for this purpose (see Appendix A). The use of approved research ethics protocols for commonly occurring situations may limit the number of research proposals that need to go to a full ethics review.
3. **On-going review**
As research progresses, further ethics issues may arise. In these cases, Principal Investigators should go back to their RECs and have any changes approved both by the REC and ESRC. Monitoring should be proportionate to the nature and degree of risk entailed in the research. If ethics review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC.
4. **Expedited Review.** In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review is carried out by one or more members of a REC, commonly its Chair, but not by a member of the department due to carry out the research.
5. **Requests for Research Ethics Committee approval.** Where a light touch review has confirmed that a research proposal requires full ethics review and approval, this should be carried out by a REC. This needs to be constituted and operate in accordance with standards and guidelines given in Section 1.
6. **Procedures for institutional monitoring should be in place.** Universities and other research organisations should establish appropriate procedures to monitor the conduct of research which has received ethics approval until it is completed, and to ensure appropriate continuing review where the research design anticipates possible changes over time that may need to be addressed.
7. **Complaints procedures should be in place.** Research organisations must have mechanisms for receiving and addressing complaints or expressions of concern about the conduct of research carried out under their auspices.
8. **Arrangements should be made for training.** The ESRC expects social scientists to be able to engage with ethics issues from the start of their research careers. Research organisations must ensure that social science postgraduate training programmes incorporate the range of issues addressed in this Framework. Specialist

training should also be considered for research supervisors and all members of RECs, including external or lay members.

9. **The additional costs incurred in carrying out ethics review** for ESRC-funded research awards are eligible costs under the arrangements for Research Councils to meet a proportion of the full economic costs of research.
10. **Arrangements should be made for multi-funder and multi-performer projects.** If the ESRC is one among a number of funders of a project, these guidelines must be drawn to the attention of all proposed funders prior to submission for funding. Moreover, research organisations engaged in collaborative research may agree to use the services of one of their RECs to review a joint project on behalf of all participants. In such cases a single review process should be agreed by all funders and researchers, the standards of which should at least satisfy the ESRC minimal ethics requirements.
11. **Duplication of submission should be avoided.** Researchers and their employing organisations should avoid duplication of ethics review, especially in respect of research that may fall under the rubric of other ethics frameworks – such as NHS National Research Ethics Service (NRES) or the Social Care Research Ethics Service. Researchers should determine whether NRES REC approval is required by contacting NRES and then providing details of the NRES response in the relevant section of the ESRC Research Proposal. ESRC does not require multiple bodies to undertake a full ethics review.
12. **Legal and data requirements must be met.** Research organisations must comply with legislative requirements and with those of data providers. Information given in this framework should not be taken as absolute, legal requirements will vary from time to time and also according to the context of the research.

I: ESRC's minimum requirements

The ESRC does not seek to impose a detailed model for ethics evaluation and conduct on researchers or research organisations (ROs); however the requirements described here in Section I will constitute the **minimum** standard for a research proposal to be eligible for ESRC funding.

Please see the definitions of key terms in Appendix C.

I.1 Ethics issues must always be addressed in the proposal

Although the ESRC does not require that ethics approval should be secured before submission of a research proposal, all proposals must state what ethics approval the applicant(s) considers will be required for the proposed research, and why.

In the first instance, it is the responsibility of the researcher, or research team, guided by their professional disciplinary standards (see Appendix D for appropriate web addresses), to decide whether a project has ethics issues and should be subject to either a light touch review or a full REC review. Normally, research proposals involving human participants and personal data, and sensitive personal data, in particular those groups noted in 'Types of Review', below, will require a full review and approval by a REC which has been established and operates in accordance with the principles and guidelines set out in this Framework for Research Ethics.

Proposals submitted to the ESRC must provide a full statement that proper consideration has been given to any ethics issues which the proposal raises. Where an ethics review is yet to be undertaken, this should be stated. All ESRC-funded grants must be approved by at least a light touch ethics review.

Projects would normally be expected to start no sooner than three months after the formal notification of funding from the ESRC, to allow for recruitment of staff and ethics approval within the RO. Initial payment of a grant will only be made once any necessary REC approval is secured. Approval for minor changes to a project following REC review is delegated to the RO, though the ESRC needs to be informed of any changes made and of the final decision to approve or not. If an ethics review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC (see Section I 'On-going review' for further information).

If review by the REC shows that a project requires major changes which will alter it so much that it can no longer attract ESRC support, no payment will be made. This is likely to be an extremely rare occurrence since the proposal will have already been subject to external peer review which should identify such severe problems. In those cases where it is agreed that ethics review is to be undertaken after an initial period of research, funds will be made available to cover the period through to the completion of the review, and continued funding will be conditional on its outcome.

1.2 Types of Review

All ESRC-funded research should undergo a light touch review, and how this is applied should be the decision of the REC. Light touch reviews identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases this is the only ethics review necessary, and this can be undertaken using a pre-defined checklist (see Appendix A). Many student projects may fall under this category. However, it cannot be assumed that all student projects can be reviewed using a light touch checklist. Those projects, including student projects, which involve more than minimal risk, should receive full REC review.

Expedited review may be appropriate in exceptional circumstances where research projects require a full review but have a short lead time and are commissioned in response to a demand of pressing importance.

Institutional policies and procedures for light touch, expedited review and full review should include a clear statement that addresses the following issues:

- Criteria for identifying research which involves minimal risks (see descriptions below)
- The system of review for such research, including the scope of the authority of those to whom responsibility for review has been 'delegated'
- Forms and procedures for submitting applications for light touch, expedited and full review
- Procedures for reporting decisions to the main institutional REC
- Procedures for periodic ad-hoc audit (of light touch, full and expedited reviews by the main institutional REC)
- A published timetable of the maximum time necessary for undertaking light touch and full ethics reviews.

Research organisations are responsible for determining when research is considered to involve more than a minimum risk. We would consider that the following research would normally be considered as involving more than minimal risk and therefore most likely to require a full ethics review.

Research involving potentially vulnerable groups, for example, with children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Some RECs have facilitated ethics approval by establishing ethics protocols for commonly occurring situations, such as research undertaken with normally developing children in mainstream school settings. Ethics approval may involve light touch review if the researcher can confirm that they are abiding by the established protocol and that this is appropriate for their research.

Research involving those who lack capacity. All research involving those who lack capacity, or who during the research project come to lack capacity, must be approved by an "appropriate body" operating under the Mental Capacity Act, 2005. Apart from a few exceptions to this (see Frequently Asked Questions), all such research is deemed 'intrusive'. It is illegal to conduct such research without approval of the 'appropriate body'. In most cases this is the NRES.

Research involving sensitive topics, for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status. Elite Interviews may fall into this category.

Research involving deceased persons, body parts or other human elements

Research using administrative data or secure data. Researchers/research centres using these data sets will need to be approved by the body supplying the data and keep data in secure areas (see Appendix D for website details). In most cases a light touch review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.

Research involving groups where permission of a gatekeeper is normally required for initial access to members. This includes research involving gatekeepers such as adult professionals (eg those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (eg the parent or husband of the participant) or a community leader.

Research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork, For further information see Frequently Asked Questions in Section 2.

Research involving access to records of personal or sensitive confidential information, including genetic or other biological information, concerning identifiable individuals.

Research which would or might induce psychological stress, anxiety or humiliation, or cause more than minimal pain.

Research involving intrusive interventions or data collection methods – for example, the administration of substances, vigorous physical exercise, or techniques such as hypnotism. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.

Research where the safety of the researcher may be in question, in particular those working in the field and locally employed research assistants working outside the UK.

Research involving members of the public in a research capacity in research data collection eg participatory research.

Research undertaken outside of the UK where there may be issues of local practice and political sensitivities. In some cases partnership with a research organisation in the area involved may prove helpful. It is also necessary to check the requirements for ethics review in the countries included in the research.

Research involving respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed.

Other research involving visual / vocal methods particularly where participants or other individuals may be identifiable in the visual images used or generated.

Research which may involve data sharing of confidential information beyond the initial consent given - for example where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

1.3 Approval by a Research Ethics Committee (REC)

Research proposals involving human participants, as well as research involving more than minimal risk noted above must normally be reviewed and approved by a REC which has been established and operates in accordance with the standards and guidelines set out in this Framework for Research Ethics.

Research organisations should ensure that there is a principal REC for their organisation but may establish secondary RECs (for example faculty, school or department based) if they believe that this is required. Where more than one REC is established, the area of responsibility of each should be set out. It would normally be defined by an area of substantive and methodological expertise. There must be clear procedures to establish the relationship between them and to facilitate co-operation and common standards.

A university or organisation-wide ethics committee might advise on broad strategy for ethics review and monitor performance overall, rather than consider applications per se. Wherever they are located, they should meet the requirements of this FRE, even at department level if this is where the decision to approve a project is to be taken. If checklists are used to identify proposals necessitating only light touch review, the checklists may be overseen by an independent review body at faculty, school or department level.

Responsibility for securing ethics review

Overall responsibility for ensuring that research is subject to appropriate ethics review and approval lies with the research organisation which employs the individual or individuals who conduct the research (but see below on joint research). Although it is expected that a research organisation will establish its own REC or RECs to review research, smaller institutions and those that do not conduct a substantial number of studies involving human participants may make arrangements to secure ethics review by an REC in another institution.

The authority of an REC should be delegated through the institution's usual governance mechanisms. It should report to the appropriate university or organisation authority. In defining an REC's mandate and authority, the organisation should make clear the jurisdiction of an REC and its relationship to other relevant bodies or authorities both within and outside the institution.

Institutions are expected to monitor the operation of RECs for which they are responsible, and the decisions they take in relation to social science proposals, according to the standards and guidelines set out here.

Ethics approval need not be secured before an application for funding is submitted, as a significant proportion of applications are not funded. The point at which a research project is submitted for review may vary according to the research design (see section 1.1). RECs should be flexible about the timing of such review.

Within the definition of research (see Appendix C), all data collection involving human participants and/or personal data and/or sensitive personal data must receive ethics approval prior to the research commencing, with the exception of the following, which are not considered 'research':

- routine audit
- performance reviews
- quality assurance studies
- testing within normal education requirements
- literary or artistic criticism.

While data collected and stored as a record at an individual level is considered 'human data', material already in the public domain is not. For example, published biographies, newspaper accounts of an individual's activities and published minutes of a meeting would not be considered 'personal data' or sensitive personal data requiring ethics review, nor would interviews broadcast on radio or television or online, and diaries or letters in the public domain.

Information provided in forums or spaces on the internet and web that are intentionally public would be valid to consider 'in the public domain', but the public nature of any communication or information on the Internet should always be critically examined, and the identity of individuals protected unless it is critical to the research, such as in statements by public officials.

Ethics review may not be required for anonymised records and data sets that exist in the public domain. This includes, for example, datasets available through the Office for National Statistics or the UK Data Archive where appropriate permissions have already been obtained and where it is not possible to identify individuals from the information provided. Specific regulations relate to the use of administrative data and secure data (see website for details in appendix). Other data providers are likely to specify their own restrictions on the access to and use of their data. These must be complied with. There may be some circumstances where ethics issues arise with the use of secondary data, as described in 1.16.

The administering authority in signing the grant proposal will be confirming that it concurs with the applicant's judgement in regard to ethics review and is prepared to administer any resulting grant on the basis specified in the proposal, carrying out full (possibly iterative) ethics review where necessary.

During peer review, referees and other assessors will be asked to comment on the ethics assessment in the proposal. If they disagree with the proposed approach to ethics issues, this could lead to the rejection of a proposal, or the making of a conditional award based upon their assessment of the necessary ethics review.

1.4 Independence of Research Ethics Committees

Universities and other research organisations are responsible for ensuring that the RECs within their institutions act independently. They must be free from bias and undue influence from the institution in which they are located, from the researchers whose proposals they consider and from the personal or financial interests of their members. To this end, institutions should ensure that RECs include members who are independent of the institution (see 1.5), set out procedures for identifying and dealing with potential conflicts of interests and regularly monitor the decisions taken.

For the decisions and advice of a REC to be respected, they must be seen to be made impartially. That is, they need to be – and be seen to be – independent. The independence of RECs is founded on their membership, on strict rules regarding conflict of interests and on regular monitoring of and accountability for their decisions.

The need to be independent also has a bearing on where RECs might be located within an institutional structure. Departmental RECs that comprise members from only one discipline or a small number of closely related disciplines may be regarded as too closely aligned with the interests of researchers. Faculty or School RECs are likely to be multidisciplinary and, apart from the requirement for at least one lay member, could include individuals from outside the institution as well as those with the requisite skills and experience to evaluate more complex and ambitious research applications. RECs at university level are also likely to be more broadly based, leaving the work of reviewing applications to RECs in faculties, schools or departments and to concentrate on policy matters and oversight of the lower-level RECs.

Where ethics permission is refused, it is appropriate for the REC to give feedback on what needs to be done in order to meet the necessary ethical standards and achieve ethics approval.

1.5 Composition of Research Ethics Committees

The membership of a REC is fundamental to ensuring that it has the range of expertise and the breadth of experience necessary to provide competent and rigorous review of the submitted research proposals, and to do so from a position that is independent of both the researchers and the institution in which it is located. Their composition and independence are important in establishing the legitimacy of the opinions which they express and the decisions they make, in the eyes of the community and wider society as well as the performers and funders of research.

RECs should be multidisciplinary and comprised of both men and women. They must include at least one lay member with no affiliation to the university or research institution in question. There must be members who have broad experience of and expertise in the areas of research regularly reviewed by the REC who have the confidence and esteem of the research community. At least one member must be knowledgeable in ethics. There must be a chairperson. RECs would also benefit from including individuals who reflect ethnic diversity, users of specialist health, education or social services, where these are the focus of research activities, individuals with experience of professional care or counselling, and

individuals with specific methodological expertise (for example, statistics or qualitative methods) relevant to the research they review. Taking all of this into account, good practice would suggest that RECs would normally need at least seven members.

An REC may seek advice and assistance from experts outside the committee in considering a research proposal. When this happens, the chair should establish that the experts have no conflict of interest in relation to the proposal.

1.6 Remit and responsibilities of Research Ethics Committees

Institutional RECs are responsible for reviewing all research involving human participants, personal data and sensitive personal data conducted under their auspices and undertaken by individuals employed by the institution that does not come under the remit of the NHS NRES. RECs should review research proposals in a way that is independent, competent and timely. In some circumstances RECs may authorise other sub-committees or their chair to conduct reviews on research involving minimal risk on their behalf. These sub-committees and chair will be accountable to the REC and through it to the appropriate institutional authorities for the decisions they make.

The primary role of a REC is to protect the dignity, rights and welfare of research participants. RECs should also give due regard to the consequences of the proposed research for others directly affected by it and to the interests of those who do not take part in the research but who might benefit or suffer from its outcomes in the future. RECs also need to consider the safety of researchers, especially where they are working abroad, in covert situations and/or conducting lone fieldwork in settings that may pose risk to their safety.

Research Ethics Committees should publish a projected timetable on the time needed to consider a proposal.

1.7 Procedures for reviewing and approving research proposals

Institutional RECs should review each research proposal submitted and may approve it as submitted, approve it subject to meeting specified conditions or reject it on ethics grounds. Where a proposal is rejected or changes are required, feedback should be given to the researcher. The decision made for each proposal, and the grounds on which it was made, should be recorded and provided to the researchers, and a copy kept on file with the proposal for a specified minimum period consistent with the institution's policy on information retention, but in any case extending beyond the lifetime of the project. As far as possible institutional support for committees should help them to support new forms of research. In making decisions in a rapidly changing research environment RECs should abide by the FRE principles initially but in the final analysis may also need to use independent experts as well as their own experience and judgement in coming to decisions.

Universities and research organisations should establish and publish working procedures and appropriate forms and systems of documentation in relation to the following:

The dates of REC meetings and the deadlines for submission of applications to be considered at each meeting. Preparation of agendas and distribution of papers to members in advance of meetings and distribution of minutes following meetings. Minimum attendance for a quorum and procedures when meetings are not quorate. It is recognised that some RECs may develop their own procedures, for example including electronic review, rather than reviewing at meetings. In these cases, RECs should publish details of their procedures, with any deadlines for submission of applications as appropriate.

Presentation of research proposals and supporting documents. While a basic set of standard information should be required for all research proposals, institutions should consider whether the way it is presented might appropriately vary between RECs, in light of the research they review. Research paradigms differ between disciplines and a 'one size fits all' approach is not always appropriate. Application forms and procedures should be kept as brief as possible and could be tailored to the requirements of particular disciplines.

The point at which research proposals should be submitted for approval. It is inappropriate and wasteful for organisations that fund research to require that ethics approval be secured before an application for funding is submitted, as a significant proportion of applications are not funded. ROs and funding agencies should be flexible about the point at which review by a REC is required. In the majority of cases this will be immediately after notification of funding, but it could also be prior to a pilot study so that participants' interests are protected; prior to seeking the agreement of potential research sites and gatekeepers so they can be assured of its good standing; or prior to the main data collection when research instruments have been tested and access to participants agreed.

Identifying, documenting and dealing with conflicts of interests

Methods of decision making and recording decisions. Research organisations should record and make clear how they come to their decisions, including whether 'lead reviewers' are designated for each proposal and whether decisions can be made on the basis of a majority view.

Prompt notification of decisions and the rationale for the decisions

Receiving and considering appeals. Research organisations may want to consider developing partnerships with other research organisations in case of appeals.

Monitoring the conduct of research following approval and continuing ethics review

Receiving and considering complaints (see 1.12).

1.8 Application forms and protocols

Research proposals, including student proposals, submitted for approval to an REC might be expected to include the following information in a way that is understandable to a lay member, though the precise way this is done is left to the discretion of the research organisation:

- Aims of the research and scientific background of the research

- Study design
- Participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited
- Potentially vulnerable groups
- Methods of data collection
- Methods of data analysis
- Response to any conditions of use set by secondary data providers
- Principal investigator’s summary of potential ethics issues and how they will be addressed
- Benefits to research participants or third parties
- Risks to participants or third parties, physical, emotional and situational, and what has been done to assess, obviate or minimise risks
- Risks to researchers, physical, emotional and situational, and in particular how researchers will be protected/supported especially in the field and outside the UK
- Procedures for freely given and adequately informed consent – information provided and methods of documenting
- Procedures for dealing with information arising in the course of fieldwork that is a cause for concern, such as disclosures from participants or behaviours or incidents observed that raise significant concerns about the safety or well-being of participants or other people
- How any data collected will be kept secure and methods of transferring data within teams
- Any data sharing outside the proposed research team
- Details of research activity that falls outside the UK and links to local institutions
- Expected outcomes, impacts and benefits of research
- Dissemination (and feedback to participants where appropriate) and possible ethics implications of dissemination plans
- Measures taken to ensure confidentiality, privacy and data protection during and beyond the end of the project
- Members of Advisory Groups and whether they pose any risk to the safety of the researchers or participants.

1.9 Criteria for Research Ethics Committees consideration of research proposals

The ethics principles set out in this FRE provide the basis for reviewing research proposals. These principles are to be considered in relation to the nature of the research outlined, the context in which it is undertaken and the accepted ethics norms and practices of the relevant research discipline.

RECs should review research proposals in terms of their ethics probity. This will entail a consideration of the design and proposed conduct of the research. These should be considered in terms of the ethics issues raised (for example, whether the method of recruitment proposed puts undue pressure on individuals to participate) and the way they are addressed. The scholarly or scientific standards of the proposal should be evaluated by appropriate peer review, typically provided by the funding agency as part of the refereeing process. The scholarly or scientific standards/merits of the research are not the

responsibility of the REC. Where the REC needs greater understanding of the scientific or scholarly merit of a proposal in order to make a judgement about ethics issues, it should seek the advice of an independent researcher with experience and expertise in the research methods and paradigm described in the proposal.

The REC should include among its membership people who are collectively familiar with a range of philosophical approaches to research ethics and with the different perspectives seen in individual research proposals. Where more than one perspective or ethics principle applies to a specific case, clear ethics reasoning will be required and debate should be encouraged. Good ethics review requires sensitivity to the context in which a research study will be conducted and good ethics reasoning requires careful thought and consideration.

The knowledge and expectations that members of RECs bring to the ethics review of research proposals are fundamental to the way they review proposals. This is particularly clear in qualitative research where it may be impossible or undesirable to meet the standard requirements for ethics approval, for example, to obtain signed consent forms from each respondent at the outset of the research.

On-going review

It is accepted that in some cases as research progresses, further ethics issues may arise. In these cases, Principal Investigators should go back to their RECs, check through the implications of the new developments and have any changes approved both by the REC and ESRC. Advisory bodies, independent experts and mentors may also assist in this process but care needs to be taken that the inclusion of these advisors does not pose additional risks to researchers and/or participants. Monitoring should be proportionate to the nature and degree of risk entailed in the research. If ethics review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC. In the End of Award Report to the ESRC, the Principal Investigator will be required to comment on any changes that have taken place, the ethics implications of these and how they were resolved.

Dissemination of findings

Ethics issues may also arise in disseminating findings. In submitting the original proposal to the ESRC, potential risk to researchers, participants and others as a result of dissemination must be highlighted. These potential risks should also be considered in the application to the REC. In the End of Award Report to the ESRC, Principal Investigators will need to report any concerns and how they were overcome.

1.10 Institutional support for Research Ethics Committees

Research organisations should provide the REC or RECs for which they are responsible with the necessary resources to carry out their responsibilities efficiently, effectively and independently. This includes, at a minimum, appropriate training for the members in the ethics, legal and scientific dimensions of the research that their REC reviews; adequate administrative and clerical support, and adequate resources, including recognition in workload planning and the allocation of academic responsibilities, to carry out reviews with due care and attention; and to attend meetings of the REC. Any additional resourcing for these requirements should fall within a research organisation's own budget. However, it

should be remembered that the additional costs incurred in carrying out ethics review specifically for ESRC-funded research are eligible costs under the arrangements for Research Councils to meet a proportion of the full economic costs of research.

Successful implementation of the FRE relies in a large part on the degree to which individual research organisations are able to build appropriate structures and create a culture that recognises the central place ethics review occupies in good research practice. Ethics training plays a central role in this process. Such training should be on-going and become an integral part of research practice, given the changing ethics environment. See section 1.13.

Research Organisations should build a programme of support and provide resources to aid staff in understanding and implementing the FRE, whether as individual researchers or as members of a local or university-wide review body responsible for implementation or compliance. The nature of such resources depends on the size of the organisation and the research it conducts. They might include:

- Web-based resources such as flow-charts or algorithms to help identify whether a proposed study requires ethics review, and the steps that must be taken to gain ethics approval, whether according to the FRE or some other framework.
- An Ethics Review Handbook or webpage that states the institution's standards and expectations with regard to the FRE, and how staff can ensure they comply with them. This could form part of a larger document covering other ethics review frameworks as well as training mentioned above.
- The use of approved protocols for commonly occurring situations. It will be the responsibility of the local REC to approve the suggested protocol for the work.
- In order to facilitate greater transparency and the sharing of solutions to ethics dilemmas, institutions are encouraged to publish their approved protocols on the web for use by others. Institutions giving access to their approved protocols cannot be expected to enter into any discussion on their use. Those making use of such protocols will need to justify to their REC why the suggested protocol is appropriate to their research.

1.11 Procedures for institutional monitoring and ad hoc audits

Research organisations are expected to establish and publish working procedures for monitoring research and for undertaking occasional ad hoc audits.

Where a study design is emergent, the REC should agree procedures for continuing ethics review (for example through a Project Advisory Group) with the researchers as a condition of approval. Where the study design is largely fixed in advance, procedures for reporting to the REC or a designated sub-committee any unforeseen events that might challenge the ethics conduct of the research or which might provide the grounds for discontinuing the study should be agreed with the researchers as a condition of approval.

It is expected that research organisations will undertake occasional ad hoc audits of ESRC-funded research. How often this is done will depend on the amount of ESRC research undertaken in the institution. In major institutions it is anticipated that an REC should undertake an audit of at least one ESRC research project per year, randomly chosen, or in

the case of a large centre, part of a project. Principal Investigators and supervisors of students need to know that they must keep good records of their ethics procedures in case they are called to account. Initially this could be a paper exercise, asking to see the consent documents, other special permissions and relevant paperwork, information on data storage and data sharing, as well as a note from the Principal Investigator on changes that have been made, and highlighting specific problems.

Where an REC or a designated sub-committee considers that a monitoring report or ad hoc audit has raised significant concerns about the ethics in the conduct of the study, it should request a full and detailed account of the research for full ethics review by the main institutional REC.

Where an REC or designated sub-committee considers that a study is being conducted in a way which is not in accord with the conditions of its approval or in a way which does not protect the rights, dignity and welfare of research participants, it should initially bring together a meeting of all those concerned with a view to resolving the difficulties. In an extreme situation, the REC may withdraw its approval, and require that the research be suspended or discontinued. The ESRC must be informed of this decision and reserves the right to recoup its grant funding, pending further investigation, in extreme cases of ethics misconduct.

Institutions should also monitor the operation of RECs for which they are responsible, and the decisions they take, in relation to the standards and guidelines set out in this Framework for Research Ethics. It should be anticipated that the ESRC may undertake occasional ad hoc audits of institutional arrangements to ensure that they are operating to the minimum standards outlined here. It is therefore important that RECs keep records of their procedures, minutes of meetings and list of proposals reviewed for a minimum of 5 years.

Regular monitoring of RECs as part of research governance procedures is fundamental to demonstrating the independence and quality of the decision they take. This would normally take the form of annual reports on their membership, procedures and decisions, and periodic detailed audit of a sample of reviews. These reports need to be made available should the ESRC wish to see them.

1.12 Complaints procedures

Research organisations must have mechanisms for receiving and addressing complaints or expressions of concern about the conduct of research carried out under their auspices. Such complaints would normally be regarded as allegations of either poor performance or unethical conduct and would appropriately be addressed through the institution's procedures for dealing with such allegations.

Rules and procedures for identifying and dealing with potential conflicts of interest are crucial to maintaining independence in the way an REC reviews applications. Potential conflicts of interest include, for example:

- conflicts between the interests of a research organisation, or a part of one, and those of a researcher making an application to the REC

- conflicts between the private interests of a member of the Committee and the interests of a researcher making an application to the REC
- conflicts between the interests of the researcher and the interests of the research participants.

Fundamental to dealing with each of these situations is the principle of prior disclosure of potential conflicts of interest and withdrawal from discussion and decision-making. Again, guidance provided by the UK Research Integrity Office (UKRIO) and RCUK Research Integrity Office may be relevant and helpful here (see Appendix D for website details).

Where a decision has gone against a proposal or has required significant revisions to its conduct, the Principal Investigator should have the right to request that the Committee or Sub-committee reconsider its decision, or to appeal to the main university or organisational REC. Where the decision under appeal was made by the main organisational REC, an Appeal Committee should be constituted. It could be appropriate for institutions to make arrangements to act as Appeal Committees for one another.

1.13 Arrangements for training research students, supervisors and member of RECs

Many research organisations already have ethics training programmes in place, organised either at university level or through devolved structures such as department or faculty-based programmes. However, successful FRE implementation requires the development over time of agreed minimum standards of training and competence, which may be achieved through programmes at institutional, faculty, departmental, or research centre or unit level.

The ESRC wants social scientists to engage with ethics issues from the start of their research careers. Universities must ensure that social science postgraduate training programmes in the doctoral centres and units incorporate the range of issues addressed in this Framework.

The aim of this training should be to build confidence in individuals to recognise the need for ethics scrutiny with regard to social science research; to understand the institution's requirements and procedures for review; and to understand how to access additional help, both internal and external to the research organisation.

In practical terms, training requirements are likely to include training for:

- individual researchers
- research supervisors
- research managers, and heads of laboratories or departments
- members of local and institution-wide RECs, including lay members
- postgraduate students in local ethics review requirements (in addition to any more general ethics training)
- undergraduate students whose projects may require ethics review.

1.14 Student research and ethics approval

The ESRC also recommends that research organisations should establish procedures specifically for reviewing research projects undertaken by undergraduate students and students on taught postgraduate courses. The same principles should apply to postgraduate student research as to staff research. Student research poses particular challenges in relation to ethics review because of the large numbers, short timescales and limited scope of the projects involved.

Nevertheless, the same high ethical standards should be expected in student research. It cannot be assumed that all students' projects involve minimal risk. Student projects involving more than minimal risk (see section 1.2) may need careful consideration and possibly a full ethics review. However, in many cases student research may be managed at school/department level and overseen by a light touch Departmental Ethics Committee using an initial checklist. Established protocols for commonly occurring research, as mentioned previously, can expedite the review process. It should be made clear to potential research participants that the study is a student project. Research organisations also need to ensure that students are not exposed to undue risk in conducting their research.

The ESRC already provides Postgraduate Training Guidelines available at www.esrc.ac.uk/funding-and-guidance/guidance/postgraduates/policy/ptguidelines.aspx. These Guidelines include reference to training in ethics and legal matters. Research organisations should ensure that training programmes that they provide incorporate the range of issues addressed in the main Framework document so that students embrace an ethics culture from the start of their research careers. Doctoral Training Centres will need to detail the ethics training that they provide their students.

1.15 Multi-funded research

Multi-funded research: If the ESRC is one among a number of funders of a project, the FRE guidelines must be drawn to the attention of all proposed funders prior to a submission for funding. In many cases, such agreement could be achieved by the research being conducted in a FRE compliant research organisation. If this is not the case, proposals submitted to ESRC must confirm that the research will adhere to FRE requirements. Research organisations engaged in collaborative research may agree to use the services of one of their RECs to review a joint project on behalf of all participants.

Jointly funded research may involve the ESRC in partnership with other Research Councils, business, other public sector organisations, research charities or the voluntary sector. A third category is research funded under a European Union Framework programme and involving research teams from different EU member states. In this case, there may be conflicting national review procedures. In each of these cases, the specific ethics review requirements will need to be considered.

Multi-performer research: Research involving participants from more than one institution can create complications for formal ethics review procedures. In order to minimise bureaucracy and avoid unnecessary duplication of efforts, research organisations should consider agreeing arrangements for accepting one another's decisions following

formal ethics review. Each institution would retain formal responsibility for overseeing the ethics review of research conducted under its auspices but would accept the decisions made by the REC of the institution where the principal investigator is based. Each institution would need to be satisfied that the research proposal has been properly scrutinised by the principal investigator's main institutional REC and that regular monitoring of the conduct of the research was taking place and was promptly reported to all institutions involved.

Research may be carried out in a number of contexts ranging from a university to a voluntary and community sector organisation, a private sector consultancy, unfunded or by an 'unattached' freelance researcher. This may present specific problems for FRE compliance. For example, a researcher may propose to collect, use or store data in a manner that has not been approved by a recognised review process. Care needs to be taken to ensure any such researchers are appropriately trained in research ethics, supported, and supervised. If the research in question is funded by the ESRC, it must comply with the requirements of the FRE. Freelance researchers, or research organisations without their own procedures for independent review, must arrange for ESRC-funded research to be submitted to an ethics review procedure that complies with FRE requirements.

Research conducted outside the UK

Where research is to be conducted outside the UK, research organisations should require researchers to establish whether local ethics review is required by the host country, and if not, how the principles of the FRE can be followed in developing and undertaking the research.

There are several considerations here:

- inequities in regard to access to research resources
- political and cultural considerations with regard to professional training and oversight; differing ethics traditions in research
- increased risk to researchers and participants particularly in covert situations and where they are working remotely
- issues about gatekeepers (for example in some societies, access to research participants may not be possible without first obtaining permission from a community leader or female participant's husband)
- considerable differences in power between the researcher and the researched.

Moreover, research ethics in some societies raises issues about what is meant by ethics, and therefore how we conceptualise notions of rights (consent, choice, volition, self-determination, etc) and the handling of personal data and sensitive personal data in an international context where data handling may not be subject to the UK Data Protection Act. These issues need to be borne in mind in regard to specific schemes involving international collaboration. In many cases it is good practice to collaborate with a local research organisation.

In addition, problems may occur where the research involves political sensitivities. Researchers may not be able to obtain permission for further research from authorities in that country unless they respect such sensitivities. Again, collaborating with a research organisation in the local area is good practice. RECs and researchers need to be alert to potential difficulties while staying true to the principles of the FRE.

1.16 Avoiding duplication of submission

Researchers and their employing organisations should avoid duplication of full ethics review. For projects requiring a full ethics review, the light touch review should identify which is the most appropriate body to undertake this. For a full review, researchers must submit proposals either to their institution's REC or to NHS National Research Ethics Service (NRES). The ESRC does not require both bodies to be involved. The appropriate body will be determined by the issues raised by the research, the nature of the data to be obtained and the population of respondents to be included in the study. This will apply to both single-discipline research, and interdisciplinary research where social and biomedical scientists are working together. If research involves no NHS patients, clinical information or resources of the NHS and does not take place on NHS property, it does not need to be reviewed by NHS NRES.

The Department of Health's Research Governance Framework applies to research involving NHS staff, patients or patients' carers and relatives (or clinical information or data related to the above) and this must be reviewed by NRES. Where research participants are recruited through the NHS or Social Care services, the proposal would require review within the UK Health Departments' Research Ethics Service (see *Governance arrangements for research ethics committees*³ section 3.1 for further information).

In addition research involving adults who come under the remit of the 2005 Mental Capacity Act requires review by NRES or the Social Care Research Ethics Committee. For a full list of the research which requires NRES approval see the NRES website. A factsheet for researchers (including Social Care) is also available to download from the Department of Health website which provides guidance on the Mental Capacity Act (see Appendix D).

1.17 Legal and data requirements must be met

Data Requirements

ROs should ensure that appropriate practical arrangements are in place to maintain the integrity and security of research data. Clear direction should be provided on where responsibilities reside in all these areas. Researchers may not realise the threat to data integrity and security presented by routinely used collection and storage methods, such as computer files on hard drives and similar devices, portable computing equipment and memory, email and databases. Periodic audit of data storage arrangements at all levels is likely to be necessary to ensure compliance with both legal obligations and good research practice. Regular staff training is another avenue for ensuring appropriate practice.

ROs should be aware of the limits of the original consent given by participants. Transferring personal data and sensitive personal data to others in which the original participants are identifiable may violate the original consent given.

UK Data Protection Act 1998 (DPA)

It is important that those undertaking research are aware that most of the Data Protection Principles embodied in the DPA apply to their work. Social science research often involves the processing of sensitive personal data. Researchers should be aware that the processing

³ www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_126474

of any information relating to an identifiable living individual constitutes 'personal data processing' and is subject to the provisions of the Data Protection Act 1998, including the eight data protection principles, summarised as follows. Note that under the Act there is a separate definition for 'sensitive personal data' (see key words).

Data:

- must be obtained for a specified and lawful purpose
- shall not be processed in any manner incompatible with that purpose
- shall be adequate, relevant and not excessive for those purposes
- shall be kept up to date
- shall be kept for no longer than is necessary for that purpose
- must be processed in accordance with the data subject's rights
- must be kept safe from unauthorised access, accidental loss or destruction
- shall not be transferred to a country outside the European Economic Area unless that country has equivalent levels of protection for personal data.

However, there are certain exemptions in Section 33 of the Act relating to the processing of data for research, for example, where complete anonymisation of data is undertaken. However, organisations and individual researchers should be aware that data 'stripping' to remove personal identifiers, and the concept of anonymisation itself, are often problematic. Careful consideration is advised before using this as a basis for exemption.

Under the Act, 'data' includes any information:

- stored in a form capable of being processed by computer or other automatic equipment
- recorded in any form for later processing by computer or other automatic equipment (such as information collected from registration forms or CCTV pictures)
- stored as part of a relevant filing system or intended to be included in one in the future, including card files or filing cabinets structured by name, address or other identifier.

A number of additional points require consideration when assessing compliance, including:

- Circumstances where international research collaborations may involve the collection or transfer of personal data overseas.
Data may not be collected from, or transferred to countries outside the EEA unless that country has adequate data protection regulations, or the explicit consent of the data subject has been obtained, or there is an appropriate contract with the recipient of the data, specifying appropriate data protection requirements that must be upheld. In most cases, the only safe option will be to ensure that participants give explicit consent for overseas transfer during data collection.
- Where the purposes of data processing for research are not necessarily determined at the time the data is obtained.
For example, information on the outcome of operations might later be used for research into the effectiveness of medical procedures. The DPA requires that personal data may only be processed for one or more specified and lawful purposes, which would exclude such processing of personal data if it had not been specified at the point of collection. However, the Act provides specific exemptions for data

processing for research, the definition of which includes historical and statistical analysis. These are not blanket exemptions and institutions and researchers must be aware of where and when they apply.

The criteria for these exemptions differ where sensitive personal data is processed. The definition of this term and the circumstances where it applies require careful consideration. Issues here include explicit consent, duties of confidentiality (such as apply to medical professionals), and the analysis of ethnic origins for equal opportunities monitoring.

Only a brief outline of the issues has been provided here. Responsibility for both interpretation and compliance resides with research organisations themselves.

Legal requirements

Research organisations (ROs) must comply with legislative requirements and with the requirements of data providers. The regulatory requirements which apply may vary depending on the locus of data collection, the location of the subjects of the research, where data is held, and the nature of the research involved. Privacy, health and safety, and intellectual property are especially likely to arise as ethics concerns in research, but all legal requirements must be met. In addition, careful consideration is needed in regard to the ethics implications that might be associated with use of secondary data.

Where a light touch review confirms that a full ethics review is not required, good research practice requires adherence to professional codes of practice, legal requirements and compliance with the Data Protection Act (DPA).

Work with potentially vulnerable populations

Independent Safeguarding Authority (ISA) and Criminal Records Bureau (CRB) Disclosures

In most cases, researchers working with vulnerable people will need to be registered with ISA (www.isa.homeoffice.gov.uk) which has links with the CRB. The CRB offers organisations a means to check the background of researchers to ensure that they do not have a history that would make them unsuitable for work involving children and vulnerable adults. The ISA ensures that the information is updated. The responsibility for ensuring that applicants are suitable to work with such groups ultimately rests with individual employers. In some cases other individuals (such as a head teacher or social services manager) may be better placed to provide information on necessary disclosures. For further details, see the Safeguarding Vulnerable Groups Act 2006; Rehabilitation of Offenders Act 1974; the Rehabilitation of Offenders Act 1974 (Exceptions Order 1975), and the British Psychological Society (BPS) Code of Research Ethics.

Proxy consent

Where proxy consent for research participants is necessary, the best interests of the vulnerable person must be the highest importance. In sensitive research involving vulnerable populations, particularly children, the competence of the researcher to undertake the research should be considered. Proxy consent should only be used when participants are unable to consent themselves or where it is legally necessary. Care should be taken that consent cannot be sought from the participants and it should not be assumed that children are unable to consent because of their age. When proxy consent is used agreed criteria

should be used to identify signs that the participant is unwilling to take part or wishes to terminate the research interaction, or fully understands to what they are consenting.

Limits to confidentiality

Researchers working with children, families and vulnerable populations should, when eliciting consent, make clear the limits to confidentiality. If for example an interview reveals that a participant or another person identified in the interview is in significant and immediate danger, the researcher will be obliged to take action in response to that disclosure. Before starting a project involving children, families or vulnerable populations, the principal researcher should have established a procedure and the necessary systems and identified contacts to activate help and support in the event of a disclosure. If the researcher feels it is necessary to break confidentiality, the participant will normally be informed what action is being taken by the researcher unless to do so would increase risk to those concerned. In projects collecting data on criminal behaviour, it may be necessary to explain to participants that confidentiality will be preserved as far as the law permits.

Secondary data sources

Secondary use of datasets needs to be given careful consideration by both the researcher and the REC, especially with regard to presumed consent and the potential risk of disclosure of sensitive personal information. This applies to the user of data and also to the researcher who originates it. Researchers who collect the data initially should be aware that the ESRC expects that others will also use it, so consent should be obtained on this basis and the original researcher must take into account the long-term use and preservation of data. Further advice on securing consent for secondary use, as well as exemplar consent forms, are available at the UK Data Archive website (www.data-archive.ac.uk). It has to be accepted, however, that in some cases it may not be possible to sufficiently anonymise data in order for it to be available at the UK Data Archive.

Secondary data falls into three categories:

- The first includes data which is not sensitive and where there is minimum risk of disclosure of the identity of individuals.
- Second is data that is protected by legislation, such as census data and administrative data. Here, the data producer has a strong interest in how researchers will access the data, and may control access to it. This category of data may only be available via 'safe settings'.
- A third category, such as the National Child Development Study (NCDS), includes data where the inclusion of information such as a birth date or postcode makes disclosure possible, perhaps via a link to other datasets. This means that such data is ethics sensitive.

A data provider (such as Economic and Social Data Service (ESDS) or the Office for National Statistics (ONS)) may also have stringent requirements and restrictions relating to access and use of secondary data that must be followed. Legal and data supplier access requirements on secondary use of datasets must be complied with, including provisions relating to presumed consent and potential risk of disclosure of sensitive personal information. Data suppliers such as the ESDS or ONS should be consulted on their requirements.

The fact that an original piece of research has gone through ethics review for its collection does not rule out ethics issues arising over its secondary use. For example, archiving data

with the UK Data Archive might of itself make disclosure more likely. Issues include being able, for example, to download data to a CD-ROM and wrongly allowing others (such as one's students) to use it without the rights to do so. Linking data can also increase the risk of identification.

There are also specific ethics issues relating to large-scale surveys, such as the Millennium Cohort Study, where social and other health or medical data is secured. The REC should consider issues such as the relation between opting in and out of the study and consent, data security of named files and data and the anonymisation of individual respondents. It should ensure that proposals involving third parties such as polling companies contracted to secure data will do so according to the ethics principles set out here. These organisations often operate according to codes of practice developed by bodies such as the Market Research Society (www.mrs.org.uk).

Data access through technology

In the future there may be an increasing likelihood of researchers accessing datasets through the technology being developed in e-social science where the issue of anonymity is compounded by debate over ownership and control of data. Moreover, this question will require special consideration in the future because of the use by social scientists of data held in public or private bio banks in as much as the initial consent to deposit may not have presumed this form of access.

2: Frequently asked questions

Assessing risk

What is the meaning of risk?

Proposals should be considered in the context of risk to the researched and the researchers. Ethics scrutiny should be proportionate to the level of risk. Risk is often defined by reference to the potential physical or psychological harm, discomfort or stress to human participants that a research project might generate. This is especially pertinent in the context of health-related research. But, in addition, social science raises a wider range of risks that needs to be considered by RECs. These include risk to a subject's personal social standing, privacy, personal values and beliefs, their links to family and the wider community, and their position within occupational settings, as well as the adverse effects of revealing information that relates to illegal, sexual or deviant behaviour. Research which carries no physical risk can be disruptive and damaging to research participants either as individuals or as whole communities or categories of people, such as those with HIV infection.

Can all risks be avoided?

Not all risks can, or in some cases, should be avoided, but it is important that RECs and researchers develop awareness of potential risks. Such risks may be difficult or impossible to quantify or anticipate in full prior to the start of a social science research project, especially in longitudinal, qualitative research and research taking place in other countries. Nevertheless, researchers should endeavour to determine possible risks and their management (not least through the methodological strategy and instruments they adopt) prior to the start of a project, which may then require more formal ethics review. The FRE Case Studies (see Appendix F) illustrate how different projects carry potentially different risks, and how these can be usefully identified through questions that help anticipate ethics difficulties. This material may also be of use to those working within medical research who undertake qualitative research as part of a non-clinical trial.

The form of vigilance required for the management of physical risk used in medical research is inappropriate for the management of the social risks that may be present in social science research. RECs should provide guidance and advice to researchers about ways in which risks can be minimised and participants protected from harm, while at the same time offering advice on the prioritisation and different degrees of risk. The establishment of approved ethics research protocols for commonly occurring situations can expedite ethics review. In order to share knowledge and experience in resolving ethics dilemmas, RECs are encouraged to place links to their approved protocols on the web. In doing so the originating REC cannot enter into any discussion of their proposed use. It will be up to each REC to ensure that the approved protocol is appropriate for the study under scrutiny.

How do you inform participants of potential risks?

Once risks have been identified, researchers should ensure that these are discussed with research participants in order to secure valid consent. When presented with sufficient appropriate information individuals will usually be able to use reasoned judgement to decide whether or not they wish to participate. There is also therefore the need to ensure that potential participants have the capacity to understand the consequences (and risks) of participating in order to give valid consent. 'Capacity' is legally defined under the terms of the 2005 Mental Capacity Act and any projects that involve those who fall under this Act must be reviewed by the NRES. The Act applies to 16-17 year olds and adults (18 years and

over) who lack capacity to make a particular decision or take a particular action for themselves at the time the decision or action needs to be taken. Guidance on the Act notes that lack of capacity may be permanent or temporary. It could be state-related (eg due to drug or alcohol use, or because of the person's emotional state at the time) or it may be temporary. The key point is that valid consent can only be secured if the potential participant has capacity at the time consent is sought. (For further information see www.legislation.gov.uk/ukpga/2005/9/contents)

Is it legitimate to expose some research participants/organisations to risk?

This might arise for two reasons. First, as is recognised elsewhere (see Tri-Council of Canada, 2002. www.pre.ethics.gc.ca/English/policystatement/introduction.cfm) research may be 'deliberately and legitimately opposed to the interests of the research participants/organisations' in cases where the objectives of the research are to reveal and critique fundamental economic, political or cultural disadvantage or exploitation. Much social science research has a critical role to play in exploring and questioning social, cultural and economic structures and processes (for example relating to patterns of power and social inequality, and institutional dynamics and regimes that disadvantage some social groups over others, intentionally or not). Such research results may have a negative impact on some of the research participants/organisations. Principles of justice should, however, mean that researchers would seek to minimise any personal harm to individual people. Secondly, researchers should also consider how to balance the potential of immediate or short-term risks to research participants against longer-term gains to future beneficiaries. It is the responsibility of the research proposers to make such a case in detail to an REC. In making a decision RECs may wish to consider safety issues and whether subjects should have the right of protection.

What about iterative research where risks only become apparent later in the research?

RECs should have mechanisms that make some provision for future advice and guidance beyond the initial ethics approval process, such as advisory panels, attached to individual projects, as well as referral back to RECs. All research can develop in ways that raise unforeseen ethics implications. This is especially the case in qualitative research where the developing nature of the research agenda, especially over a long period of time, may make it harder to ensure that the rights and dignity of the subject are respected and protected without further review.

What are the risks in disseminating findings?

The media can be very helpful in disseminating findings, but the possible impact on research participants, their families and organisations needs to be thought through particularly where anonymity may be jeopardised.

For example, descriptions of participants (eg in case studies) need to take care to ensure that they do not risk making those who take part identifiable, particularly if sample sizes are small or participants have distinctive characteristics that may make them recognisable. In some cases, for example in elite interviews, participants may wish to have their views expressed but researchers need to be alert to the original understanding of the person interviewed. Did they know what would happen to the findings? Have they given permission for their name to be identified and if not what steps are possible to anonymise the data? What is the impact on their families and careers? Did they give permission for the material to be data archived or shared with other researchers? Political sensitivities may arise when findings are contrary to local or national policy. It may be important to publish critical

findings about policies and organisations, but was this within the original remit of the research? Were participants aware that this could be a consequence of their participation? When working with commercial and government organisations, Principal Investigators should look carefully at the forms they are asked to sign concerning possible publication of the findings. Researchers should be particularly careful in publishing and using information about third parties.

Consent

What is informed consent?

Informed consent, also known as valid consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion (see below) so that prospective participants can make an informed and free decision on their possible involvement. Typically, the information should be provided in written form, time should be allowed for the participants to consider their choices, and the forms should be signed off by the research participants to indicate consent.

Where participants are not legally responsible, their legal representatives or guardians should be consulted as well as the individual. Where participants are not literate, verbal consent may be obtained but this should wherever possible be witnessed and recorded. In other circumstances, for example telephone interviews, this may not be possible. Where consent is not to be secured, a full statement justifying this should be submitted to the REC review and approved. In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent (see key terms); it may also be necessary to re-negotiate consent during the lifetime of the research.

The primary objective is to conduct research openly and without deception. Deception (ie research without consent) should only be used as a last resort when no other approach is possible. Any research involving deception must be submitted to the REC review and approved. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

What does it mean that research participants must participate voluntarily, free from any coercion?

In all cases of research, researchers should inform participants of their right to refuse to participate or withdraw from the investigation whenever and for whatever reason they wish. There should be no coercion of research participants to take part in the research.

Adult research participants, however, may be given small monetary reimbursement for their time and expenses involved. In some instances, it may be justified to use techniques such as a free prize draw or book vouchers, to encourage survey responses. Respondents must not be required to do anything other than agree to participate or return a questionnaire to be eligible to a free prize draw, and incentives must not be offered that require the respondent to spend any money. Where children are involved, it is often appropriate to acknowledge their help with gifts to participating schools and/or personal gifts. Incentives may be permissible, but anything which implies coercion is not.

How do you obtain consent in multi-disciplinary projects?

In cases of multi- or inter-disciplinary research the definition of informed consent should be given very careful consideration. The relationship between researchers and researched may vary between disciplines or in projects using diverse methodologies. In the case of participatory social science research, consent to participate is seen as an ongoing and open-ended process. Consent here is not simply resolved through the formal signing of a consent document at the start of research. Instead it is continually open to revision and questioning. Highly formalised or bureaucratic ways of securing consent should be avoided in favour of fostering relationships in which ongoing ethics regard for participants is to be sustained, even after the study itself has been completed. Review mechanisms will need to enable this where appropriate.

Do participants have a right to withdraw consent?

In giving consent, participants have as mentioned above, the right to withdraw consent as well as the right not to answer particular questions. All research should indicate the point at which data will have been anonymised and amalgamated and cannot then be excluded. Some RECs give a date after which participants cannot withdraw consent or ask for data destruction. If data is to be archived and shared, participants need, as far as possible, to give specific consent to this. In some cases it may not be appropriate to archive data.

What if it is not possible to obtain informed consent?

Informed consent may be impracticable or meaningless in some research, such as research on crowd behaviour, or may be contrary to the research design, as is sometimes the case in psychological experiments where consent would compromise the objective of the research. In some circumstances – such as when users of illegal drugs and illegal groups are involved - written consent might also create unnecessary risks for research participants. Even in this last case a researcher should seek informed consent where possible to secure the trust and confidence of those involved. In some contexts consent may need to be managed at a point beyond the completion of research fieldwork, for example, where covert observation is necessary and warranted. This might apply to research in the field of deviance especially where it involves illegal or immoral behaviour.

Covert research may be undertaken when it may provide unique forms of evidence or where overt observation might alter the phenomenon being studied. The broad principle should be that covert research must not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance which cannot be uncovered in other ways are likely to be discovered. Normally, social scientists should ensure that research participants are aware of and consent to arrangements made with regard to the management and security of data, the preservation of anonymity, and any risk that might arise during or beyond the project itself, and how these might be minimised or avoided. Disciplinary professional codes may be helpful here (see Appendix D). Where the research design is such that valid consent cannot be obtained from participants before data are gathered from them, REC review and approval of the protocol must always take place at the highest level.

How do you obtain consent from vulnerable people?

In cases where research involves potentially vulnerable groups such as children, older persons or adults with learning difficulties (for those who fall under the remit of the Mental Capacity Act 2005 see below), every effort should be made to secure actively given informed consent from individual participants. Passive assent, including group assent (with

consent given by a gatekeeper) should be avoided wherever possible, and every effort should be made to develop methods of seeking consent that are appropriate to the groups being studied, using expert advice, support and training where necessary.

In the case of research on children, one cannot expect parents alone to provide disinterested approval on their children's behalf. In such cases, every effort should be made to deal with consent through dialogue with both children and their parents (or legal equivalent). Again, there may be circumstances where seeking consent from parents could jeopardise the research (for example, in research into teenage sexuality or teenage pregnancy). In such circumstances, researchers will need to regard the potential risk to the principal participants of the research as a priority.

How do you obtain consent from participants who fall under the Mental Capacity Act 2005?

In the case of research with adults who lack capacity under the terms of the 2005 Mental Capacity Act these projects must be reviewed by the NRES Research Ethics Committee. Guidance on the Act⁴ states that researchers should assume that a person has capacity, unless there is proof that they do not have capacity to make a specific decision, and that potential participants must receive support to try to help them make their own decision. The potential participant has the right to disagree with the decisions that others (such as relatives or carers) might make.

If it is established that an adult does not have the capacity to decide whether to participate, the Act requires that the researcher must consult with a specified consultee as set out in the Guidance to the Act (2008). If possible, this should be a personal consultee. The researcher must take reasonable steps to identify someone who knows the person who lacks capacity well but is not acting in a professional or paid capacity. The guidance states that it should be someone whom the person who lacks capacity would trust with important decisions about their welfare. Thus, a personal consultee could be a family member or close friend of the person, but not a paid carer or other professional such as a social worker. Remuneration does not cover family members receiving some of the person's pension or other benefits as a payment towards their share of the household expenses.

If no personal consultee can be identified, a nominated consultee should be proposed by the researcher. This is someone who is prepared to be consulted by the researcher, but has no connection with the research project. That could be someone from a relevant organisation (such as a local church or charity), but could also be someone who knows the person in a professional capacity (and thus could not be a personal consultee), such as the person's GP, social worker or carer, providing they have no connection with the research project.

Medical research

What happens when research involves tissue samples (including blood)?

UK research involving human tissue (including blood) is subject to the 2004 Human Tissue Act, or The Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), and should adhere to the Codes of Practice issued by the Human Tissue Authority. Ethics approval should be

⁴ See Chapter 11: www.opsi.gov.uk/acts/acts2005/related/ukpgacop_20050009_en.pdf

obtained from NRES research ethics committees (normally NHS MRECs or their equivalent) or UKECA-recognised ethics committees⁵.

Where research involves the need to secure tissue samples (including blood), participants should be informed of their rights over such samples and data derived from them, especially whether they have or do not have the right to retrieve such samples. Responsibility for the proper use, curation and eventual disposal of such samples does not lie with the ESRC, and we accept no liability for complaints or grievances associated with such research. Responsibility for this material lies with the researcher's employing organisation. The use, curation and disposal of samples should be in accordance with the terms of consent given by the donor and the relevant legislation. The RO should ensure that its governance procedures are sufficiently robust to enable proper and effective review of this research, even though it may be relatively infrequent. All research involving the use of tissue or other biological material must be reviewed and approved by an REC. A dilemma may arise when such material indicates that the research participant is at risk of a serious disease. As far as possible, this likelihood should be anticipated before the start of the research and decisions taken how such cases will be handled should they arise.

What happens when research is undertaken with medical clinicians?

Initially, a light touch review by the RO's REC should identify those projects that need to be reviewed by NRES regardless of the level of risk. Such projects involve any of the following groups: NHS patients and their families (including carers and past patients, if identified through NHS records); NHS staff; clients of adult social care services and their families (if identified via councils with social services responsibilities); social care staff (employed or contracted by councils with social services responsibilities). A full list of groups can be found on the NRES website.

It is expected that a light touch review by an REC will be able to provide an effective filter for projects that might otherwise have been inappropriately sent to a NRES REC including those that while involving a physically invasive technique do not do so for clinical purposes. Similarly, the Framework provides for review by an REC of large scale, longitudinal social science studies that may seek information relating to respondents' personal health profile.

Internet research

Why should internet research receive full ethics review?

In a fast developing area RECs may need to involve an independent expert in assessing research proposals that break new grounds. Internet research and other research using new technologies can take place in a range of settings, for example, email, chat rooms, web pages, various forms of 'instant messaging'. These can pose new ethics dilemmas.

For example, what constitutes 'privacy' in an online environment? How easy is it to get informed consent from the participants in the community being researched? What does informed consent entail in that context? How certain can the researcher be that they can establish the 'real' identity of the participants? When is deception or covert observation justifiable?

⁵ Or other ethics committees recognised by the United Kingdom Ethics Committee Authority (UKECA)

Researchers, research participants and reviewers of research ethics will often encounter new or unfamiliar ethics questions and dilemmas. There is a growing literature on ethics in online research. A good starting point is the Association of Internet Researchers 2002 Guidelines and the BPS 'Conducting Research on the Internet: Guidelines for ethics practice in psychological research online (2007)'.

Research governance

What are the links between ethics principles and governance?

The RCUK Policy and Code of Conduct on the Governance of Good Research Conduct (Integrity, Clarity and Good Management) is a requirement of all research councils, and provides guidelines on necessary provisions (see Appendix D for weblink).

The UK Research Integrity Office Code of Practice for Research (see Appendix D for weblink) is a reference tool for research organisations to use when revising their codes of practice for research. It complements existing and forthcoming guidance on research conduct, such as that provided by Research Councils UK, the Wellcome Trust and the Council for Science and Technology. It also includes a one-page recommended checklist for researchers: a non-technical checklist summarising the key points of good practice in research, based upon the more detailed standards provided in the Code.

The Code is applicable to all subject areas and does not attempt to micro-manage research. Recognising that some organisations have developed their own guidance, the intention is that research organisations can use the principles and standards outlined as benchmarks when drafting or revising their own, more detailed, codes of practice. Use of the benchmarks contained in the Code can assist research organisations in fulfilling the requirements of regulatory, funding and other relevant bodies.

The UKRIO checklist is included in Appendix A and may be used by RECs in addition to their own REC forms.

In addition, it should be noted that the Department of Health's Research Governance Framework requires that research within its remit must secure research governance approval from individual NHS Trust research and development departments, in addition to NRES MREC ethics approval.

Appendix A: Example research ethics initial checklist

A checklist should be completed for every research project. It is used to identify whether a full application for ethics approval needs to be submitted. Below is an example of a checklist that could be used in a UK research organisation to initially determine the level of risk of harm entailed in a proposed study.

Before completing this checklist please refer to the research organisations Code of Practice on Ethical Standards for Research Involving Human Participants. The principal investigator or, where the principal investigator is a student, the supervisor, is responsible for exercising appropriate professional judgement in this review. This checklist must be completed before potential participants are approached to take part in any research.

Project details

Project title:

Applicant details

Name of researcher (applicant):

Role:

Contact address:

Email:

Telephone:

For students only

Module name and number or MA/MPhil course and department:

Supervisor's or module leader's name:

Example research ethics initial checklist

Please answer each question by ticking the appropriate box:

	Yes	No
Research that may need to be reviewed by NHS NRES Committee or an external Ethics Committee (if yes, please give brief details as an annex)		
Will the study involve recruitment of patients or staff through the NHS or the use of NHS data or premises and/or equipment?		
Does the study involve participants age 16 or over who are unable to give informed consent? (eg people with learning disabilities: see Mental Capacity Act 2005. All research that falls under the auspices MCA must be reviewed by NHS NRES.)		
Research that may need a full review		
Does the research involve other vulnerable groups: children, those with cognitive impairment, or those in unequal relationships? (eg your own students)		
Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (eg students at school, members of self-help group, residents of nursing home?)		
Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non-public places)		
Will the study involve discussion of sensitive topics? (eg sexual activity, drug use)		
Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind?		

Will tissue samples (including blood) be obtained from participants?		
Is pain or more than mild discomfort likely to result from the study?		
Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?		
Will the study involve prolonged or repetitive testing?		
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?		
Is there a possibility that the safety of the researcher may be in question? (eg in international research: locally employed research assistants)		
Does the research involve members of the public in a research capacity (participant research)?		
Will the research take place outside the UK?		
Will the research involve respondents to the internet or other visual/vocal methods where respondents may be identified?		
Will research involve the sharing of data or confidential information beyond the initial consent given?		
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		

Principal Investigator:

Signed:

Date:

Supervisor or module leader (where appropriate):

Signed:

Date:

If you have answered **'no' to all questions**, send the **completed and signed form** to your Department's representative on the Faculty/School Ethics Committee with any further required documents, for their records.

If you have answered **'yes' to the first section of the Research checklist** (ie if your research may be subject to specific ethics review other than the RO's REC), you will need to send this completed form to the Research Ethics Committee for reference and submit your research for ethics approval to the appropriate body. Once ethics approval is granted, a copy should be sent to the Faculty/School Ethics Committee for their records.

If you have answered **'yes' to any of the other questions in the Research checklist**, you will need to describe more fully how you plan to deal with the ethics issues raised by your research. Your proposal will need to be approved by the Research Ethics Committee. You should submit your plans for addressing the ethics issues raised by your proposal using an ethics approval application form, which should be sent to the Faculty/School/ Department Research Ethics Officer. Forms can be obtained from the Faculty/School/Department /University website.

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

Points to consider when planning research

This section aims to facilitate the process of considering ethics around social science research: it is not intended to be definitive but may help to highlight potential issues to researchers.

Further information on the issues raised in this list can be found in the main body of the framework as well as in ethics guidelines from Learned Societies and subject-specific guides. Please see Appendix D for web links to websites that may be useful.

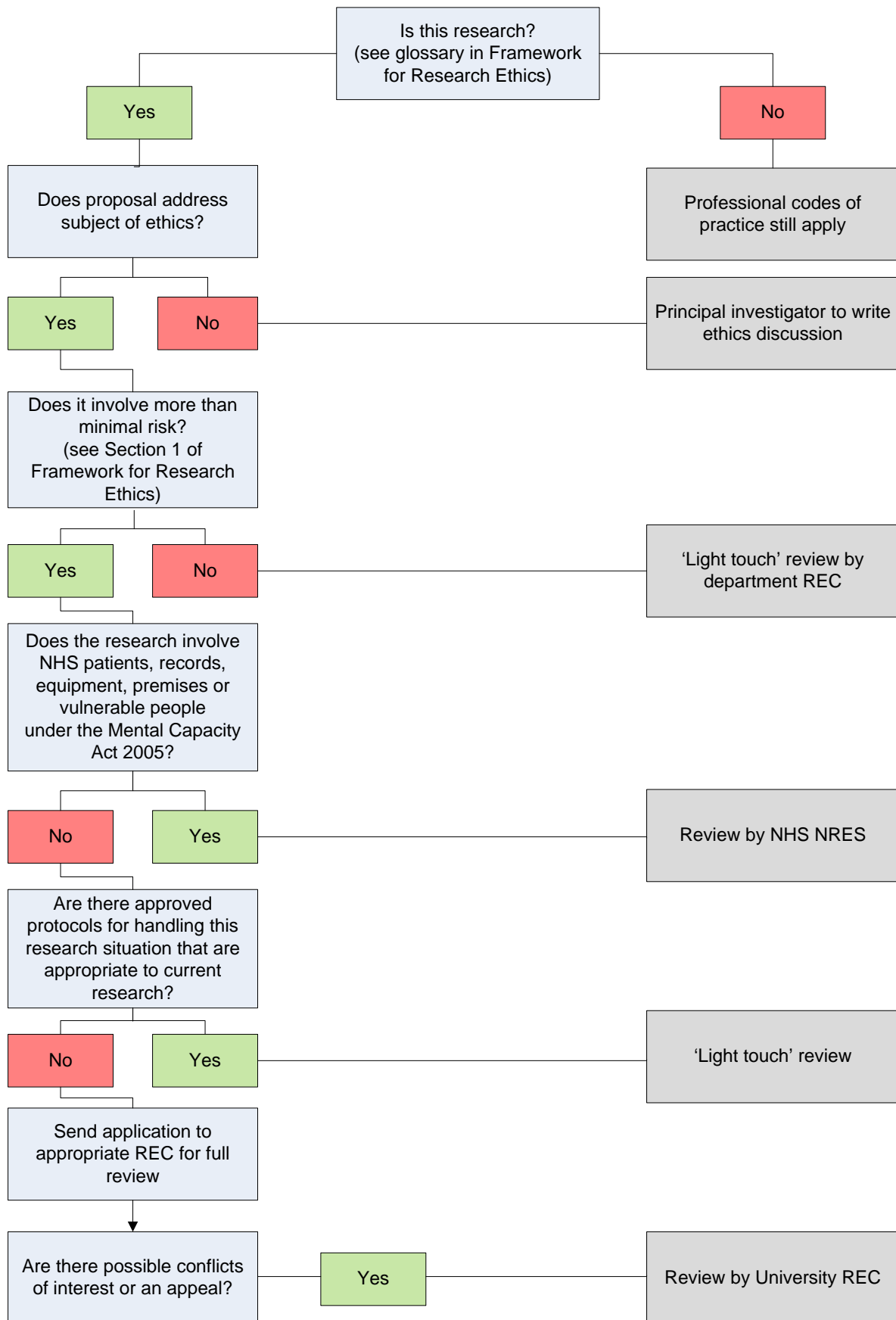
The following list of points to consider are examples of likely areas you will need to have explored if submitting a full ethics review.

- Have you considered risks to:
 - the research team?
 - the participants? Eg harm, deception, impact of outcomes
 - the data collected? Eg storage, considerations of privacy, quality
 - the research organisations, project partners and funders involved?
- Might anyone else be put at risk as a consequence of this research?
- What might these risks be?
- How will you protect your data at the research site and away from the research site?
- How can these risks be addressed?
- Details and recruitment of participants:
 - What types of people will be recruited? Eg students, children, people with learning disabilities, elderly?
 - How will the competence of participants to give informed consent be determined?
 - How, where, and by whom participants will be identified, approached, and recruited?
 - Will any unequal relationships exist between anyone involved in the recruitment and the potential participants?
 - Are there any benefits to participants?
 - Is there a need for participants to be de-briefed? By whom?
- What information will participants be given about the research?
- Who will benefit from this research?
- Have you considered anonymity and confidentiality?
- How will you store your collected data?
- How will data be disposed of and after how long?
- Are there any conflicts of interest in undertaking this research? Eg financial reward for outcomes etc.
- Will you be collecting information through a third party?
- Have you considered consent?
 - If using secondary data, does the consent from the primary data cover further analysis?
 - Can participants opt out?
 - Does your information sheet (or equivalent) contain all the information participants need?
 - If your research changes, how will consent be renegotiated?

- Have you considered ethics within your plans for dissemination/impact?
- Are you conducting research outside the UK? Are there any additional issues that need to be considered as a result? Eg local customs, local 'gatekeepers', political sensitivities
- Which Ethics Committee is most appropriate for your research?
- Have you considered the time you need to gain ethics approval?
- Have you considered what legislation your project will need to abide by? Eg Data Protection Act, Freedom of Information Act, Human Rights Act
- How will the ethics aspects of the project be monitored throughout its course?
- Is there an approved research ethics protocol that would be appropriate to use?
- How will unforeseen or adverse events in the course of research be managed? Eg do you have procedures to deal with any disclosures from vulnerable participants?

A recommended checklist for researchers can be found on the UKRIO website at www.ukrio.org/what-we-do/code-of-practice-for-research.

Appendix B: Flowchart of review process



Appendix C: Key terms glossary

Please see below for key terms used in the Framework for Research Ethics. Rather than produce a full glossary, links are provided to several resources which may be useful when considering ethics terminology. Glossaries may also be available from research organisation RECs and Learned Societies.

Assent: Agreement from an individual not able to provide free and informed consent to take part in research.

Elite interviews: These are interviews with senior people who may be chosen for inclusion in a research study because of the public role they hold in their own right (eg Government Ministers), or because they represent views of their general position (eg judges, newspaper editors).

In elite interviews it is often argued that formal written consent is not necessary because by consenting to see the researcher, the participant is in fact giving consent. However, all such participants should receive an initial letter giving the name and status of the researcher carrying out the study, a brief rationale of the study including its purpose and value and why the individual is being invited to take part. The person interviewed should be aware what will happen to any findings, whether the data will be shared with others, and whether he/she will be identified. Where researchers are not able to follow the minimum procedure identified above, these research proposals should go for a full ethics review.

Enduring consent: This is where there is no time limit on consent given. Human participants do not need to be re-contacted should any of their personal data be reused for further research. Securing enduring consent may be essential in longitudinal studies. It may also be important for data that is placed on the UK Data Archive. Principles of preserving confidentiality apply.

Ethics protocols: The use of approved protocols for commonly occurring situations such as research with normally developing children in schools. These can expedite ethics review as Principal Investigators can confirm in a 'light touch' review to their REC that there is an approved protocol that appropriately covers the ethics issues raised by their research. It will be the responsibility of the local REC to approve the suggested protocol for the work.

Expedited review: In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review is carried out by one or more members of a Research Ethics Committee (REC), commonly its chair, and not by a member of the Department due to carry out the research.

Human participants: Human participants (or subjects) are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and fetuses, human tissue and bodily fluids, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

Informed consent: Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement. Typically, the information should be provided in written form, time should be allowed for the participants to consider their choices and the forms should be signed off by the research participants to indicate consent.

Where participants are not literate, verbal consent may be obtained but this should wherever possible be witnessed and recorded. In other circumstances, for example telephone interviews, written or witnessed consent may not be possible, but verbal consent should be secured.

Where consent is not to be secured, a full statement justifying this should be submitted to the REC review and approved.

In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent. The primary objective is to conduct research openly and without deception. Deception (ie research without consent) should only be used as a last resort when no other approach is possible. Any research involving deception must be submitted to the REC review and approved. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

Lay member: This person should have no affiliation to the research organisation apart from membership of the REC. This term is used in reference to a member of a REC.

Light touch review: All ESRC funded research should undergo at least a light touch review and this should be the decision of the REC. Light touch reviews identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases this is the only ethics review necessary, and this can be undertaken using a checklist (see Appendix A). RECs need to approve that only a light touch review is necessary.

Personal data: Under the Data Protection Act 1998 'personal data' is defined as data which relates to a living individual who can be identified a) from those data or, b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

Research: Research is defined as any form of disciplined inquiry that aims to contribute to a body of knowledge or theory.

Research ethics: Research Ethics refers to the moral principles guiding research, from its inception through to completion and publication of results and beyond – for example, the curation of data and physical samples after the research has been published.

Research Ethics Committee: A Research Ethics Committee (REC) is defined as a multidisciplinary, independent body charged with reviewing research involving human participants to ensure that their dignity, rights and welfare are protected. The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions.

Sensitive personal data: Under the DPA 1998 this means personal data consisting of information as to (a) the racial or ethnic origin of the data subject, (b) his/her political opinions, (c) his/her religious beliefs or other beliefs of a similar nature, (d) whether he/she is a member of a trade union (within the meaning of the [1992 c. 52.] Trade Union and Labour Relations (Consolidation) Act 1992), (e) his/her physical or mental health or condition, (f) his/her sexual life, (g) the commission or alleged commission by him/her of any offence, or (h) any proceedings for any offence committed or alleged to have been committed by him/her, the disposal of such proceedings or the sentence of any court in such proceedings.

Transparency in research ethics: The full, accurate, and open disclosure of relevant information. Where the research involves new and innovative methodologies, this is especially important.

Valid consent: For consent to be 'valid' the participant must be capable of understanding all the potential risks involved. Where this may be in doubt, the Mental Capacity Act 2005 may apply (see Appendix D).

Appendix D: Professional ethics codes and relevant legislation

- British Psychological Society Code of Conduct and Ethical Guidelines www.bps.org.uk/what-we-do/ethics-standards/ethics-standards
- Criminal Records Bureau www.homeoffice.gov.uk/agencies-public-bodies/crb/
- Data Protection Act 1998 www.legislation.gov.uk/ukpga/1998/29/contents
- Department of Health Research Governance www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962
- Freedom of Information Act 2000 www.legislation.gov.uk/ukpga/2000/36/contents
- Health and Social Care Act 2008 www.legislation.gov.uk/ukpga/2008/14/contents
- Human Rights Act 1998 www.legislation.gov.uk/ukpga/1998/42/contents
- Human Tissue Act 2004 www.legislation.gov.uk/ukpga/2004/30/contents
- The Medicines for Human Use (Clinical Trials) Regulations 2004 www.legislation.gov.uk/uksi/2004/1031/contents/made
- Mental Capacity Act 2005 www.legislation.gov.uk/ukpga/2005/9/contents
- Code of Practice on the Mental Capacity Act 2005 www.dca.gov.uk/menincap/legis.htm#codeofpractice
- Mental Capacity Act factsheet and guidance for researchers www.dh.gov.uk/en/socialcare/deliveringadultsocialcare/mentalcapacity/mentalcapacityact2005/dh_078789
- MRC Clinical Trials Unit Glossary www.ctu.mrc.ac.uk/glossary.aspx
- The Ministry of Defence Research Ethics Committee (MODREC) www.science.mod.uk/engagement/modrec/modrec.aspx
- NHS, Governance Arrangements for NHS Research Ethics Committees www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4005727
- NHS Integrated Research Application System (IRAS) www.myresearchproject.org.uk/signin.aspx
- NHS National Research Ethics Service Glossary www.nres.nhs.uk/applications/glossary
- NRES guidance for applicants www.nres.nhs.uk/applications/
- Standard Operating Procedures for Research Ethics Committees in the United Kingdom www.nres.nhs.uk/nres-publications/publications/standard-operating-procedures
- National Offender Management Service (NOMS) Ethics Committee www.justice.gov.uk/publications/research-and-analysis/noms
- Online Ethics Center glossary www.onlineethics.org/cms/glossary.aspx
- Rehabilitation of Offenders Act 1974 www.legislation.gov.uk/ukpga/1974/53
- Research Councils UK (RCUK) Governance of Good Research Conduct www.rcuk.ac.uk/publications/researchers/grc
- The Research Ethics Guidebook www.ethicsguidebook.ac.uk
- Safeguarding Vulnerable Groups Act 2006 www.legislation.gov.uk/ukpga/2006/47/contents
- Secure Data Service (SDS) www.ukdataservice.ac.uk/get-data/secure-access.aspx
- Social Care Research Ethics Committee www.screc.org.uk
- Social Science Research Ethics guide www.lancs.ac.uk/researchethics
- Social Research Association Ethical Guidelines www.the-sra.org.uk/guidelines.htm

- Tri-Council Ethics Glossary www.pre.ethics.gc.ca/english/tutorial/glossary.cfm
- UK Data Archive www.data-archive.ac.uk
- UK Research Integrity Office (UKRIO): www.ukrio.org.uk/home
- UKRIO Code of Practice for Research www.ukrio.org/what-we-do/code-of-practice-for-research
- 'Understanding the Mental Capacity Act' (2007 PowerPoint presentation by David Neal, Head of Policy, NRES) www.npsa.nhs.uk/easysiteweb/getresource.axd?assetid=7580
- Universal Ethical Code for Scientists www.bis.gov.uk/policies/science/science-and-society/communication-and-engagement/universal-ethical-code
- Wellcome Trust Biobank Ethics and Governance Framework www.wellcome.ac.uk/about-us/publications/reports/biomedical-ethics/wtd003284.htm

Useful links to professional associations

- Association of Internet Researchers www.aoir.org/documents/ethics-guide
- American Anthropological Association www.aaanet.org/committees/ethics/ethcode.htm
- The British Psychological Society Ethics and Standards www.bps.org.uk/the-society/code-of-conduct/code-of-conduct_home.cfm
- The British Psychological Society 'Conducting research on the internet: Guidelines for ethics practice in psychological research online' (2007) www.bps.org.uk/publications/policy-guidelines/research-guidelines-policy-documents/research-guidelines-policy-docum
- The British Society of Gerontology www.britishgerontology.org
- The British Sociological Association 'Statement of Ethics Practice' www.britisoc.co.uk/about/equality.aspx
- British Educational Research Association 'Ethical Guidelines for Educational Research' (2011) www.bera.ac.uk/resources/ethics-and-educational-research
- British Society of Criminology Code of Ethics www.britisoccrim.org/codeofethics.htm
- Social Research Association 'Ethical Guidelines' and 'Data Protection Act 1998: Guidelines for Social Research' and 'Code of Practice for the Safety of Social Researchers' www.the-sra.org.uk/guidelines.htm
- Universities and Colleges Employer Association 'Guidance on Health and Safety in Fieldwork' www.ucea.ac.uk/en/publications/index.cfm/guidance-on-health-and-safety-in-fieldwork

Appendix E: Key changes to the framework

2010 revisions

The Research Ethics Framework (REF) (now the Framework for Research Ethics (FRE)) was published in 2005, and the ESRC committed to a process of regular review to ensure the framework was kept up to date in order to reflect changing scientific agendas and policy developments. In light of this, the ESRC carried out a review of the framework in 2009.

ESRC established a small review panel in conjunction with Professor Ann Buchanan, acting as chair, to consider the responses from the research ethics consultation undertaken in early 2009. This consultation received over 100 comments from academics, ESRC board and committee members, universities, Learned Societies and stakeholder groups. The responses were largely positive and constructive, with input from the Department of Health, the Association of Research Ethics Committees (AREC) and Vice Chancellors. In addition, expert witness statements have been received on various case studies to provide context for problematic ethics issues.

The panel was also asked to consider any emerging issues in the social sciences alongside responses from the consultation and to agree a set of changes and recommendations for the framework to propose to ESRC. Within this, the panel considered the use of the existing framework by HEIs and other ROs and the monitoring of ESRC-funded research. The findings from these questions have further informed the panel on areas where revisions and clarifications were necessary within the re-drafted framework.

Responses to the consultation have indicated that a more engaging and user friendly version of the Framework on the website, making it more accessible to a wider range of users, would be welcomed. This web space will enable the adoption of new legislation, an area for case studies and example protocols and a 'living list' of useful links which ROs and researchers will be encouraged to contribute to.

Key content changes 2010

Over the last four years, much new legislation has been introduced as well as several amendments to existing acts and laws. Perhaps the most significant piece of legislation for social scientists today is the Mental Capacity Act (2005). However, several other pieces of legislation and changes to existing laws have highlighted the timeliness of the review of the ESRC Research Ethics Framework. Links to relevant legislation and guidance from users of this legislation (eg discipline specific Learned Societies' guidance) are provided in the framework.

In addition, there is a clear link between governance and ethics. The RCUK Research Conduct and Research Integrity Policy has now been released which brings together questions of research integrity and research ethics, and therefore overlaps with aspects of the current ESRC REF. The revised framework compliments this policy to promote good practice and governance of research.

It has been agreed that the new framework should retain its familiarity as far as possible and changes are only made where necessary. There are a few new features in the revised

framework, including a key terms glossary, a FAQs section and a more interactive website. See below for further information on these structural changes.

Purpose of Research Ethics Committee and its role and responsibilities

Reminders are included that a Research Ethics Committee (REC) should facilitate good practice and that the principal aim of ethics review is to protect, as far as possible, all groups involved in research (funders, institutions, researchers and participants) throughout the lifetime of the research. It is proposed that once a REC has met, its decision and comments are fed back to the researchers. This amendment to procedures will encourage a dialogue between RECs and researchers and help inform and promote best practice.

The Framework encourages Research Ethics Committees to publish a projected timetable on the time needed to consider a proposal. This should assist researchers when planning to submit a research proposal to ESRC as well as allay fears as far as possible that ethics review could delay research.

Institutions are encouraged to undertake periodic reviews of research projects funded by ESRC and to record the results. These reports will need to be made available to ESRC if requested. In addition, ESRC may wish to undertake dipstick audits of institutional arrangements (this will include non-UK institutions when funding with overseas partners) to ensure that they are operating to at least the minimum standards outlined within the framework. It is therefore important that RECs keep records of their procedures, minutes of meetings and list of proposals reviewed for a minimum of 5 years.

Types of review

The review identified that under the original framework there was some confusion regarding ethics review. Some researchers interpreted the framework in a way that suggested options of (i) full review, (ii) an expedited review if necessary or (iii) no review of the proposed research in cases where no ethics issues are anticipated.

The revised framework clarifies that all research must go through at least a light touch review as a minimum standard. This light touch review is likely to be relevant for research where the potential for risk of harm to participants and others affected by the proposed research is minimal.

The revised framework also clarifies that expedited review should be used in exceptional circumstances where a research proposal involving possible risk of harm can receive a full review at short notice. It is proposed that an expedited review is carried out by one or more members of a Research Ethics Committee (REC), commonly its chair, and not by a member of the Department(s) due to carry out the research.

Where light touch or subsequent peer review has confirmed that a research proposal requires full ethics review and approval, this should be carried out by a REC under the same conditions as stated in the original REF. Further guidance is provided regarding when researchers should consider full review for their proposed research.

The Framework for Research Ethics (FRE) will encourage researchers to consider full ethics review if the research is to be carried out in international settings or with international partners as particular issues may arise which require scrutiny. Similarly elite interviews,

internet based research (particularly involving visual images), data sharing and data archiving may also raise issues during and after the research commences which should be considered.

Ongoing review

The revised framework highlights the importance of remaining aware of potential risks to all groups involved in research throughout its lifetime. Therefore, it may be necessary to consult with a REC or members of a REC after the start of an award and to consider emerging ethical concerns. These may arise at any time throughout the lifetime of a research project and also during the dissemination phases. The revised framework encourages a starting point of being risk aware whilst not being risk averse. The importance of ongoing review was raised both within the consultation and during an internal audit of ESRC Ethics and Scientific Misconduct.

Students

The revised framework includes clear guidance to clarify that student research should be treated in the same manner as all other research and subject to ethics review. It is expected that much student research will only need to be subject to a light touch review or expedited review. It must not be assumed, however, that all students' projects involve minimal risk. Student projects involving more than minimal risk will need a full ethics review. The ESRC FRE aims to encourage social scientists to engage with issues of ethics from the start of their research careers. Therefore, doctoral training centres (DTCs) will need to detail the ethics training that they provide to their students. This is addressed in the ESRC Postgraduate Training and Development Guidelines.

International/Security

Since the development of the original Research Ethics Framework, the ESRC has funded an increasing volume of overseas research (the ESRC-DFID scheme in particular), as well as research relating to sensitive issues, including the "New Security Challenges/Radicalisation" call. Responses to the consultation raised issues relating to these areas, highlighting sensitivities including risk to researchers and participants, ethical guidelines from other funders or project partners, and the ethics of researching particularly sensitive areas. The changes clarify the ESRC's position (in terms of ensuring its own conduct is ethical), and will include protocols and case studies where possible and provide clear guidance on risk awareness in these scenarios.

Limits to confidentiality

The revised framework provides a clarification on limits to confidentiality and expectations on researchers. Researchers working with vulnerable populations, especially children, highlighted the need to make clear the limits to confidentiality when eliciting consent from the vulnerable person (and parent/carer). If for example a child or vulnerable person reveals that they are in significant and immediate danger, the researcher will be obliged to ensure that the child/vulnerable person is protected. Before starting a project, the principal researcher will normally have established a procedure and the name of a person who will take the responsibility for protecting the vulnerable persons/child in the event of a disclosure. If the researcher feels it is necessary to break confidentiality, the child/vulnerable person will normally be informed what action has been taken by the researcher. By providing clear guidance on this and other issues in the framework, it is expected that researchers will take steps to mitigate unnecessary risk to participants as much as possible.

Internet and technology

Responses highlighted the changes to and the vast increase of the use of e-technology (both in carrying out research on the internet and with storing and sharing data). The issues surrounding internet and technology were the most frequently cited in the course of the consultation. In light of this, the revised framework seeks to address these concerns by recommending full ethics review where internet research or data sharing feature in a research proposal and may be judged necessary. The framework emphasises that as a rapidly developing area, legislation and guidance will continue to evolve and this needs to be recognised by researchers and RECs. In addition, the framework seeks to provide guidance on undertaking research relating to the internet, for example; concerning social networking sites, public forums and people's use of the internet.

Key structural changes 2010

The revised framework seeks to retain the familiarity of the original framework and, as a result, wording and structure have been altered as little as possible. Some changes to the structure of the framework are described here. The foreword has also been revised (and a few other sections replaced or removed).

Protocols and case studies

Responses from HEIs and RECs commented that the development and use of ethics protocols can serve to streamline the process of ethics review. Case studies and protocols will be added to the Framework. As a living document to the web version of the framework, it is intended that more protocols and case studies can be added in the future to the web version of the framework.

Frequently Asked Questions (FAQs) section

A new FAQs section is included within the revised framework. This section aims to highlight emerging issues and address questions and clarifications from the consultation. By including this section, the FRE can be updated as necessary. Currently, questions in this section cover issues including risk, consent and the links between governance and ethics. The section references other sections of the FRE as well as external guidance as necessary. The FAQs will build in a more user-friendly element to the framework and will serve as a reminder for all groups involved in research to remain risk aware throughout all stages of research and its dissemination.

Key terms/ glossary

A new key terms section is being included to streamline the existing framework and to provide consistency in terminology. This glossary will reflect emerging issues as well as break down some of the complexities of the language used in the context of ethics (ie valid/informed consent).

Checklists/Flowcharts

The original ethics flowchart has been updated to reflect new legislation with an emphasis on risk awareness rather than risk aversion. In addition, a list of issues to be considered when planning research has been included to enable researchers to address the ethics surrounding their proposed research. This, alongside the flowchart, will support researchers in making judgements about whether a full review is necessary, whether they have fully considered potential ethics issues, and so on. These tools will also be made available on the

website so that they are accessible to researchers, RECs, other funders and partners for use.

Web addresses

An appendix with helpful web addresses for Learned Societies, links to legislation as well as RCUK and UKRIO guidance is included. The ESRC encourages site visitors to contact the office with suggested additions to this appendix.

2012 revisions

The update in September 2012 included re-formatting the layout, introducing a comprehensive table of contents, updating web links, clarifying the review process flow chart (Appendix B), and some minor revisions to content.

Appendix F: Case studies and protocols

We welcome new case studies and protocols which illustrate the challenges around research ethics in different areas. If you or your research organisation would like to submit a case study or protocol, please contact the ethics team: ethics@esrc.ac.uk. Your case study should not exceed three sides of A4 and include:

- ESRC grant reference and title
- Description of study (brief details of your project including aims, subjects and methods)
- Ethics questions raised and approaches (brief details of the ethics approaches and issues addressed for this study including specific ethical issues, ie approval routes, guidance followed. This should include any issues that arose during the life of the grant as well as those addressed prior to the start of the grant)
- Summary of lessons learned (that may be useful to other researchers in a related area)
- Further reading (relevant links and publications if appropriate).

Case study: Young Lives

Description of study: Young Lives is an international study of childhood poverty funded by the UK Department for International Development (DFID). The study is longitudinal and involves 12,000 children growing up in four countries over 15 years: Ethiopia, the state of Andhra Pradesh in India, Peru and Vietnam. Two cohorts of children – a younger cohort who were born in 2001-2 and an older cohort born in 1994-5 – are being followed, with the younger children being tracked from infancy to their mid-teens, and the older children into adulthood. A variety of survey and qualitative methods are used to collect data with children, parents, and others in communities. Young Lives aims to gain a deeper understanding of children's experiences of poverty, the outcomes of poverty for children, the intergenerational transmission of poverty, how families on the margins move in and out of poverty, and the policies that can make a difference to their lives.

Ethics questions raised and approaches:

The study raises numerous ethics questions about research with children and in developing countries; research that is longitudinal, thus requiring sustaining of relationships over time; and research that involves the archiving of collected data. Thus ethics questions are ongoing, and affect the way we work in many ways.

In planning the first survey round, the academic consortium that set up Young Lives was attentive to research ethics within the epidemiological/medical paradigm. Formal approval for Young Lives was obtained from the ethics committee of the Social Science Division of the University of Oxford in 2006 (www.admin.ox.ac.uk/curec). Because the study was breaking new ground, the following ethics guidelines were used:

- Guidelines from the University of Oxford's Department of International Development, adapted from the ethical guidelines of the Association of Social Anthropologists of the Commonwealth, and based on the Helsinki guidelines.
- Save the Children Child Protection Policy (2003).

Initially, ethics approaches in Young Lives were developed collaboratively with the country research teams. In addition, both the survey and the qualitative research teams underwent training sessions at which ethics were discussed, and fieldwork manuals contain detailed ethics guidance. Following piloting of the qualitative research methods in 2007, a Memorandum of Understanding for fieldworkers was developed, setting out some basic guidance about research procedures and respectful communication with research participants. This is now being used with the survey teams too.

Specific ethical issues: consent

In training fieldworkers discuss and understand that informed consent must be freely given and voluntary, and that people need time to think about participation:

No project staff should pressurise, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressurised by other family or community members. Staff should not make any promises they cannot or are unlikely to keep. The respondents will have at least 24 hours to consider whether they want to take part and will be free to withdraw from the study at any time. Whilst the study procedures are designed to ensure that consent is informed and voluntary, the only person who can really ensure that is you, the fieldworker. You must make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to. (Fieldworker Manual for the Round 3 survey)

In relation to consent from children, the manual emphasises the following:

It is vital to take extra care to explain in ways that they can understand why you are there, why you are interviewing them and what the information is to be used for. It is also important to bear in mind that children are generally taught from a very young age that they must obey adults. This makes it very difficult for them to refuse you. So you must make every effort not to put any pressure on them to participate in the study and to make it clear that there will be no adverse consequences for them if they refuse to take part. Similarly, you should explain the concept of anonymity in words they can understand. They should know that their identity will be kept a secret and that the information will not be used to identify them or to describe their life in particular, but rather to explain the typical life of a child in their community.

Ongoing scrutiny of research ethics

Ethics questions that arise during the survey and qualitative research are recorded, transcribed and translated, and thus are a systematic part of the research documentation. This means that ethics questions can be monitored throughout the course of the study and that ethics is seen as a process, not a one-off event.

Summary of lessons learned:

Understanding the dynamic nature of communities is crucial in longitudinal research. While broad shared ethics practices are important, these need to be applied with some flexibility according to each situation that arises. This is both specific and dynamic to each situation, which may change from year to year. Researchers should be aware that they are not going into neutral situations – change can be rapid, and the changes themselves need careful documentation.

- Survey and qualitative research teams undergo additional training sessions before each round of fieldwork, and ethics questions are discussed across the study, with the aim of developing a shared understanding of research ethics.
- Young Lives has developed an ongoing Memorandum of Understanding for fieldworkers. This acknowledges power differentials between researcher teams and participants according to gender ethnicity and class, as well as age.
- Consent is understood as an ongoing process and is renegotiated at each stage of the study.
- To ensure that staff knew what to do should they encounter children they believe may be suffering from abuse or exploitation; we use the child protection protocols developed by Save the Children (2003). Research teams are encouraged to discuss any concerns with the lead quantitative or qualitative researchers. The research team based at Oxford provide guidance and support.
- For parents, children and community members, expectations of the research are inevitably high, and time is taken to explain the study as clearly as possible. Awareness of the contexts in which the research is being conducted is crucial to understanding how ethics operate in practice. In poor communities, it is likely that any outsiders become the objects of speculation, and it can be difficult for people to distinguish visits by researchers from development interventions which may be more familiar to them.
- Fieldworkers use locally relevant language, images and concepts when explaining complex notions. For example, when explaining archiving, they reassure participants about anonymity, and that identifying features of places, people and organizations are disguised in preparing data for archiving. For example, in Peru, the term 'un archivo' is understood, since almost all villages and communities own archives with documentation regarding the village, which are for public consultation. In Vietnam, researchers used the word for 'storage' - pack and store away - pointing to a cupboard or box. Children see the researchers typing notes on their laptops, and researchers show them what they are doing, and explain that the information will be kept in Hanoi and England for many years.
- Ethics concerns are reported to local teams and to Oxford, and efforts are made to respond to difficult situations appropriately.
- Young Lives country teams report study findings to participants and other community members in locally useful and relevant ways.

Further reading

Virginia Morrow (2009) The Ethics of Social Research with Children and Families in Young Lives: Practical Experiences, Young Lives Working Paper 53

Young Lives research ethics: www.younglives.org.uk/what-we-do/research-methods/ethics