Research Ethics Framework

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Ethics Framework (REF)

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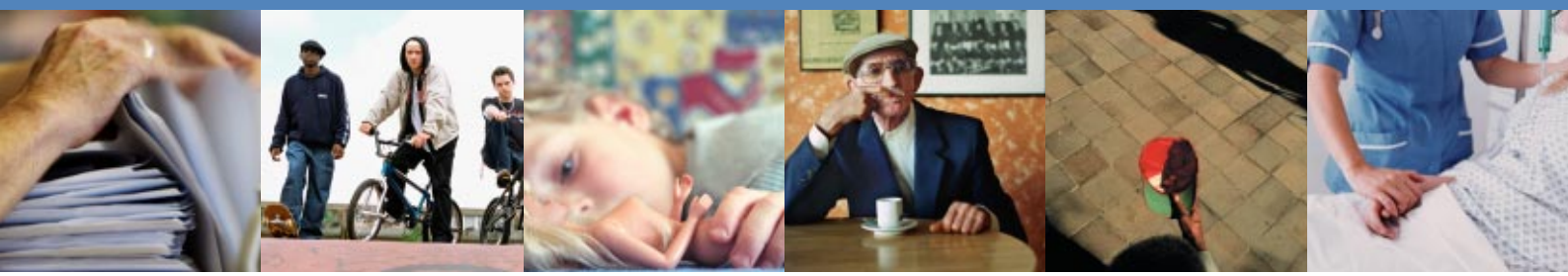

Research Ethics Framework (REF)

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INTRODUCTION

The ESRC expects that the research it supports will be carried out to a high ethical standard. This Framework sets out the ESRC's approach, aims and methods. These aims and methods are amplified in the accompanying set of policy Guidelines.

Background and principles of the Research Ethics Framework

This Research Ethics Framework (REF) is intended to sustain and encourage good ethical practice in UK social science research. Almost without exception, social science research in the UK has been carried out to high ethical standards. But the growing range and sophistication of social science research requires this Framework to make the ESRC's ethical requirements more explicit. It provides a frame of reference for new and established researchers in social science and for interdisciplinary research involving social science. This document sets out what the ESRC requires by way of ethical approval for the research it is asked to support, and sees as good practice for all social science research. Whilst the REF is available for use by other funders if they wish, it is mandatory for ESRC – funded research.

Social science is broad and varied, but often involves human beings. Other ethical frameworks for research on human subjects, such as that which addresses biomedical research, may not be appropriate, which is why a framework specific to social science is necessary. In some areas of social science ethical issues are limited, but in others they raise significant challenges that need to be addressed at an appropriate point or points. The ESRC expects that the research it supports will be designed and conducted in such a way that it meets key ethical principles, and is subject to proper institutional and professional oversight in terms of ethical research governance to ensure that these principles are met. These principles are intended to ensure that unethical research is prevented from the outset.

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

- Research should be designed, reviewed and undertaken to ensure integrity and quality
- Research staff and subjects must 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 and exceptional research contexts for which detailed guidance is provided in the policy Guidelines
- The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected
- Research participants must participate in a voluntary way, free from any coercion
- Harm to research participants must be avoided
- 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.
- The responsibility for ensuring that research is subject to appropriate ethical review, approval and monitoring lies with the institution seeking or holding an award with the ESRC and which employs the researchers performing it, or some of the researchers when it is acting as the co-ordinator for collaborative research involving more than one organisation. Institutions should have clear, transparent, appropriate and effective procedures in place for ethical approval whenever it is necessary.

- Ethical 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 expedited ethical review, novel use of existing data and especially data linkage may, in some contexts, raise ethical issues. Research involving primary data collection will always raise ethical issues that must be addressed.
- Breaches of good ethical practice in ESRC – funded research will be treated as a very serious matter by the Council. They 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.

Procedures

- 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 will not seek to impose a particular model for achieving these expectations. It will ensure that its peer review of proposals addresses ethical issues, and engage in dipstick testing of institutions with awards to check that commitments to ethical review have indeed been followed through by institutions.
- The ESRC does not require that ethical approval should be secured prior to submission of a research proposal. A proposal must state what the applicant considers to be the ethical approval that will be required for their proposed research, and if so how it will be obtained. The administering authority in signing the application form will be confirming that it concurs with that judgment and is prepared to administer any resulting award on that basis , carrying out expedited or full (possibly iterative) ethical review where necessary. If a research organisation does not have arrangements to ensure, as far as possible, that its research complies with this Framework it will not be possible for it to undertake ESRC-funded research.
- During peer review, referees and assessors will be asked to comment specifically on whether they agree with the ethical self-assessment in the proposal.
- If referees or assessors disagree with the proposed ethical review, this will either be grounds for rejection of an application where it calls into question researcher competence or the feasibility or validity of their proposal, or for a conditional award requiring further review.
- Before the start of a project, funds will not flow until the administering institution provides written confirmation that the required ethical approval has been received. This notification should precede or accompany the starting certificate. If ethical review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC.
- The ESRC's recognition process for postgraduate training will identify specific requirements in relation to research ethics.

The ESRC's minimum requirements

The ESRC will not seek to impose a detailed model for ethical evaluation and conduct. But the following requirements will constitute the minimum standard for a research proposal to be eligible for ESRC funding. The requirements are summarised over the page, and detailed in the accompanying annex.

1. Ethical issues always to be addressed in the proposal

As set out above, the ESRC does not require that ethical approval should be secured prior to submission of a research proposal. A proposal must state whether the applicant considers that ethical approval will be required for their proposed research, and explain the grounds for their view. This may involve reference to the relationship of the proposed work to the appropriate professional disciplinary standards. The administering authority in signing the application form will be confirming that it concurs with that judgment and is prepared to administer any resulting award on the basis specified in the application, carrying out full (possibly iterative) ethical review where necessary. During peer review, referees and assessors will be asked to comment on the ethical self-assessment in the proposal and if referees or assessors disagree with the proposed ethical review, this could lead to rejection of a proposal or a conditional award requiring specific review.

2. Expedited review

This is likely to be most relevant for research where the potential for risk of harm to participants and others affected by the proposed research is minimal, as confirmed by the ESRC's peer review of the proposal. The secondary use of some datasets may be uncontroversial and require only light touch, expedited review.

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.

3. Approval by a research ethics committee required

Where peer review has confirmed that a research proposal requires full ethical review and approval, this should be carried out by a REC. This needs to be constituted and operate in accordance with the following standards and guidelines. In particular, a REC must have at least one academic member from outside the Department conducting the research and at least one appropriately trained lay member. If the chair of the REC is also a member of the Department making the proposal, the institution should ensure that this function is performed by another member of the REC for this particular proposal. 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. As well as research with living human subjects, research involving deceased people with living relatives, body parts, or other human elements will require ethical approval and a broad view should be taken of possible ethical problems arising from research. Ethical expectations will vary over time and institutions must ensure that researchers and REC members receive training that reflects these changing expectations.

Institutional RECs may consider each relevant research proposal before it is submitted but must do so at least after it has been recommended for award by the ESRC and before the work starts. The proposal may be approved as submitted, approved subject to meeting specified conditions, or rejected on ethical grounds.

Ethical review may be more appropriate at a later stage for some kinds of research, or ethical issues may arise during a project. Where this is the case the ESRC must be informed. Otherwise, subsequent payments on the award could be delayed or, in extreme cases, refused.

4. Procedures for institutional monitoring should be in place

Universities and other research institutions should establish appropriate procedures to monitor the conduct of research which has received ethical 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. Monitoring should be proportionate to the nature and degree of risk entailed in the research. It should include consideration of best-practice procedures for the secure holding and preservation of data, including guidance issued by the ESRC.

5. **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.

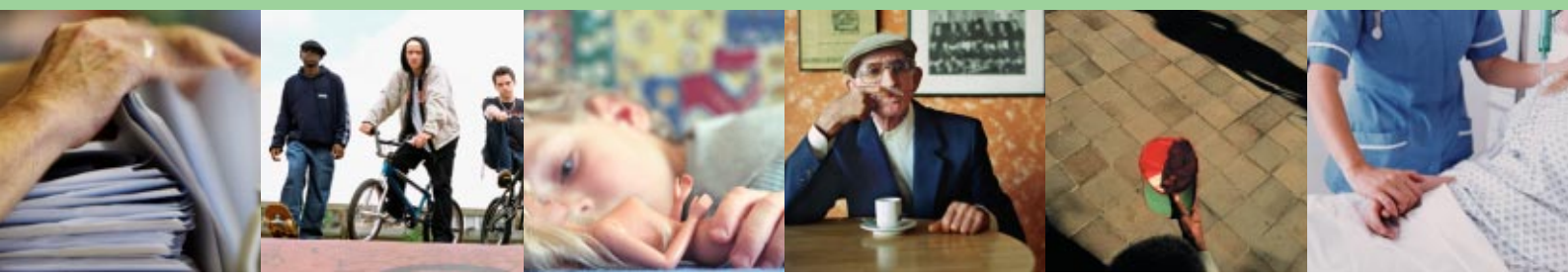
6. **Arrangements should be made for research students**
   The ESRC wants social scientists to engage with ethical issues from the start of their research careers. Universities must ensure that social science postgraduate training programmes incorporate the range of issues addressed in this Framework. Specialist training should also be considered for research supervisors.

7. The additional costs incurred in carrying out ethical review for ESRC funded research are eligible costs under the arrangements for Research Councils to meet a proportion of the full economic costs of research.

8. **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 funder(s) 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.

9. **Avoiding duplication of submission**
   Researchers and their employing organisations should avoid duplication of ethics review, especially in respect of research that may fall under the rubric of other ethical frameworks – such as that of the Department of Health's Research Governance Framework. Researchers must submit proposals either to their institution's REC or to a Department of Health Local or Multi-site Research Ethics Committee as appropriate, but the ESRC does *not* require both bodies to be involved. The appropriate body will be determined by the issues to be raised by the research, the nature of the data to be obtained and the population to be included in the study. This will apply to both single discipline and interdisciplinary research where social and biomedical scientists are working together.

10. **Legal and data requirements must be met**
    Research organizations must comply with legislative requirements and with the requirements of data providers. Privacy, health and safety, and intellectual property are especially likely to arise as ethical concerns in research, but all legal requirements must be met. Data supplier access requirements with regard to the secondary use of datasets must be complied with at all times, including any provision relating to presumed consent and potential risk of disclosure of sensitive information. Data suppliers such as the Office for National Statistics or the Economic and Social Data Service should be consulted on their particular requirements.



REF POLICY GUIDELINES

The ESRC Research Ethics Framework: Detailed guidance on requirements and procedures

These Guidelines provide further information and clarification of the Economic and Social Research Council's Research Ethics Framework.

They are structured as follows:

INTRODUCTION

SECTION 1 provides further guidance on the Framework's minimum requirements

SECTION 2 provides guidance on the identification of risk and how research proposals should address it

SECTION 3 provides guidance on the relationship between research governance and ethics

SECTION 4 provides some of the background context within which the REF was developed, including a brief commentary on the main research paradigms found within social science

SECTION 5 provides some illustrative case studies and a suggested checklist for the scrutiny of research proposals within universities, specialised research centres and agencies, and other research organisations.

INTRODUCTION: THE IMPORTANCE OF THE REF, ESRC SANCTIONS, AND THE MEANING OF RESEARCH

These Guidelines provides additional guidance on the Council's Research Ethics Framework (REF), introduced during 2005. It offers advice about the process of ethical scrutiny and review which is needed to inform research planning and practice. The REF is a "living document." It was developed after extensive consultation with key stakeholders and a wide range of interested parties. The ESRC is committed to developing the REF over time, taking into account the experiences of the ESRC and research organisations as well as future challenges arising from the wider ethics environment. The ESRC views the implementation and development of the REF as a collaborative exercise, involving key stakeholders including the social science research community.

All ESRC-funded research must be subjected to review according to the provisions and standards described in the REF. The principal sanction that can be brought against a research organisation which fails to meet REF requirements is that it will not be possible for it to undertake ESRC-funded research. Breaches of good ethical practice in ESRC funded research will therefore be treated as a very serious matter by the Council. They could result in the immediate suspension of the individual project and other projects based at the contracting institution or coordinated by it, and a halt to the consideration of further applications from that institution.

SECTION 1: THE ESRC'S MINIMUM REQUIREMENTS

The ESRC does not seek to impose a detailed model for ethical evaluation and conduct on researchers or research organisations (ROs). But the requirements described here in Section 1 will constitute the minimum standard for a research proposal to be eligible for ESRC funding. Before these are described, some key terms are defined in Box 1. Guidance on the ESRC's minimum requirements now follows:

Box 1: Key Terms

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

'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.

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.

'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 foetuses, 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).

1. Ethical issues must always be addressed in the proposal

1.1 Although the ESRC does not require that ethical approval should be secured before submission of a research proposal, all proposals must state whether the applicant considers that ethical approval will be required for their proposed research and why.

1.1.2 In the first instance, it is the responsibility of the researcher, or research team, guided by their professional disciplinary standards, to decide whether a project is ethically sensitive and should be subject to either a 'light touch' review (see para 1.2 below) or full REC approval. Normally, research proposals involving human participants would be reviewed and approved by a REC which has been established and operates in accordance with the principles and guidelines set out in this Research Ethics Framework.

1.1.3. Grant applications to the ESRC must provide a full statement by the proposers that they have given proper consideration to any ethical matters which the proposal raises. Where an ethics review is yet to be undertaken, this should be stated. Where the proposers regard ethics review as unnecessary, a statement that justifies this view is needed and should be expressed with reference to the exemptions noted below (para 1.3.2.5). Referees will be asked to give special attention to this statement in light of the detailed case made in the full proposal. If referees, or the relevant ESRC Commissioning Panel or Board are not persuaded that ethics approval is not required, the grant may still be supported, but will require subsequent REC approval.

1.1.4 Normally projects would 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 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.

1.1.5 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 success.

1.2 Expedited review

Expedited review of research proposals can occur and is likely to do so for a number of reasons. One is where the potential for risk of harm to participants and others affected by the proposed research is minimal, as confirmed by the ESRC's peer review of the proposal. The secondary use of some datasets may be uncontroversial and require only light touch, expedited review. Expedited review may also be needed for research projects that have a short lead time and are commissioned in response to a demand of pressing importance.

1.2.1 Institutional policies and procedures for expedited review should include a clear statement that addresses the following issues:

- criteria for identifying research which involves minimal risks (see 1.2.2)
- the sub-committee or chair to which responsibility for reviewing such research has been delegated, and the scope of their authority
- forms and procedures for submitting applications for expedited review
- procedures for reporting decisions to the main institutional REC
- procedures for periodic audit (perhaps annual) of normal and expedited reviews by the main institutional REC.

Chair's action is likely to be the most common form of expedited review. Other forms of expedited review can include review by sub-committees of an REC and review by a 'virtual' committee. These approaches have the advantages of drawing on a wider range of individuals to take part in ethical review and of facilitating swifter review. This may also help 'demystify' research ethics review and develop a more sophisticated understanding of the issues amongst those who take part in it.

1.2.2 The following research would normally be considered as involving more than minimal risk:

- research involving vulnerable groups – for example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship
- 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
- research involving groups where permission of a gatekeeper is normally required for initial access to members – for example, ethnic or cultural groups, native peoples or indigenous communities

- research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out
- research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals
- research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain
- research involving intrusive interventions – for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy. Participants would not encounter such interventions, which may cause them to reveal information which causes concern, in the course of their everyday life.

1. 3 Approval by a Research Ethics Committee

1.3.1 Research proposals involving human participants must normally be reviewed and approved by a Research Ethics Committee (REC) which has been established and operates in accordance with the standards and guidelines set out in this Research Ethics Framework.

1.3.1.1 Research organisations should ensure that there is a principal REC for their institution and may establish secondary (for example school or department based ones) 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–wide ethics committee might advise on broad strategy for ethics review, and monitor university performance overall, rather than consider applications per se. Wherever they are located, they should meet the requirements of this REF, even at department level if this is where the decision to approve a project is to be taken.

1.3.2 *Responsibility for securing ethical review*

1.3.2.1 Overall responsibility for ensuring that research is subject to appropriate ethics review and approval lies with the University or research organisation which employs the individual or individuals who conduct the research (but see also 1.14 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 ethical review by an REC in another institution.

1.3.2.2 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 institution should make clear the jurisdiction of an REC and its relationship to other relevant bodies or authorities both within and outside the institution.

1.3.2.3 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.

1.3.2.4 Ethical approval need not be secured before an application for funding is submitted, as the majority of applications are not funded. The point at which a research project is submitted for review may vary according to the research design(see 1.1.5 above). RECs should be flexible about the timing of such review.

1.3.2.5 Within the definition of research given above, all data collection involving human participants normally requires prior ethical approval with the exception of the following, which are not considered 'research': routine audit, performance reviews, quality assurance studies, testing within normal education requirements, service evaluations, polling on current public policy issues, and 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' requiring ethical review. Nor would interviews broadcast on radio or television or online, and diaries or letters in the public domain.

1.3.2.6 Ethical 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 ESRC Data Archive where appropriate permissions have already been obtained and where it is not possible to identify individuals from the information provided. However, 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 ethical issues arise with the use of secondary data, as described in para 1.16.4.

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

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

1.4 Independence of Research Ethics Committees

1.4.1 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 1.5.1), should set out procedures for identifying and dealing with potential conflicts of interests and should regularly monitor the decisions taken.

1.4.2 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.

1.4.3 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 schools or departments and to concentrate on policy matters and oversight of the lower-level RECs.

1.5 Composition of Research Ethics Committees

1.5.1 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 research proposals submitted to it, 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.

1.5.2 RECs should be multidisciplinary and comprised of both men and women. They must include at least one lay member from the local community 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 and who have the confidence and esteem of the research community. At least one member must be knowledgeable in ethics. There must be a chair. RECs would also benefit from including individuals who reflect the ethnic diversity of the local community, 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.

1.5.3 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

1.6.1 Institutional RECs are responsible for reviewing all research involving human participants, or drawing on secondary data carrying personal or organisational information (such as corporate data) conducted under their auspices, that is, by individuals employed by the institution. 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 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.

1.6.2 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 may also want to consider the safety of researchers. Such consideration should refer to the institution's research governance provisions.

1.7 Procedures for considering and approving research proposals

1.7.1 Institutional RECs should consider each research proposal submitted and may approve it as submitted, approve it subject to meeting specified conditions or reject it on ethical grounds. 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.

1.7.2 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
- 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 ethical approval be secured before an application for funding is submitted, as the majority 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. The decision resides initially with the research team. A system of light initial peer review within a department would assist this process and help establish the most appropriate point for ethical scrutiny.

- identifying, documenting and dealing with conflicts of interests
- methods of decision making and recording decisions

Research organisations should make clear and record 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 reasons for them
- receiving and considering appeals
- monitoring the conduct of research following approval and continuing ethical review
- receiving and considering complaints (see 1.12).

1.8 Application forms and protocols

1.8.1 Research proposals submitted for approval to an REC might be expected to include the following information, though the precise way this is done is left to the discretion of the research organisation:

- aims of the research
- scientific background of the research
- study design
- participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited, 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 ethical issues and how they will be addressed
- benefits to research participants or third parties
- risks to participants or third parties
- risks to researchers
- procedures for informed consent – information provided and methods of documenting initial and continuing consent
- expected outcomes, impacts and benefits of research
- dissemination (and feedback to participants where appropriate)
- measures taken to ensure confidentiality, privacy and data protection.

1.9 Criteria for considering research proposals

1.9.1 The ethical principles set out in this REF 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 ethical norms and practices of the relevant research discipline.

1.9.2 RECs should review research proposals in terms of their ethical probity. This will entail a consideration of the design and proposed conduct of the research. These should be considered in terms of the ethical 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. Where the REC queries the scientific or scholarly merit of a proposal, it should seek the advice of an independent researcher with experience and expertise in the research methods and paradigm described in the proposal.

1.9.3 Members of RECs should also be familiar with a range of philosophical approaches to research ethics and with the different perspectives they bring to individual research proposals. Where more than one perspective or ethical principle applies to a specific case, clear ethical reasoning will be required and debate should be encouraged. Good ethical review requires sensitivity to the context in which a research study will be conducted and good ethical reasoning requires careful thought and consideration.

1.9.4 The knowledge and expectations that members of RECs bring to the ethical 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 ethical approval, for example, to obtain signed consent forms from each respondent.

1.10 Institutional support for Research Ethics Committees

1.10.1 Universities and or 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 ethical, 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 internal budget. However, it should be remembered that the additional costs incurred in carrying out ethical 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.

1.10.2 Successful implementation of the REF will rely in 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 will play 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.

1.10.3 Many institutions 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 REF 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.

1.10.4 The aim of this training should be to build confidence in individual abilities 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
- training for members of local and institution-wide RECs, including lay members
- training for postgraduate students in local ethics review requirements (in addition to any more general ethics training)
- training for undergraduate students whose projects may require ethics review.

1.10.5 Research Organisations should build a programme of support and provide resources to aid staff in understanding and implementing the REF, 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 is likely to depend 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 REF or some other framework
- an Ethics Review Handbook that states the institution's standards and expectations with regard to the REF, and how staff can ensure they comply with them. This could form part of a larger document covering other ethics review frameworks as well
- training as mentioned above.

1.11 Procedures for institutional monitoring should be in place

1.11.1 Universities and other research organisations would be expected to establish and publish working procedures for monitoring research.

1.11.2 Where a study design is emergent, the REC should agree procedures for continuing ethical 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 any unforeseen events that might challenge the ethical conduct of the research or which might provide the grounds for discontinuing the study to the REC or a designated sub-committee should be agreed with the researchers as a condition of approval.

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

1.11.4 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 consider withdrawal of its approval and require that the research be suspended or discontinued. ESRC must be informed of this decision and reserves the right to recoup its grant funding, pending further investigation, in extreme cases of research misconduct.

1.11.5 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 Research Ethics Framework.

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.

1.12 Complaints procedures should be in place

1.12.1 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 academic misconduct and would appropriately be addressed through the institution's procedures for dealing with such allegations.

1.12.2 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; and conflicts between the interests of the researcher and the interests of the research participants. Fundamental to dealing with each of these situations is the principle of prior disclosure of potential conflicts of interest and withdrawal from discussion and decision-making.

1.12.3 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 institutional REC. Where the decision under appeal was made by the main institutional 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 should be made for research students

1.13.1 The ESRC wants social scientists to engage with ethical issues from the start of their research careers. Universities 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.

1.13.2 Universities and research organisations should establish procedures specifically for reviewing research projects undertaken by undergraduate students and students on taught postgraduate courses. Student research poses particular challenges in relation to ethical review because of the large numbers, short timescales and limited scope of the projects involved. Student projects are carried out primarily as educational exercises rather than to generate new theoretical or empirical insights and this should be taken into account in reviewing the content, though not the ethics, of the study.

It should be made clear to potential research participants that the study is a student project.

1.13.3 While the same high ethical standards should be expected in student research, the process of ethical review may be more appropriately managed at department level and overseen by research supervisors. This does not lessen the requirement for universities to ensure that students are not exposed to undue risk in conducting their research.

A case could be made for considering student research through a particular form of expedited review. Undergraduate and taught postgraduate research might be reviewed by multidisciplinary committees with a proportion of the members from outside the school or faculty but within the University. As student projects are not externally funded individually, there is less of a conflict of interests within the University.

1.13.4 The ESRC already provides *Postgraduate Training Guidelines* through its Training and Development Board, available at www.esrcsocietytoday.ac.uk. These Guidelines include reference to training in ethical and legal matters (section D2.4). Universities 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.

1.14 Arrangements should be made for multi-funder and multi-performer projects

1.14.1 *Multifunded research:* If the ESRC is one among a number of funders of a project, the REF guidelines must be drawn to the attention of all proposed funders prior to a submission for funding. 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.

1.14.2 Jointly funded research may involve the ESRC in partnership with other Research Councils, business, other public sector organisations, research charities or the voluntary sector. It may also be international. 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 three cases, the question arises: what ethics review requirements will apply to the research?

1.14.3 If the ESRC is one of the funders of the research, compliance with the REF is required. In order to request ESRC funding it will be necessary to have an agreement with the other funders that the proposed study will comply with the REF. This requirement should be drawn to the attention of other proposed funders prior to submission for funding. In many cases, such agreement could be achieved by the research being conducted in a REF compliant research organisation. If this is not the case, written agreement that the research will be subject to REF requirements will be necessary

1.14.4 *Multiperformer research:* Research involving participants from more than one institution creates complications for formal ethical review procedures. In order to minimise bureaucracy and avoid unnecessary duplication of efforts, universities and research organisations should consider agreeing arrangements for accepting one another's decisions following formal ethical review. Each institution would retain formal responsibility for overseeing the ethical 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.

1.14.5 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 or an 'unattached' freelance researcher. This may present specific problems for REF 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.

1.14.6 Researchers not based in academic institutions may be relatively isolated in their work and not enjoy the institutional support available to academic researchers. Freelance researchers and non-academic employing organisations may not have the capacity and resources to support independent review. Also, researchers in such organisations or alone are perhaps less likely to undergo ethics training than their academic colleagues.

1.14.7 If the research in question is funded by the ESRC, it must comply with the requirements of the REF. 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 REF requirements.

1.14.8 *Research conducted outside the UK*

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

There are a number of considerations here: inequities in regard to access to research resources, political and cultural consideration with regard to professional training and oversight, and considerable differences in power between the researcher and the researched. Moreover, research ethics in developing regions 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: 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 such as the ESRC/DFID programme.

1.15 Avoiding duplication of submission

1.15.1 Researchers and their employing organisations should avoid duplication of ethics review, especially in regard to research that may fall under the rubric of other ethical frameworks such as the Department of Health's Research Governance Framework. Researchers must submit proposals either to their institution's REC or to a Department of Health Local or Multi-site Research Ethics Committee L(M)REC as appropriate. 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 and interdisciplinary research where social and biomedical scientists are working together.

1.16 Legal and data requirements must be met

1.16.1 Research organizations (RO) must comply with legislative requirements and with the requirements of data providers. Privacy, health and safety, and intellectual property are especially likely to arise as ethical concerns in research, but all legal requirements must be met. In addition, careful consideration is needed in regard to the ethical implications that might be associated with use of secondary data (see 1.16.4 over the page).

Even where formal ethical review is not required, good research practice requires adherence to professional codes of practice and compliance with the Data Protection Act (DPA).

1.16.2 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.

1.16.3 *UK Data Protection Act 1998*

1.16.3.1 It is important that those undertaking research be 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 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.

1.16.3.2 Data must be obtained for a specified and lawful purpose; and 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; and kept for no longer than is necessary for that purpose; be processed in accordance with the data subject's rights; be kept safe from unauthorised access, accidental loss or destruction; and shall not be transferred to a country outside the European Economic Area unless that country has equivalent levels of protection for personal data.

1.16.3.3 However, there are certain exemptions in Section 33 of the Act relating to the processing of data for research. The provisions of the DPA also do not apply if 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.

1.16.3.4 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); or 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.

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

- Circumstances where international research collaborations may involve transfer of personal data overseas. Data may not be 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 subjects 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 racial or ethnic origins for equal opportunities monitoring. The Data Protection (Processing of Sensitive Personal Data) Order 2000 permits sensitive data processing which 'is in the substantial public interest and is necessary for research purposes and does not support measures with respect to the particular data subject except with their specific consent nor cause or be likely to cause substantial damage and distress'.

1.16.3.6 Only a brief outline of the issues has been provided here. Responsibility for both interpretation and compliance resides with research organisations themselves. Additional resources recommended for academic institutions include reviews by Davies (2002) at: http://www.bathspa.ac.uk/schools/graduate-school/data-protection/research-data-protection-act.pdf and material produced by the University of Lancaster: http://www.dpa.lancs.ac.uk/approved/research.htm

Other useful resources include: Joint Information Systems Committee (JISC):
http://www.jisc.ac.uk/pub99/sm09_data_prot.html and the University Of Essex
http://www2.essex.ac.uk/dataprotection/data.htm
Comprehensive guidance on the law can be found at: http://www.dataprotection.gov.uk/

1.16.3.7 *Work with vulnerable populations: Criminal Records Bureau (CRB) Disclosures*

In certain cases, research that involves vulnerable people may require CRB Disclosures (see http://www.disclosure.gov.uk/). 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. Requests for CRB Disclosures and the level of disclosure requested must balance the need to prevent unsuitable people from working in sensitive areas against the risk of discrimination against ex-offenders who have become rehabilitated. 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. Arrangements must be in place to ensure that any disclosure information obtained by a research organisation in the course of ethics review procedures is kept in accordance with the DPA. For further details, see the Rehabilitation of Offenders Act 1974, the Rehabilitation of Offenders Act 1974 (Exceptions Order 1975) and BPS Guidelines for Minimum Standards of Ethical Approval in Psychological Research.

1.16.4 *Secondary data sources*

1.16.4.1 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 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 ESRC expects that others will also use it, so consent should be obtained on this basis and the original researcher must take into account of 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 ESRC Data Archive web site (www.data-archive.ac.uk).

1.16.4.2 Secondary data falls into three categories:

i) The first includes data which is not sensitive and where there is minimum risk of disclosure of the identity of individuals. It may be used without ethical clearance.

ii) Second is data protected by legislation, such as census data. Here, the data producer has a strong interest in how researchers will access the data, and may control access to it. This data may only be available via 'safe settings'.

iii) A third category, such as NCDS, includes data where the inclusion of a birth date makes disclosure possible, perhaps via a link to other datasets. This means that such data is ethically sensitive.

1.16.4.3 A data provider (such as ESDS or the 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 information. Data suppliers such as the ESDS or ONS should be consulted on their requirements.

1.16.4.4 The fact that an original piece of research has gone through ethical review for its collection does not rule out ethical issues arising over its secondary use. For example, archiving data with the ESDS might of itself make disclosure more likely. Issues include being able, for example, to download NCDS data to a CD Rom and wrongly allowing others (such as one's students) to use it without the rights to do so.

1.16.4.5 There are also specific ethical issues relating to large-scale surveys, such as the Millennium cohort study, where social and other health or medical data is secured. An 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 ethical 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.

1.16.5 There may in the future 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 especial consideration in the future because of the use by social scientists of data held in public or private biobanks inasmuch as the initial consent to deposit may not have presumed this form of access.

SECTION 2: IDENTIFYING RISK IN SOCIAL SCIENCE RESEARCH

Proposals should be considered in the context of risk to the researched and researchers. The following section provides guidance on what constitutes risk in social science research, and how that relates to ethical scrutiny.

2.1 The meaning of risk

Given the plurality of methodologies used in social science there is a diverse range of risks that professional social science has to manage, both for the research subject and the researcher, as well as more formal risk-related considerations that derive from legal or regulatory provisions.

2.1.2 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 subjects either as individuals or as whole communities or categories of people, such as those with HIV infection.

2.1.3 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. 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 REF Case Studies (see section 5) illustrate how different projects carry potentially different risks, and how these can be usefully identified through questions that help anticipate ethical 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.

2.1.4 Once risks have been identified, researchers should ensure that these are discussed with research participants in order to secure proper informed consent. However, 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 often the case in psychological experiments where consent would compromise the objective of the research. In some circumstances – such as users of illegal drugs – written consent might also create unnecessary risks for research subjects. Even in this last case, however, 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.

2.1.5 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 of and different degrees of risk.

2.1.6 Where research projects combine social science and other disciplines (such as joint research with clinicians) initial review should be undertaken by the chair of the REC to consider the nature of the risks and whether the proposal should to be referred to an LREC. This will arise primarily if the research involves any form of clinical intervention. The primary consideration in deciding whether such additional referral is needed should be the nature of the risks involved in the context of the proposed research. The objective is for expedited review and not duplication of effort. It is expected that a REC will be able to provide an effective filter for projects that might otherwise have been inappropriately sent to an LREC 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. Despite this filtering role, RECs based within ROs should not review proposals that deal with clinical research. These should go to an NHS LREC/MREC.

2.1.7 Some research that poses risks to research subjects in a way that is legitimate in context of the research and its outcomes. This might arise for two reasons. First, as is recognised elsewhere (see Tri-Council of Canada, 2002. http://www.pre.ethics.gc.ca/English /policystatement/introduction.cfm) research may be 'deliberately and legitimately opposed to the interests of the research subjects' 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 subjects. Principles of justice should, however, mean that researchers would seek to minimise any personal harm to such people. Secondly, researchers should also consider how to balance the potential of immediate or short-term risks to research subjects 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.

2.2 Iterative ethics review and risk

RECs should have mechanisms that make some provision for future advice and guidance beyond the initial ethics approval process. All research can develop in ways that raise unforeseen ethical 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.

SECTION 3: GOVERNANCE, ETHICS AND ETHICAL PRINCIPLES

This section of the REF provides a brief discussion of the meaning of and relationship between ethics and the governance of research, and discusses the ethical principles that underpin good research around the world.

3.1 The distinction between ethics and research governance

While ethical principles and review concern the rights, dignity and safety of research subjects, research governance concerns the development of shared standards and mechanisms that permit the proper management and monitoring of research and, if necessary, allow sanctions to be brought in cases of research misconduct. These two dimensions are linked. It is clear that a strong ethical culture and literacy are dependent not only on professional self-regulation but also on sound structures of formal governance within research organisations. In universities, for example, standardising review procedures across departments and faculties would clearly resolve some of the anomalies and inconsistencies that characterise today's research ethics terrain.

Research governance mechanisms should also permit the scrutiny of research activity that is not formally defined as an externally or internally funded research project.

3.1.1 In general terms, research governance would presume that a research organisation has:

- Mechanisms in place to enable timely and expedited review of research and research proposals. These may involve differing degrees of formality and levels of responsibility
- Procedures that are flexible and sensitive to the differing needs of researchers and levels of risk involved in their research
- Procedures to protect the interests of research staff and research students
- The capacity to deal with cases of research misconduct, complaints or appeals
- The capacity to advise on statutory or legal considerations that might affect research.

3.2 Statement of the principles of ethical research

There are six core principles that inform the ESRC Research Ethics Framework. They are:

3.2.1 *Research should be designed, reviewed and undertaken in a way that ensures its integrity and quality*

This principle is at the heart of the REF and needs little further elaboration. It means that researchers and RECs should ensure that from the start, the development and consideration of proposals is informed by a commitment to research that is accountable and of the highest quality. Accountability underlies each of the following principles, while quality is expressed through good scientific design, the anticipation of likely difficulties and how these might be addressed, and the ways in which objectives will actually be delivered during the work.

3.2.2 *Research staff and subjects must 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 and exceptional research contexts.*

This principle underpins the meaning of informed consent. Informed consent entails giving as much information as possible about the research so that prospective participants can make an informed decision on their possible involvement. Typically, this information should be provided in written form and signed off by the research subjects. Where consent is not to be secured a full statement justifying this should be provided. Paragraph 3.2.5.2 describes the circumstances where informed consent may need to be managed differently. The primary objective is to conduct research openly and without deception. Deception (i.e. research without consent) should only be used as a last resort when no other approach is possible. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

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 ethical regard for participants is to be sustained, even after the study itself has been completed. Review mechanisms will need to enable this where appropriate.

In cases of international research or work that relates to non-majority culture, the conventional meaning of informed consent may be problematic because the conventional model of consent rests on the 'primacy of the individual'. The individual is seen as both the owner of rights and the bearer of reciprocal duties to the rights of others. This emphasis on the individual can seem inappropriate or meaningless in some cultural contexts, where the individual may take less precedence than broader notions of kin or community. This may be especially so when social scientists work in developing countries.

In cases where research involves vulnerable groups such as children, older persons or adults with learning difficulties, every effort should be made to secure their informed consent. However, in cases where this is seen as impossible or where the research subjects are considered not competent to give their assent to the research, the issue of honesty and consent may need to be managed via proxies, who should be either those with a duty of care or who can provide disinterested independent approval depending on the individual circumstances). 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 this could jeopardise the research (again in some areas of deviance, such as research into teenage sexuality or teenage pregnancy). In such circumstances, researchers will need to regard the potential risk to the principal subjects of the research as a priority.

Where research involves the need to secure tissue or blood samples, participants should be informed of their rights over such samples and data derived from them, especially whether they have or (more normally) 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 the Council accepts 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. 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.

3.2.3 *The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected*

This third principle requires that researchers take steps to ensure that research data and its sources remain confidential unless participants have consented to their disclosure, and in this latter case ensure that plans have been made for their storage and access to them.

3.2.4 *Research participants must participate in a voluntary way, free from any coercion*

In all cases of research, researchers should inform subjects 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 subjects to participate in the research. Consent has to be freely given in order to be valid. This is linked to the issue of covert research and deliberate deception. Deception by definition precludes consent and should only be used in a research setting where open and transparent research is impossible, whether because of the risks it might create for the researcher or participant, or in work where consent can be secured without providing the participant with full information about the project to avoid jeopardising its performance.

3.2.5 *Harm to research participants must be avoided*

This principle requires that social science research should be conducted in such a way that it minimises harm or risk to social groups or individuals. Participants' interests or well-being should not be damaged as a result of their participation in the research, even though in the short term there may be experimental procedures that generate some limited risk (see 3.2.5.2 below). At the same time, no group should be unreasonably excluded from the research. In regard to this last point, research should be commissioned, designed and undertaken in such a way as to respect the interests of all social groups whatever their age, disability, race, ethnicity, religion, culture, gender or other characteristics. Some research will focus on a specific group and it would be inappropriate to seek wider levels of inclusivity across social groups in such research.

In addition, researchers should attempt to avoid harm not only to an immediate population of subjects, but to their wider family, kin and community. Research designs should consider potential harm to respondents' organisations or businesses as a result of the work. There is no simple rule for getting the right balance between these potential risks and effects. In order to assist RECs to come to a decision, researchers should endeavour to explain the likely effects of the research beyond the immediate respondents, where this is likely to be relevant. A related matter is the way in which research is communicated, especially where material is sensitive or results could be misconstrued and subsequently used by third parties against the interests of the research participants or researchers themselves.

3.2.5.2 There may be exceptional circumstances in some fields of research when, with the consent of the participant, some short-term and minimal degree of harm which causes no lasting effects nor prolonged personal discomfort might be acceptable, for example, in laboratory-based social science research, where exposure to minimal personal risk could produce results that will have longer-term benefit to the respondent and others.

3.2.6 *The independence and impartiality of researchers must be clear, and any conflicts of interest or partiality must be explicit*

The research should be conducted so as to ensure the professional integrity of its design, the generation and analysis of data, and the publication of results, while the direct and indirect contributions of colleagues, collaborators and others should also be acknowledged. In addition, this principle requires that investigators ensure that there is no undeclared conflict of interest (which may be personal, academic or commercial) in their proposed work and that the relation between the sources of funding and researchers' control over results is made clear, specifically in relation to the ownership, publication and subsequent use of research data.

Researchers need also to consider more generally the form and context of the publication of research results, especially where they are approached by the media prior to full publication of their work. They should try to ensure that media coverage does not compromise research participants, co-researchers or funding bodies or breach confidentiality. It is essential that relations with the media be agreed by the research team and managed by the lead investigator. The ESRC's Communications Toolkit at www.esrcsocietytoday.ac.uk and the ESRC's communications team provide advice about the procedures that should be followed.

Summary

- Researchers and research organisations should ensure that appropriate governance procedures and mechanism are in place to oversee social science research
- The ethical principles of integrity, honesty, confidentiality, voluntary participation, impartiality and the avoidance of personal risk to individuals or social groups characterise social science research that is conducted in a professional and ethical manner
- The key concept of informed consent needs to be understood by both researchers and RECs in light of the context, aims and objectives of the research and may require ongoing review and advice from fellow professionals or a REC itself.

SECTION 4: CONTEXT FOR THE RESEARCH ETHICS FRAMEWORK

4.1 As the principal funding agency for UK social science research, the ESRC insists that the research it supports be designed and conducted in such a way that it meets certain ethical principles and is subject to proper professional and institutional oversight in terms of research governance. It was created because although the Council already provides general guidance in regard to these matters, there was a clear need to extend and develop its guidelines in response to the growing complexity and demands made of research today. The REF and these Guidelines were developed to help shape the process of ethical scrutiny and review that should inform research planning and practice in social science.

4.1.2 The REF is the result of extensive consultations across the UK social science community , notably the funding bodies that comprise the UK Strategic Forum for the Social Sciences. It is also informed by consultation with professional associations, other research councils and government departments. It provides a broadly based, detailed and robust policy statement on ethics and ethics review processes. Where relevant, reference has been made in this document to ethics guidelines and provisions originating from other UK and international research agencies.

4.1.2.1 *The Purpose of the REF*

The purpose of the REF is to provide clear and practical guidelines on the principles and process of ethics review within UK social science research. It was developed in part to respond to wider debates within the UK and elsewhere regarding the ethical oversight of social research. These include:

- Changes in social science research, and in associated research methods, especially related to the increase in the volume of interdisciplinary research, and work that crosses the social and other sciences
- Changes in the research context, such as increasing globalisation and advances in information and communication technologies, data sharing, and their ethical and legal implications
- Changes in the policy context, and the development of new governance and ethics codes with which social science will need to engage such as the Department of Health's 'Research Governance Framework', and the UK government's 'Ethical Assurance of Government Social Research' guidelines
- The development of new 'standard operating procedures' for ethics review overseen by the NHS Central Office for Research Ethics Committees (COREC)
- Changes in public attitudes including demands for increasing transparency in the pursuit of all areas of scientific research and practice.

4.1.2.2 The REF complements codes developed by other Research Councils and is the principal reference point for UK social science.

4.1.2.3 The Framework has been designed to encourage good ethical practice within UK social science research, recognising and building on the traditions of ethics review informed by professional self-regulation and peer review. UK social science is internationally respected not only for the quality of its research but also the high standards to which it aspires. Such standards are the basis on which the Framework will depend for its proper and effective deployment.

4.1.2.3.1 The changing research environment has indicated the need for a more formal statement about the position of social science and how ethical standards, and especially scrutiny, might be most effectively and efficiently applied. These guidelines exist to help research organisations and the research community itself to respond to these new demands. research organisations in the UK are aware of these wider changes in the ethics landscape and have been developing new procedures for ethics scrutiny at a local level. These too have informed the development of this REF.

4.1.2.4 Another driver for the framework has been the need to articulate more fully how the research pursued within social science reflects a range of paradigms and methodologies which create distinct issues in regard to ethical scrutiny. The following section serves simply to outline some of the main characteristics of the social science approach. We hope that it is useful to RECs and research funding agencies elsewhere.

4.2 Social science research paradigms

4.2.1 Social science research encompasses a wide range of disciplines and is often undertaken within complementary fields typically linked with the humanities, or more applied areas such as social policy. All social science is being critical, diverse in its methodological approach, and generative of new theoretical and empirical work on society that may – though it need not – have policy relevance. This has implications for the process of ethics review.

4.2.1.1 Social science research may involve human participants or subjects directly as the source of primary data, or indirectly via access to secondary data already secured and available to all researchers. Researchers must pay attention to all ethical issues and principles relating to the potential risks of the research to all involved, including research subjects, the researchers themselves, and their employing organisations and funding agencies where this applies. Questions about informed consent, confidentiality, and accountability must also be addressed.

4.2.2 This broad range of social science research techniques raises questions about the appropriate process of ethics review, and indeed the meaning of ethics itself. Research methodologies vary and so do the value systems on which they are based. This requires that they be reviewed in terms of the appropriate theoretical framework. Ethical practice cannot be regarded as self-evident but, instead, needs to be considered in the light of wider theoretical and normative positions. It is always embedded in and shaped by social processes that reflect different historical and cultural contexts. This is apparent most clearly between different national cultures.

4.2.2.1 The ESRC's REF recognises that the ethics principles on which it is founded will always be subject to interpretation and dialogue, especially where this involves multi-disciplinary research. Growing interdisciplinarity in research requires greater dialogue between fields, and this should foster shared learning and a predisposition towards greater reflexivity in the determination of ethical judgement. This is a sign of strength rather than weakness in ethical debate.

4.2.2.2 Methodologies based on participatory, action-oriented techniques also raise questions about the practice of ethics-based social science, especially where there is a strong commitment to qualitative research. Ethics review of qualitative research needs to attend to the iterative and uncertain character of this research process. It must demand the same ethical standards as other approaches while accepting that outcomes and measures of risk or benefit may be less easily defined before the start of the research. This contrasts very strongly with ethical practice relating to quantitative studies. This problem is faced by researchers working in a variety of settings (including the NHS) where qualitative approaches are also widely used. RECs need to review qualitative research proposals in light of the often uncertain and iterative research process they involve.

4.2.3 Given this rich diversity of research strategies across the social sciences, the application of ethics standards and principles needs to be undertaken with care, recognising that the potential ethical questions that are raised, and how they are managed and shape the research process, will vary between different research contexts. The assessment of 'risk' – in terms of its dimensions, hierarchy and prioritisation – needs to be informed by these deliberations.

SECTION 5: ILLUSTRATIVE CASE STUDIES AND PROTOCOLS

The following Case Studies exemplify a variety of different types of research proposal that may come before an REC. Each of the cases is followed by a series of questions that would need to be answered by those reviewing the proposal in order to decide how it might be best handled. The purpose of these Cases is not to give 'right answers' but to raise awareness about some of the ethical and practical issues that could arise. In addition an example of a protocol that is typical of that found in research organisations is provided. Further examples of cases where informed consent is an issue are available via the ESRC Research Methods Programme and its project on consent; see http://www.sociology.soton.ac.uk/Proj/Informed_Consent /Resources.htm

CASE STUDY 1: Homelessness, begging and drug use

Professor Andrews, a social anthropologist, leads a team of researchers including a social worker, a pharmacologist and a statistician in the medical school who are proposing to carry out a study of patterns of migration, homelessness, street begging and drug use in the city. The study is funded by the ESRC with additional support from the City Council. The local drugs charities and DAATs have agreed to co-operate with the research team. The research team intends to carry out ethnographic work in two areas where begging is most common and to recruit 100 individuals through hostels for the homeless for more formal interviews and urine testing.

Initiating research ethics review

- This proposal would need to go to full review by an REC given the sensitivity of the issues it raises and the potential risks to both researchers and participants.

Making an application

- The applicant should consider a number of issues when addressing the ethical dimensions of this proposal, including its potential benefits, the risk of harm, the processes of recruitment, mechanisms of gaining consent, privacy, confidentiality of information and any additional information that would be requested by the REC (e.g. information sheets). How might informed consent be properly defined in this proposal, especially where subjects are vulnerable and may be reluctant to give consent? It might make sense for consent to be given at different stages of the project rather than via a one-off agreement.

Reviewing the application

There are a number of questions that would need to be addressed by the REC in handling this application, including:

- How would the review be organised within the committee? Who on the committee would look at this proposal (everyone, discipline specialist, methodological specialist?)? Would the ethnographic component be considered by different people or using different criteria from the interviews and the urine testing?
- What criteria (or guidelines) would be used in assessing it? Would these be generic or specific to the disciplines and approaches taken? In particular:
- How would the Committee go about assessing the level and diversity of risk?
- What procedures and documentation would it require in relation to informed consent?
- What other concerns might be identified? The university's reputation, legal position, etc?

- Would the involvement of the City Council be considered relevant to ethics review? Would the collaboration of DAATs be considered relevant?

There are no 'obvious' answers to these questions: they require debate within the Committee itself. A REC might also invite the applicants to explain or defend their proposal in person.

Reporting back to applicants

- Good practice would suggest that RECs should be able to report back within two-three months of receipt of an application, or sooner, depending on the frequency of meetings. This would also fall within the ESRC REF's three month period between notification of funding and start of the project.
- Feedback might include commentary on issues for consideration or elaboration, or set out what the committee requires be done to gain approval.
- The university REC might also need to consider how it might respond if contacted by a charity for the homeless which expressed concern about the study.

CASE STUDY 2: Enhancing the independence of older people with dementia in residential care

Dr Brackenbury, a reader in architecture and design, in collaboration with colleagues in social policy, sociology and gerontology, has been asked by a specialist housing trust to look at ways in which it can design residential facilities to enhance the independence of residents and their engagement in running their home. A PhD student with an ESRC case studentship will also be involved in the research. The team are proposing an action research strategy, starting by talking to residents in six places about their home as a 'home' and observing the way the residents, care providers and managers interact. On the basis of this information, they then propose to suggest and monitor changes in four of the homes over the next two years.

Initiating research ethics review

- This again would need to go to a REC for review. There are ethical issues relating to the welfare of residents, professional risks in regard to criticisms that might be made of management, and questions of how the researchers would handle any strong criticism of the home staff.

Reviewing the application

- There are a number of issues that might be considered in reviewing the application: Would the way the research was regarded be affected by whether the residential homes were run by the local authority, a housing charity or a private individual or company?
- Would the PhD student be asked to put in a separate application?
- Would action research be regarded as raising any particular ethical issues or requiring any particular form of ethics review?

Further monitoring and advice

- How would the university respond if contacted by a relative of one of the residents who expressed concern about the study?

CASE STUDY 3: Teachers' views on the impact of league tables

Ms Cardew is an MPhil student with a 1+3 studentship from the ESRC. For her dissertation, she proposes to carry out a survey of teachers' views on the value of league tables and their impact on the distribution of resources within schools. She has taken a random sample of 100 schools from published league tables for secondary schools and plans to send a questionnaire to the heads of English, history, maths and science at each school.

Initiating research ethics review

- As noted above, ethical review of student's research may be more appropriately managed at department level and overseen by research supervisors. There may be a case for expedited review.

Reviewing the application

- Consideration should be given to the questions raised by the proposal, especially the implications of the results for those within schools responsible for resource allocation.
- What prior training does the student have in this field?

Further monitoring and advice

- Ms Cardew should be offered ongoing support in regard to future ethical review if this is requested.

CASE EXAMPLE 4: Clinical trial of stem cell therapy

Dr Dewar (a sociologist) is Deputy Director of a Multidisciplinary Research Centre on Bio-Technologies. As part of its core programme of research, he is proposing to collaborate in a clinical trial of neural stem cell implantation in the treatment of Alzheimer's Disease. The trial will be conducted by a team of neuro- and biomedical scientists, ophthalmologists and ophthalmic surgeons. Dr Dewar's concern is with the way patients and their families construct the potential risks, benefits and implications of the treatment and how this shapes and is shaped by involvement in the trial. His plan is to employ a post-doctoral researcher to follow a cohort of 20 patients and their families through the trial from the point at which they are contacted as potential participants.

Initiating research ethics review

- This would be considered by an LREC given its clinically invasive nature through the trial.

Reviewing the application

In reviewing this interdisciplinary application there are a number of issues that the LREC might be likely to consider:

- The balancing of immediate concerns against long-term benefits
- Informed consent and the implications of the trial for the patient and their wider kin
- The different notions of risk – clinical vs social – and how these are to be handled and integrated in the project
- How Dr Dewar's postdoc will be assisted during the project as a whole
- How the Committee would assess the level and diversity of risk for Dr Dewar's study
- What other concerns might be identified, such as the university's legal position.

Reporting back to applicants

- An LREC is required to respond to applications within 60 days of receiving them.

Further monitoring and advice

- How would the university respond if contacted by a clinician who expressed concern that Dr Dewar's researcher was affecting his relationship with his patients?

CASE EXAMPLE 5: International study of health related quality of life

Dr Evans, a health psychologist, is part of an international collaboration funded by an international charity to look at the effectiveness of mobility aids in improving the health related quality of life of individuals following a stroke. The study is to be carried out in UK, France, Latvia, Lithuania and Belarus. The proposal involves a baseline assessment of mobility and quality of life (using the WHO quality of life instrument), followed by adaptations to the home and the provision of walking aids and electric mobility carts and a follow-up questionnaire and interview a year later.

Initiating research ethics review

- This would be referred to a REC.

Reviewing the application

- The Committee should consider the project as a whole, not just the component carried out in the UK
- It would need to address the fact that the study was being conducted by an international team. The applicants would need to show that the collaborators understood, endorsed and acted on the principles of the REF
- The Committee might also be concerned with the longer term implications of the study for the countries in which it was conducted (e.g. with the way the results were used and the access that less affluent countries had to the benefits of the research).

Further monitoring and advice

Following approval, there should be the possibility of the chair or designated members of the committee being available to provide advice on ethical issues as they arise.

APPENDIX A – RESEARCH ETHICS REVIEW CHECKLIST

An example of a checklist that could be used in a UK university to determine the level of risk of harm entailed in a proposed study.

This checklist should be completed for every research project that involves human participants. It is used to identify whether a full application for ethics approval needs to be submitted. If a full application is required, Form XX should be used.

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

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

Section I: Project Details

1. Project title:	

Section II: Applicant Details

2. Name of researcher (applicant):	
3. Status (please click to select):	Undergraduate Student/Postgraduate Student/Staff
4. Email address:	
5a. Contact address:	
5b. Telephone number	

Section III: For Students Only

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

Supervisor: Please tick the appropriate boxes. The study should not begin until all boxes are ticked:

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

Comments from supervisor:

Section IV: Research Checklist

Please answer each question by ticking the appropriate box:

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

If you have answered 'no' to all questions, **send the completed and signed form E1/SS to your Department's representative on the School Research and Consultancy Committee, for their records.** Undergraduate and MA **students should retain a copy of the form and submit it with their research report or dissertation** (bound in at the beginning). Work that is submitted without the appropriate ethics form will be returned unassessed. MPhil/PhD students should submit a copy to the Research Degrees Board with their application for Registration, and forward a copy to the [*designated*] Research Ethics Officer. Members of staff should send a copy to the [*designated*] Research Ethics Officer.

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

If you answered 'yes' to ***question 11***, you will *also* have to submit an application to the appropriate external health authority ethics committee, *after* you have received approval from the School Research Ethics Officer. For research conducted in *****shire, applications to the Applied and Qualitative Research Ethics Committee must be signed by the [*designated*] Faculty/School/Department Research Ethics Officer before they are submitted. Information on how to obtain this form is also available on the School web site.

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

Signed
Date
Principal Investigator
Supervisor or module leader (where appropriate)
Signed
Date

APPENDIX B – FLOWCHART OF REVIEW PROCESS

Is ethical approval required? Typical flow chart for proportionate review within a tiered system

E·S·R·C
ECONOMIC
& SOCIAL
RESEARCH
COUNCIL

The Economic and Social Research Council is the UK's leading research and training agency addressing economic and social concerns. We aim to provide high-quality research on issues of importance to business, the public sector and government.
The issues considered include economic competitiveness, the effectiveness of public services and policy, and our quality of life.

The ESRC is an independent organisation, established by Royal Charter in 1965, and funded mainly by the Government.

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