ESRC Framework for research ethics
Updated January 2015

Introduction

The Economic and Social Research Council (ESRC), in facilitating innovative and high quality research, expects that the research we support will be carried out to a high ethical standard. By establishing the Framework for Research Ethics (FRE) we confirm our commitment to a process of regular review through consultation with the research community and stakeholders, to ensure ethical standards reflect changing scientific agendas and policy developments.

This document establishes key principles and minimum requirements and confirms what we regard as good practice for all social science research. It also identifies requirements for ethics review for the research we are asked to support. Whilst adherence to these requirements is **mandatory** for ESRC-funded research, the guidance is also a useful tool to other audiences including other funders, research organisations (ROs), Research Ethics Committees (RECs), individual researchers, research teams (including teams with non-academic researchers) and research participants.

The principal ethics consideration should be to ensure the maximum benefit of the research whilst minimising the risk of actual or potential harm. Ethical procedures should seek to protect, as far as possible, all groups involved in research including participants, researchers and research teams, ROs, non-academic collaborative researchers (and organisations) and funders, throughout the lifecycle of the research. The research lifecycle includes the planning stage, the period of funding for the project and all activities that relate to the project once funding has ended. The research lifecycle also includes knowledge exchange and impact activities, the dissemination process and the archiving, future use, sharing and linking of data.

All individuals involved in ESRC-funded research, including researchers, research support staff, research managers and administrators, should abide by the principles set out in this framework, and guidance available from the:

- ESRC research funding guide - http://www.esrc.ac.uk/RFG
- Guidance and information for ESRC-funded students - http://www.esrc.ac.uk/funding-and-guidance/postgraduates/esrc-students/index.aspx
- ESRC research data policy - http://www.esrc.ac.uk/about-esrc/information/data-policy.aspx
- The UUK Concordat to Support Research Integrity - http://www.universitiesuk.ac.uk/highereducation/Pages/TheconcordattosupportresearchintegrityIntegrity.aspx
- RCUK Policy and Guidelines on Governance of Good Research Conduct - http://www.rcuk.ac.uk/publications/researchers/grc/

For use alongside ethics review, an example checklist on research integrity is provided by the UK Research Integrity Office (UKRIO) (http://www.ukrio.org/publications/checklist-for-researchers/).

In a fast-moving research environment, new situations arise and new forms of research

emerge which cannot all be covered within this document. As part of our commitment to the promotion of high ethical standards, we encourage the research community to share guidance, experience and solutions to ethical dilemmas to facilitate innovative research. We welcome the submission of relevant case studies for inclusion to our portfolio at ethics@esrc.ac.uk. RECs have an important role in facilitating ethical research, and we encourage RECs to share their expertise with each other and provide a supportive environment for their research community.

Our principles and expectations for ethical research

There are six key principles of ethical research that we expect to be addressed:

- Research participants should take part voluntarily, free from any coercion or undue influence, and their rights, dignity and (when possible) autonomy should be respected and appropriately protected.

- Research should be worthwhile and provide value that outweighs any risk or harm. Researchers should aim to maximise the benefit of the research and minimise potential risk of harm to participants and researchers. All potential risk and harm should be mitigated by robust precautions.

- Research staff and participants should be given appropriate information about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks and benefits, if any, are involved.

- Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.

- Research should be designed, reviewed and undertaken to ensure recognised standards of integrity are met, and quality and transparency are assured.

- The independence of research should be clear, and any conflicts of interest or partiality should be explicit.

To implement these principles:

- Responsibility for the conduct of ESRC-funded research by all staff, in line with relevant ethics principles, rests with the principal investigator and the administering RO. However all researchers are expected to take personal responsibility for undertaking research to the highest ethical standards.

- Responsibility for determining the appropriate ethics review required lies with the principal investigator and the research team. Ensuring that research is subject to appropriate ethics review and monitoring lies with the RO seeking or administering an ESRC grant. A single review process should be agreed in collaborative research involving more than one organisation or multi-discipline research. The applicant should ensure that participating organisations and collaborative researchers are satisfied that the research proposal has received adequate ethics review, and that regular monitoring of the conduct of the research takes place and is promptly reported to all organisations or multi-discipline researchers involved.

- ROs should have clear, transparent and effective procedures for ethics review and governance and appropriate mechanisms for monitoring.

- Research should be designed in such a way that the dignity and (when possible) the autonomy of research participants is respected and appropriately protected.

- Ethics review should always be proportionate to the potential risk. Where possible, risks should be minimised; for example, whether the research involves primary data collection or the re-use of existing data.

- Research involving primary data collection will always raise issues of ethics that must be addressed. Whilst the re-use of some datasets may be relatively uncontroversial and require only light-touch ethics review, novel use of existing data and especially data linkage, as well as some uses of administrative, internet-mediated data and controlled data, will raise ethics issues.

ESRC will ensure compliance with the FRE through the following procedures:

- We will only fund ROs that have processes in place that comply with the Council's minimum expectations as set out in this framework. However, we do not seek to impose a particular model for achieving these expectations. We will ensure that our peer-review of proposals addresses ethics issues, and we will also engage in cross-Research Council assurance activities to check that commitments to thorough ethics assessment and review of projects are indeed being followed by the ROs.

- Ethics issues should be identified in the proposal's ethical information section. Although we do not require an ethics review to be completed prior to submission of a research proposal, we do expect researchers to have thought about and detailed the potential ethical implications of their research. The proposal's ethical information section should detail the possible ethical implications of the research during the lifecycle of the project, what measures will be taken for ongoing review, what ethics review is required and how the review will be secured. Where an ethics review is yet to be undertaken, this should be stated, along with how and when this will happen. By submitting a proposal to us, the RO is confirming acceptance of the proposal's ethical information and confirming that it is prepared to administer any resulting grant on the basis specified in the proposal and is committed to an appropriate and iterative review process.

- During proposal consideration, peer-reviewers and introducers we approach will be asked to consider whether the ethical information provided by the applicant adequately addresses ethics issues that may be encountered within or occur as a result of the research. If peer-reviewers or panel introducers disagree with the proposed approach to ethics within the proposal, this will either be grounds for a conditional grant or rejection of a proposal where it calls into question researcher competence or the feasibility or validity of their proposal.

- Funded proposals should normally commence no sooner than three months after the formal notification of funding to allow for recruitment of staff and ethics review. If an ethics review is required at a later stage in the project, this should be discussed with us when confirmation of funding is received, and funding arrangements will need to be

agreed with the lead ESRC officer. At a minimum we expect that ethics review will be carried out prior to the stage in the project that the research will be undertaken. In those cases where it is agreed that ethics review is to be undertaken after the project funding has commenced, funds will be made available to cover the period through to the completion of the review, and continued funding will be conditional on the outcome of the ethics review.

- If review by the REC shows that a project requires major changes which will alter it substantially and the project can no longer attract ESRC support, payments may be suspended and the grant terminated. This is likely to be an extremely rare occurrence since the proposal will already have undergone external peer-review which should identify such severe problems.

- Approval for minor changes to a project following REC review is delegated to the RO. If ongoing review by a REC shows that a project requires major changes in the lifetime of the research which will alter it so much that it can no longer attract ESRC support, this should be referred to ESRC.

- The ESRC's guidance and information for ESRC-funded students (http://www.esrc.ac.uk/funding-and-guidance/postgraduates/esrc-students/index.aspx) will identify any specific requirements in relation to research ethics.

- Breach of compliance with the ESRC Framework of Research Ethics and RCUK Policy and Guidelines on Governance of Good Research Conduct (http://www.rcuk.ac.uk/publications/researchers/grc/) in ESRC-funded research will be treated as a serious matter. Where this occurs, the RO, principal investigator and researchers will be called to account by the ESRC and sanctions may apply depending on the severity of the breach. These could result in the immediate suspension of the individual project and other projects based at or under the co-ordination of the administering RO and a halt to the consideration of further proposal submissions from that RO.

1. **ESRC's minimum requirements**

The requirements described here in Section 1 constitute our minimum requirements for a research proposal to be eligible for ESRC funding.

1.1 Ethics issues should be identified in the proposal

Although the ESRC does not require that ethics review should be completed before submission of a research proposal, all applicants should complete the ethical information section. Applicants should identify ethical issues that could possibly arise during the lifecycle of the project, what ethics review the applicant(s) considers will be required for the proposed research, and why (see proposal example of ethical information). Where an ethics review is yet to be undertaken, this should be stated, along with how and when this will happen. All ESRC-funded grants should undertake the appropriate ethics review.

In the first instance, it is the responsibility of the researcher, or research team, guided by standards set by their professional societies, disciplinary bodies and research organisations, to decide what ethics issues may arise within the research and whether the project should be subject to either a light-touch or a full REC review. Research proposals involving human participants and personal data will usually require a full review by a REC that has been established and operates in accordance with the principles and guidelines set out in this framework. Researchers should consider the privacy requirements of the UK Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents), when undertaking research using personal data, including research where individuals are potentially identifiable through data linkage. In particular, research proposals involving the groups noted in section 1.2.1 would be expected to require a full review.

1.2 All ESRC-funded research should be subject to ethics review

Ethics reviews should assess the likelihood and magnitude of risks, considering both the minimal risk of serious harm, and moderate risk of minimal harm, as ethical considerations are different in each situation. All ESRC-funded research should undergo the appropriate ethics review. It is the responsibility of the researcher to determine if the project should be subject to a light-touch or full review. If a light-touch review is requested, this must be fully justified. The REC is expected to ensure that the appropriate ethics review is undertaken.

Research organisations (ROs) will often provide a pre-defined checklist that researchers should consider when determining the type of ethics review required. See Appendix A for an example checklist.

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

- criteria for identifying research that involves more than minimal risks (see example descriptions below)
- the system of review for such research, including the scope of the authority of those to whom responsibility for review has been 'delegated'
- forms and procedures for submitting applications for light-touch, expedited and full review
- procedures for reporting decisions to the principal REC
- procedures for periodic ad-hoc audit (of light-touch, full and expedited reviews by the principal REC)
- a published timetable of the maximum time necessary for undertaking light-touch and full ethics reviews.

Types of review

A light-touch review, when fully justified, identifies projects where the actual or potential risk of harm to participants (and others affected by the proposed research) is minimal. Many student projects may require only a light-touch review. However, this cannot be assumed; projects, including student projects, which involve more than minimal risk, should receive a full REC review. Some RECs have facilitated ethics approval for research

with potentially vulnerable people by establishing ethics protocols for commonly occurring situations, such as research undertaken with typically-developing children in mainstream school settings. If the researcher can confirm that they are abiding by the established protocol and that this is appropriate for their research, a light-touch review may be justified. The use of individual RO-approved research ethics protocols for commonly occurring situations may limit the number of research proposals that need to go to a full ethics review.

Expedited review may be appropriate in exceptional circumstances where research projects require a full review but have a short lead time and are commissioned in response to a demand of pressing importance. Most RECs only permit expedited review in exceptional and clearly justified cases. Such exceptions may include external drivers which are beyond the control of the researchers (eg access to a sample) which mean that ethics clearance is required within a short timescale, or when perhaps fieldwork is linked to a particular event or period that is outside the researcher's control. An expedited review should meet the criteria required for a full review and should not be carried out by REC members who are in a position of dependence with the applicant which could be perceived as a conflict of interest.

It is the responsibility of the researcher or research team, guided by standards set by their professional societies, disciplinary bodies and ROs to determine whether their project should be subject to a light-touch or full review. However, the REC is expected to ensure that the appropriate ethics review is undertaken. The following section provides examples of research that we would expect to require full ethics review because it will entail more than minimal risk. It is likely that much research activity will require full ethics review, and methods such as further analysis of data are not necessarily exempt from full review.

Research potentially requiring a full ethics review
Research involving:

- Potentially vulnerable people, for example children and young people, those with a learning disability or cognitive impairment, or potentially vulnerable individuals in a dependent or unequal relationship.

- People who lack capacity to make decisions or who during the research project come to lack capacity. Such research should be reviewed by an appropriate body operating under the Mental Capacity Act 2005

- (http://www.legislation.gov.uk/ukpga/2005/9/contents). Normally this will be a REC recognised by the Secretary of State and Welsh Ministers and operating under the Health Research Authority (HRA) Governance Arrangements for Research Ethics Committees (GAfREC) (http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/#sthash.rH7OVRVy.dpuf). Research conducted in Scotland should be reviewed by the Scotland 'A' REC (http://www.nhsresearchscotland.org.uk/226_Research+Ethics.html) which is operating under The Adults with Incapacity (Scotland) Act 2000

(http://www.legislation.gov.uk/asp/2000/4/section/10).

- Potentially sensitive topics, for example participants' sexual behaviour, illegal or political behaviour, experience of violence, abuse or exploitation, mental health, their personal or family lives, or their gender or ethnic status. Elite interviews may also fall into this category.

- Deceased persons. Researchers should adhere to relevant legislation ie Human Tissue Act 2004 (http://www.legislation.gov.uk/ukpga/2004/30/contents), Human Tissue (Sc) Act 2006 (http://www.legislation.gov.uk/asp/2006/4/contents) and to the relevant NHS policy requirements for REC reviews. See also HTA Code of Practice (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm), NHS Research Scotland (NRS) (http://www.nhsresearchscotland.org.uk/).

- Body parts or other human elements**.** Researchers should adhere to relevant legislation ie Human Tissue Act 2004 (http://www.legislation.gov.uk/ukpga/2004/30/contents), Human Tissue (Sc) Act 2006 (http://www.legislation.gov.uk/asp/2006/4/contents) and to the relevant NHS policy requirements for REC reviews. See also HTA Code of Practice (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm), NHS Research Scotland (NRS) (http://www.nhsresearchscotland.org.uk/).

- Administrative or controlled data. Appropriate approval within the relevant governance regime(s) is needed for use of these datasets. In many cases a light-touch review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.

- Individuals or groups where permission of a gatekeeper is normally required for initial or continued access to participants. This includes research involving gatekeepers such as adult professionals (eg those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (eg the parent or husband of the participant) or a community leader, and research where participants are in a dependent relationship with the gatekeeper (eg employees recruited through their workplace). Permission for access to other groups, for example participants in a long term cohort study, may also need to be requested from a data producer who controls access to the group.

- Justified deception or research conducted without participants' valid and informed consent at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork (see Frequently Asked Questions).

- Access to records of personal or sensitive confidential information, including genetic or other biological information, concerning identifiable individuals. See the Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents).

- Intrusive interventions or data collection methods, for example the administration of substances; vigorous physical exercise; or techniques where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life. Also research which would or might induce psychological stress, anxiety or humiliation, or cause more than minimal distress.

- Risk to the safety of the researcher, for example researchers working in the field and international research assistants working outside the UK in their own community.

- Members of the public in a research capacity in research data collection, eg participatory research.

- International partners or research undertaken outside of the UK where there may be issues of local practice and political sensitivities. In some cases partnership with a RO in the geographical area involved may prove helpful. It is also necessary to act in accordance with the legal and ethics review requirements in the countries included in the research. Researchers should also consider these issues when undertaking social media research, as most of this is international in scope as data are often drawn from a range of international settings.

- Social media and participants recruited or identified through the internet, in particular when the understanding of privacy in these settings is contentious where sensitive issues are discussed - for example in 'closed' discussion groups where there is potential for quotes to be identifiable and including where visual images are used.

- Other visual / vocal methods, particularly where participants or other individuals may be identifiable in the material (eg images, sound recordings) used or generated.

- Linking or sharing of personal data or confidential information beyond the initial consent given (including linked data gathered outside of the UK), for example where the research topic or data-gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

1.3 Criteria for ethical consideration of research proposals

Our principles provide the basis for the ethics review of research proposals submitted to ESRC. They should be considered in relation to the nature of the outlined research, the context in which it is undertaken and the applicant should be guided by standards set by their professional societies, disciplinary bodies and research organisations.

RECs should review research proposals in terms of their ethics probity. This will entail a consideration of the design, outputs and proposed conduct of the research. These should be considered in terms of the ethics issues raised (for example, whether the method of recruitment proposed puts undue pressure on individuals to participate) and the way the issues 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 review process. The scholarly or scientific merits of the research are not the primary responsibility of the REC. Where the REC needs greater understanding of the scientific or scholarly merit of a proposal in order to make a judgment about ethics issues and potentially methodologically unsound research, it should seek the advice of an independent researcher with experience and expertise in the research methods and paradigm described in the proposal.

Where more than one perspective or ethics principle applies to a specific case, clear ethics reasoning will be required and debate should be encouraged. Good ethics review requires sensitivity to the context in which a research study will be conducted, and good ethics reasoning requires careful thought and consideration.

The knowledge and expectations that members of RECs bring to the ethics review of research proposals are fundamental to the way they review proposals. In some research it may be impossible or ethically undesirable to meet standard ethical requirements, for example to obtain signed consent from participants at the outset of the research. Research deviating from the ESRC and/or REC-expected ethical requirements must be fully justified.

Ongoing review
As research progresses, further ethical issues may arise. Principal investigators should check through the implications of the issues and have these reviewed by the appropriate REC. Non-conflicting advisory bodies, independent experts and mentors may also assist in this process. Ongoing monitoring should be proportionate to the nature and degree of risk and harm entailed in the research. If ongoing review by a REC shows that a project requires major changes in the lifetime of the research, which will alter it so much that it can no longer attract ESRC support, this should be referred to the lead ESRC officer.

Pathways to impact and dissemination
Risk to researchers, participants and others (eg potentially stigmatised or marginalised groups) as a result of potential impact, knowledge exchange and dissemination activity should be considered as part of the ethical information submitted in the research proposal. These ethical issues should also be considered by researchers in the proposal submitted for review to the appropriate REC.

1.4 RECs should be constituted and operate in accordance with the framework standards

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

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

Within the definition of research, all data collection and analysis involving human participants and/or personal data should undergo ethics review prior to the research commencing, with the exception of the following, which are not considered 'research'. However, ESRC would not usually provide funding to support a project engaged in only these activities below:

- Routine audit
- Performance reviews
- Quality assurance studies
- Testing within normal education requirements
- Literary or artistic criticism.

While data collected and stored as a record at an individual level are considered personal data, material already in the public domain are 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 ethics review, nor would interviews broadcast on radio or television or online, nor diaries or letters in the public domain.

Information provided in forums or spaces on the internet that are intentionally public would be considered 'in the public domain', but the public nature of any communication or information on the internet or through social media should always be critically examined, and the identity of individuals protected, wherever possible, unless it is critical to the research, such as in statements by public officials. For research that involves the use of social media, researchers will also need to abide by the regulations set by the data producers subject to such regulations being consistent with legal and ethical guidelines (see also internet-mediated research in FAQs). The potential for identifiabilty of online sources, as well as ethical debates about how privacy is constituted in digital contexts, means that full ethics review may be appropriate for research involving these communities. For example, people often assume that social media sources are public domain, but it is quite likely that some service users – including children – may not understand the implications of what they are doing, and those harvesting data may also uncover illegal images or activities.

Research that involves anonymised records and datasets that exist in the public domain may only require a light-touch review. This includes, for example, datasets available through the Office for National Statistics or ESRC's data service providers where appropriate permissions have already been obtained and where the risk of identifying individuals from the information provided is negligible. Specific regulations relate to the use of administrative and controlled data (other data producers are likely to specify their own restrictions on the access to and use of their data), which should be complied with. There may be some circumstances where ethics issues arise with the re-use of data, as described in section 1.11

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

between them and to facilitate co-operation and common standards, including arrangements to escalate deliberations to a principal REC where light-touch review is being used or delegation is in operation.

A REC might advise on broad strategy for ethics review and monitor performance overall, rather than consider applications per se. Wherever they are located, RECs should meet the requirements of this FRE, even at department level if this is where the decision to review a project is to be taken. If checklists are used to identify the type of review required, the checklists may, if necessary, be overseen by an independent review body at faculty, school or department level.

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

ROs 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.

Independence of Research Ethics Committees
ROs are responsible for ensuring that the RECs within their organisation act independently. They should be free from bias and undue influence from the RO in which they are located, from the researchers whose proposals they consider and from the personal or financial interests of their members. The independence of a REC is founded on their membership, on strict rules regarding conflict of interests and on regular monitoring of and accountability for their decisions.

Composition of Research Ethics Committees
The membership of a REC is fundamental to ensuring that it has the range of expertise and the breadth of experience necessary to provide competent and rigorous ethics review of the submitted research proposals, and to do so from a position that is independent of both the researchers and the RO in which it is located. Its composition and independence are important in establishing the legitimacy of the opinions expressed and the decisions made, in the eyes of the community and wider society as well as the researchers and funders of research.

RECs should be multidisciplinary and comprised of both men and women. They should include at least one lay member with no affiliation to the RO in question. There should be a chairperson and members who have broad experience and expertise in the areas of research regularly reviewed by the REC and members who have the confidence and esteem of the research community. RECs would also benefit from including individuals who reflect ethnic diversity, users of specialist health, education or social services (where these are the focus of research activities), individuals with experience of professional care or counselling, and individuals with specific methodological expertise (for example, quantitative or qualitative methods) relevant to the research they review. A REC should include among its membership people who are collectively familiar with a range of

philosophical approaches to research ethics and with the different perspectives seen in individual research proposals. Taking all of this into account, good practice would suggest that RECs would need at least seven members.

A 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.

Remit and responsibilities of Research Ethics Committees
RECs should provide supportive, reflexive governance to researchers and operate a system of ongoing monitoring and supportive reflection that promotes mutual learning for researchers and REC members. RECs are responsible for reviewing all research involving human participants and personal data conducted under their auspices and undertaken by individuals employed by the organisation that does not come under the remit of the UK Health Departments and Health Research Authority (http://www.hra.nhs.uk/). RECs should review research proposals in a way that is independent, competent and timely. In some circumstances RECs may authorise other sub-committees or their chair to conduct reviews on research involving minimal risk on their behalf. These sub-committees and chair will have no conflicts of interest with the project and will be accountable to the REC and through it to the appropriate organisational authorities for the decisions they make.

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

RECs should publish a projected timetable on the time needed to consider a proposal.

REC procedures for reviewing research proposals
RECs should review each research proposal submitted. Where a proposal does not meet the expected ethical standards or changes are required, it is appropriate for the REC to give feedback on what needs to be done. 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 RO's policy on information retention; this period should extend beyond the lifetime of the project. RECs should be encouraged by the RO to support high impact and new forms of research.

ROs should establish and publish working procedures and systems of documentation in relation to:

- 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. Where RECs develop their own procedures, for example electronic review, RECs should publish details of these procedures, with any deadlines for submission of applications as appropriate.

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

- Identifying, documenting and dealing with conflicts of interests (see section1.6).

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

- Prompt notification of decisions and the rationale for the decisions. RECs should publish a timetable for completion of ethics review and a commitment to providing a decision within the timeframe which normally should not exceed 60 days.

- Receiving and considering appeals. Grounds and mechanisms for appeal should be clearly stated. ROs may want to consider developing partnerships with other ROs in case of appeals. It could be appropriate for ROs to make arrangements to act as Appeal Committees for one another.

- Monitoring the conduct of research following initial review and through ongoing ethics review

- Receiving and considering complaints and transparency of decision-making (see section 1.6).

Ethics review application forms and protocols
Research proposals, including student proposals, submitted for review to a REC might be expected to include most, but not necessarily all, of the following information in a way that is understandable to a lay member, though the precise way this is done is left to the discretion of the RO:

- Aims of the research and scientific background of the research.
- Study design.
- Participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited.
- Potentially vulnerable individuals or groups.
- Methods of data collection and analysis.
- Response to any conditions of use set by data custodians and data producers.
- Principal investigator's summary of potential ethics issues and how they will be addressed. For projects that include non-academic or international collaborators, this summary should be agreed by all parties.
- Benefits to research participants or third parties and how this will be maximised.
- Risks to participants or third parties and what has been done to assess, obviate or minimise risks.
- Risks to researchers and in particular how researchers will be protected or supported, especially in the field and outside the UK.
- Procedures for freely given and adequately informed and valid consent – information provided and methods of documenting.
- Procedures for dealing with information arising in the course of fieldwork that is a cause for concern, such as disclosures from participants or behaviours or incidents observed that raise significant concerns about the safety or wellbeing of participants or other people.
- How any data collected will be kept secure, and methods of transferring data within teams, in compliance with the UK data protection legislation.
- Mechanisms for managing data-sharing outside the proposed research team.
- Details of research activity that falls outside the UK and links to overseas institutions.
- Expected outcomes, impacts and benefits of research.
- Pathways to impact and dissemination (and feedback to participants where appropriate) and possible ethics implications of these plans.
- Data management and curation; what measures have been taken to ensure confidentiality, privacy and data protection during and beyond the end of the project? See the ESRC Research Data Policy (http://www.esrc.ac.uk/about-esrc/information/data-policy.aspx).
- Members of Advisory Groups should have no conflicts of interests with researchers or participants.

ROs support for Research Ethics Committees
ROs should provide the REC or RECs for which they are responsible with the necessary resources to carry out their responsibilities efficiently, effectively and independently. All REC members should have sufficient baseline knowledge of ethical issues, and we encourage ROs to support REC members to engage in training and/or seminars which

would help them to make effective ethical judgments. ROs should endeavour to equip RECs and other supervisory staff with a critical framework for supporting good ethical practice and high ethical standards in research.

These resources should include, at a minimum, appropriate training for the members in the ethics, legal and scientific dimensions of the research that their REC reviews; adequate administrative and clerical support, and adequate resources, including recognition in workload planning and the allocation of academic responsibilities, to carry out reviews with due care and attention; and to attend meetings of the REC. Any additional resourcing for these requirements should fall within a RO's own budget. However, it should be remembered that the additional costs incurred by the host RO in carrying out ethics review specifically for ESRC-funded research are eligible costs under the arrangements for Research Councils to meet a proportion of the full economic costs of research.

Successful implementation of the FRE relies in a large part on the degree to which individual ROs have built appropriate structures and a culture that recognises the central place that engaging in ethical reflection occupies in good research practice. Encouraging a mindset towards a robust ethics culture and provision of training plays a central role in this process. Such training should be ongoing and become an integral part of research practice, given the changing ethics environment (see section 1.7)

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

- Web-based resources such as flow-charts or algorithms to help identify what ethics review is required by a proposed study, and the steps that should be taken for REC review, whether according to the FRE or other appropriate framework with more stringent requirements.
- An ethics review handbook or webpage that states the ROs standards and expectations with regard to the FRE, and how staff can ensure they comply with these standards and expectations. This could form part of a larger resource covering other ethics review frameworks as well as training mentioned above.
- The use of approved protocols for commonly occurring situations. It will be the responsibility of the local REC to review the suggested protocol for the individual proposals.

In order to facilitate greater transparency and the sharing of solutions to ethics dilemmas, ROs are encouraged to publish their approved protocols on the web for use by others. ROs giving access to their approved protocols cannot be expected to enter into any discussion on their use. Those making use of such protocols will need to justify to their RO why the suggested protocol is appropriate to their research.

1.5 ROs should establish procedures for monitoring research

ROs should establish and publish working practices and procedures for monitoring research which encourage a grassroots culture of robust collective governance.

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

ROs should undertake occasional ad hoc audits of ESRC-funded research. How often this is done will depend on the amount of ESRC research undertaken in the RO. In major ROs it is anticipated that a REC should undertake an audit of at least one ESRC research project per year, randomly chosen, or in the case of a large centre, part of a project. Principal investigators and supervisors of students need to know that they should keep good records of their ethics procedures in case they are called to account. This could be a desk-based exercise, asking to see the consent documents, other special permissions and relevant paperwork, information on data storage and data sharing, as well as a note from the principal investigator on changes that have been made, and highlighting specific problems.

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

Where a 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 review or in a way which does not appropriately protect the rights, dignity and welfare of research participants, it should initially bring together a meeting of all those concerned with a view to resolving the difficulties. In an extreme situation, the REC may withdraw its support, and require that the research be suspended or discontinued. The ESRC should be informed of this decision and reserves the right to recoup its grant funding in extreme cases of ethics and research misconduct, pending further investigation.

ROs should also monitor the operation of RECs for which they are responsible. It should be anticipated that we may undertake occasional ad hoc audits of organisational arrangements to ensure that they are operating to the minimum standards outlined here. It is therefore important that RECs keep records of their procedures, minutes of meetings and list of proposals reviewed for a minimum of five years.

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

available should we wish to see them.

1.6 Complaints, appeals and conflict of interest procedures should be in place

Complaints - ROs should publish procedures and mechanisms for receiving and addressing, in a timely manner, complaints or expressions of concern about the conduct of research carried out under their auspices. Such complaints would normally be regarded as allegations of either poor performance or unethical conduct and would appropriately be addressed through the RO's procedures for dealing with such allegations. Such mechanisms might include providing research participants with the contact details of a responsible officer within the RO who is independent of specific research projects and is empowered to instigate appropriate investigation of any complaints in a timely manner.

Appeals – ROs should publish procedures and mechanisms for receiving and addressing, in a timely manner, appeals from researchers. 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 principal REC. Where the decision under appeal was made by the principal REC, an appeal committee should be constituted. It could be appropriate for ROs to make arrangements to act as appeal committees for one another.

Conflicts of interest - rules and procedures for identifying and dealing with potential conflicts of interest are crucial to maintaining independence in the way a REC reviews applications. Potential conflicts of interest include (but are not limited to):

- Conflicts between the interests of a RO, 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 REC and the interests of a researcher making an application to the REC.
- Conflicts between the interests of the researcher and the interests of the research participants.

Fundamental to dealing with each of these situations is the principle of prior disclosure of potential conflicts of interest and withdrawal from discussion and decision-making. Guidance provided by the UK Research Integrity Office (UKRIO) (www.ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf) and the RCUK Policy and Guidelines on Governance of Good Research Conduct (http://www.rcuk.ac.uk/publications/researchers/grc/) may be helpful.

1.7 Arrangements should be made for training researchers, research students, supervisors and member of RECs

Many ROs already provide ethics training programmes, arranged either at organisational level or through devolved structures such as department or faculty- based programmes. However, successful FRE implementation requires the development of agreed minimum standards of training and competence (which should be kept up to date with the changing ethics issues within the research lifecycle). These minimum standards may be achieved

through programmes at organisational, faculty, departmental, research centre or unit level.

We expect social scientists to engage with ethics issues from the start of their research careers. ROs should ensure that social science postgraduate training programmes in the doctoral centres incorporate the range of issues in this framework.

The aim of this training should be to build confidence in individuals to recognise the need for ethics scrutiny with regard to social science research; throughout the lifecycle of the research, which includes the research activity, knowledge exchange and impact activities and further ethical consideration required for potential re-use of data; training should also help individuals understand the RO's requirements and procedures for review; and to understand how to access additional help, both internal and external to the RO.

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

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

1.8 Student research and ethics review

The same principles should apply to student research as to all other research. The ESRC recommends that ROs 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 ethics review because of the large numbers, short timescales and limited scope of the projects involved. Supervisors of research postgraduate students should work closely with their students in considering ethical aspects of proposed research in keeping with this framework.

The same high ethical standards should be expected in student research. It cannot be assumed that all students' projects involve minimal risk. Student projects involving research potentially requiring a full ethics review may need careful consideration. However, in many cases student research may be managed at school/department level and overseen by a light-touch departmental ethics committee using an initial checklist. Established protocols for commonly occurring research, as mentioned previously, can expedite the review process. It should be made clear to potential research participants that the study is a student project. ROs also need to ensure that students are not exposed to undue risk in conducting their research.

The ESRC already provides Guidance and information for ESRC-funded students (http://www.esrc.ac.uk/funding-and-guidance/postgraduates/esrc-students/index.aspx). These guidelines include reference to training in ethics and legal matters. ROs should ensure that training programmes they provide incorporate the range of issues addressed in

the main framework document so that students embrace an ethics culture from the start of their research careers. Doctoral Training Centres should detail the ethics training that they provide for their students.

1.9 Arrangements should be made for collaborative research

The FRE guidelines should be drawn to the attention of all proposed collaborators or project partners, providing co-funding or in-kind contribution, prior to a submission for funding. In many cases requirements can be satisfied by the research being conducted in a FRE-compliant RO. If this is not the case, proposals submitted to ESRC should confirm that the research will adhere to our requirements. ROs 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.

Projects involving researchers from more than one RO can create complications for formal ethics review procedures. ROs and other partners engaged in collaborative research may agree to use the REC of the RO where the principal investigator is based to review the project on behalf of all participants. A single review process should be agreed by all researchers, the standards of which should at least satisfy the ESRC minimum ethics requirements. Researchers and their co-producing partners also need to agree to an iterative and shared process of ethics review as the project develops. Each RO needs to be satisfied that the research proposal has been properly scrutinised by the appropriate REC, for example the principal investigator's REC, and that regular monitoring of the conduct of the research is taking place and is promptly reported to all ROs involved.

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

Where research is to be conducted outside the UK or involves international partners, ROs should require researchers to establish whether ethics review is required by the non-UK ROs, and how the principles of the FRE can be followed in developing and undertaking the research. Legal and ethical requirements for all the partner countries must be ensured.

There are several considerations here:

- inequities in regard to access to research resources
- political and cultural considerations with regard to professional training and oversight; differing ethics traditions in research
- increased risk to researchers and participants where they are working remotely

- issues about gatekeepers (for example in some societies, access to research participants may not be possible without first obtaining permission from a community leader or female participant's husband)
- considerable differences in power between the researcher and the participant.

Moreover, research ethics in some societies raises issues about what is meant by ethics, and therefore how we conceptualise notions of rights (for example: consent, choice, volition or self-determination) and the handling of personal data or linking and sharing of data in an international context where data handling may not be subject to the UK Data Protection Act (http://www.legislation.gov.uk/ukpga/1998/29/contents). These issues need to be borne in mind in regard to specific schemes involving international collaboration. In many cases it is good practice to collaborate with a local RO or other relevant local experts (eg an NGO). Researchers should also consider these issues when undertaking social media research as most of this is international in scope, as data is often drawn from a range of international settings.

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

Co-funded research may involve the ESRC in partnership with other Research Councils, business, other public sector organisations, civil society sector or research funded under a European Union framework programme and involving research teams from different EU member states. For co-funded research there may be conflicting national or international review procedures. In each of these cases, co-funders will discuss and agree the ethics review requirements. There should be a commitment of mutual recognition of ethical consideration between funders, where possible, of common standards, and if not it should be made clear where researchers should go for advice.

1.10 Duplication of submission should be avoided

Researchers and ROs should avoid duplication of ethics review. The appropriate review body will be determined by the issues raised by the research, the nature of the data to be obtained and the population of participants to be included in the study. This will apply to both single-discipline research and interdisciplinary research, especially where social and biomedical scientists are working together. For a full review ESRC does not require an organisational REC and a NHS REC to be involved. Researchers should submit proposals either to the REC of their RO or to HRA (http://www.hra.nhs.uk/) for review by NHS RECs across the UK, including the Gene Therapy Advisory Committee (GTAC), and to the Social Care REC.

The Governance Arrangements for Research Ethics Committees (GAfREC) (http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/)apply to research involving research participants recruited through the NHS or Social Care services, and such research should be reviewed by a recognised and appropriate REC (see Appendix D).

In addition, research involving adults who come under the remit of the Mental Capacity Act 2005 (http://www.legislation.gov.uk/ukpga/2005/9/contents) or the Adults with Incapacity (Scotland) Act 2000 (http://www.legislation.gov.uk/asp/2000/4/contents) requires review by a recognised and appropriate REC operating under the GAfREC (http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/) or Scotland 'A' REC. For a full list of the research which requires HRA/NRES REC approval see the HRA approval decision tool (http://www.hra-decisiontools.org.uk/ethics/). The HRA and NHS Scotland research ethics service (http://www.nhsresearchscotland.org.uk/226_Research+Ethics.html) also provide guidance on the scope of the research provisions under the Mental Capacity Act 2005 (http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/) and Adults with Incapacity (Scotland) Act 2000 (http://www.legislation.gov.uk/asp/2000/4/contents).

1.11 Legal and data protection requirements should be met

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

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

UK Data Protection Act 1998 (DPA)
It is important that those undertaking research are aware that the Data Protection Principles embodied in the DPA apply to their work. Social science research often involves the processing of 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 (http://www.legislation.gov.uk/ukpga/1998/29/contents). Helpful guidance can be found at the ICO guide to data protection (https://ico.org.uk/for-organisations/guide-to-data-protection/).

Legal requirements
ROs should comply with all relevant legal requirements and with the requirements of data custodians. The regulatory requirements which apply may vary depending on the locus of data collection, the location of the subjects of the research, where data are held, and the nature of the research involved. Privacy, health and safety, and intellectual property are especially likely to arise as ethics concerns in research, but all legal requirements should be met. In addition, careful consideration is needed in regard to the ethics implications that might be associated with the re-use and re-purposing of data. Where a principal investigator confirms that a full ethics review is not required, the research will still need to

adhere to professional codes of practice, legal requirements and compliance with the Data Protection Act, 1998.

Work with potentially vulnerable groups
In most cases, researchers working with vulnerable people will need to secure Disclosure and Barring Service (DBS) clearance (https://www.gov.uk/government/organisations/disclosure-and-barring-service). The DBS offers organisations a means to check the criminal record of researchers to ensure that they do not have a history that would make them unsuitable for work involving children and vulnerable adults. 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 (see the Safeguarding Vulnerable Groups Act 2006 (http://www.legislation.gov.uk/ukpga/2006/47/contents); Rehabilitation of Offenders Act 1974 (http://www.legislation.gov.uk/ukpga/1974/53); the Rehabilitation of Offenders Act 1974 (Exceptions Order 1975 (http://www.legislation.gov.uk/uksi/2013/1198/contents/made)).

Proxy consent
Proxy consent can be obtained by a person authorised to act on behalf of a vulnerable person. Where proxy consent for research participants is necessary, the best interests of the vulnerable person should be of the highest importance. Proxy consent should only be used when participants are unable to consent themselves or where it is legally necessary. Care should be taken when consent cannot be sought from the participants, and it should not be assumed that agreement cannot be sought from children because of their age. When proxy consent is used agreed criteria should be provided to confirm participants fully understands to what they are participating, and criteria identifying signs of participants' unwillingness to take part or wishing to terminate the research interaction.

Limits to confidentiality
Researchers should, when eliciting consent, make clear the limits to confidentiality, particularly when working with potentially vulnerable individuals or groups - for example when undertaking research with children, families and vulnerable populations, or individuals involved in illegal activities. If for example an interview reveals that a participant or another person identified in the interview is in significant danger, the researcher will be obliged to take action in response to that disclosure. Researchers should have established procedures, necessary systems and appropriate contacts in place to activate help and support in the event of a disclosure. If the researcher feels it is necessary to break confidentiality, the participant should normally be informed what action is being taken by the researcher, unless to do so would increase risk to those concerned. In projects collecting data on criminal behaviour, it may be necessary to explain to participants that confidentiality will be preserved as far as the law permits. Any disclosures of otherwise confidential information should be fully justified in the public interest and researchers must be able to defend their actions fully, for example to avert serious harm, and disclosures should only be made to parties empowered to act on the information.

Data re-use
Re-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

personal data. This applies to the researcher originating the data and the users of the data. Researchers who initially collect the data should be aware that the ESRC expects that others will also re-use the data. The original researcher should take into account the long-term use, including the potential for data linkage and preservation of data, when obtaining consent. Further advice on securing consent for data re-use, as well as exemplar consent forms, are available at the UK Data Service's website (http://ukdataservice.ac.uk/manage-data/plan.aspx). In some cases it may not be possible to sufficiently anonymise data in order for it to be available at the appropriate ESRC Data Service Provider (for example the UK Data Service) through a standard End User License, but alternative secure access methods could be arranged.

Data re-use falls into three categories:

- Non-sensitive data or data where there is minimal risk of disclosure of the identity of individuals.
- Data protected by legislation, for example personal data which includes census data and personal data provided for administrative purposes. Here, the data producer and data custodian has a strong interest in how researchers will access the data, and may control access. This category of data may only be available via 'safe settings', see for example ESRC's Administrative Data Research Network (http://www.adrn.ac.uk/) and the Safe Haven Farr Institute (http://www.ed.ac.uk/schools-departments/molecular-clinical-medicine/health-services-research-unit/projects/safe-haven) collaboration, which have been set up, respectively, to ensure the safe use of administrative data and patient and research data for medical research across all diseases.
- Data such as the National Child Development Study (NCDS), where the inclusion of information such as a birth date or postcode makes disclosure possible, perhaps via a link to other datasets. This means that such data are ethically sensitive.

A data producer such as the Office for National Statistics (ONS) or other government departments may also have stringent requirements and restrictions relating to access and re-use of data that should be followed. Legal and data producer access requirements on the re-use of datasets should be complied with, including provisions relating to presumed consent and potential risk of disclosure of personal data. Appropriate ESRC Data Service Providers, for example the UK Data Service, should be approached in the first instance for advice on current data producer requirements. Researchers may also consult directly with data producers regarding project-specific issues.

The fact that an original piece of research has gone through ethics review for its collection does not rule out ethics issues arising over its re-use. Data which have been anonymised may have a residual risk of disclosure, or may become disclosive when linked with other data within the public domain. The licensing regime provided by ESRC's Data Service Providers mitigates this risk considerably.

There are also specific ethics issues relating to large-scale and longitudinal surveys, such as the Millennium Cohort Study, where social and other health or medical data is secured. The REC should consider issues such as the relation between opting in and out of the study and consent, data security of named files and data and the anonymisation of individual respondents. It should ensure that proposals involving third parties such as

polling companies contracted to secure data will do so according to the ethics principles set out here. These organisations often operate according to codes of practice developed by bodies such as the Market Research Society (https://www.mrs.org.uk/).

Data access through technology
Researchers are now making greater use of datasets which have been generated through internet-mediated technology and social media. Researchers need to consider the ethical issues which arise; for example, the interpretation of anonymity and whether participants (eg social media users) would consider data in the public domain to be private, the meaning of informed consent in this context and the important issue of what permissions a researcher has over the data supplied by the data producer (eg Facebook or Twitter data).

Data access through biobank
Social scientists are also making greater use of data held in a public or private biobank where broad consent is often utilised. The UK Biobank (http://www.ukbiobank.ac.uk/ethics/) is an example of broad consent and has stringent measures in place to ensure that participants are not identified.

2. Frequently asked questions

2.1 Assessing risk

What is the meaning of risk?
Proposals should be considered in the context of the risks of the project. Ethics scrutiny should be proportionate to the level of risk and appetite for risk in the specific context of the research proposed and its potential benefits. Risk is often defined by reference to the potential physical or psychological harm, discomfort, stress or reputational risk to human participants (and participating groups, organisations and funders) 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 participant'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, though it may carry no physical risk, can be disruptive and damaging to research participants as individuals or to whole communities or categories of people, such as those with HIV infection.

Can all risks be avoided?
Not all risks can, or in some cases should, be avoided, but it is important that researchers and RECs develop awareness of potential risks. Such risks may be difficult or impossible to quantify or anticipate in full prior to the start of a research project, especially in longitudinal, ethnographic research and research taking place in other countries. Nevertheless, researchers should endeavour to determine possible risks and their management (not least through the methodological strategy and instruments they adopt) prior to the start of a project, which may then require more formal ethics review. The FRE case studies (http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx) illustrate how different projects carry potentially different risks, and how these can be usefully identified through questions that help anticipate ethics difficulties.

Research projects that involve researchers from more than one discipline can include further risk, especially where the research team includes researchers from non-social science areas or non-academic research organisations. For example, social science researchers working with medical researchers who undertake qualitative research as part of a non-clinical trial should be aware of potential risks when working in interdisciplinary research. The form of vigilance required for the management of physical risk used in medical or biomedical research is inappropriate for the management of the social risks that may be present in social science research. RECs should provide guidance and advice to researchers about ways in which risks can be minimised and participants protected from harm, while at the same time offering advice on the prioritisation and different degrees of risk.

How do you inform participants of potential risks?
Once potential risks have been identified, researchers should ensure that these are discussed with research participants in order to secure valid consent. When presented with sufficient information individuals will usually be able to use reasoned judgment to decide whether or not they wish to participate. There is also therefore the need to ensure that potential participants have the capacity to understand the consequences (and risks) of

participating in order to give valid consent. 'Capacity' is legally defined under the terms of the Mental Capacity Act 2005 and the Adults with Incapacity (Scotland) Act 2000, and any projects that involve participants who fall under these Acts must be reviewed by a 'recognised' REC operating under the GAfREC (http://www.ukbiobank.ac.uk/ethics/) or Scotland 'A' REC. The Mental Capacity Act 2005 applies to 16-17 year olds and adults (18 years and over) who lack capacity to make decisions because of an impairment, mental disorder or 'disturbance in the functioning of the mind and brain'. Guidance on the Mental Capacity Act notes that lack of capacity to make a decision may be permanent or temporary. It could be state-related (eg due to drug or alcohol use, or because of the person's emotional state at the time). 'Intrusive' research involving people without capacity to consent should comply with the specific provisions for research (Sections 30-33 of the Mental Capacity Act 2005) in order to be lawful. Intrusive procedures are defined as the ones requiring consent in law, including the use of personal information. Code of Practice under the Adults with Incapacity Act clarifies that 'an adult does not have impaired capacity simply by virtue of having an addiction, psychotic illness or learning difficulties and disabilities' (p.6). The Scottish Act states that the wishes of the individual should be taken into account and any intervention should benefit the individual (Section 51 of the Adults with Incapacity (Scotland) Act 2000). The key point for both Acts is that valid consent can only be secured if the participant has capacity to make a decision at the time consent is sought. (see Department of Health, Mental Capacity Act 2005 and consent for research (http://www.wales.gov.uk/dhss/publications/health/mentalhealth/mentalcapacityact/2117019/mcaconsente.pdf?lang=en) and Adults with Incapacity Act 2000- Code of Practice, Part 5 (http://www.scotland.gov.uk/Publications/2010/10/20153801/4)).

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

What happens when risks only become apparent later in the research?
All research can develop in ways that raise unforeseen ethics implications. Ethics training provided by ROs should ensure that researchers are able to identify ethical issues throughout the lifecycle of the research. RECs should have mechanisms that make some provision for future advice and guidance beyond the initial ethics review process, such as advisory panels, attached to individual projects, as well as referral back to RECs. The nature and likelihood of unanticipated risks will depend on the research design and

methodology, but it is expected that all researchers should give attention to the potential for unanticipated ethics considerations to arise in the course of their research.

What are the risks in disseminating findings?
The media can be very helpful in disseminating findings, but the possible impact on research participants, their families and organisations, and populations from which the sample is drawn needs to be thought through, particularly where anonymity may be jeopardised or where there is potential for stigmatisation of individuals or groups or of misuse or misrepresentations of research findings (eg to further political agendas).

For example, descriptions of participants (eg in case studies) need to take care to ensure that they do not risk making those who take part identifiable, particularly if sample sizes are small or participants have distinctive characteristics that may make them recognisable. In some cases, for example in elite interviews, participants may wish to have their views expressed but researchers need be to alert to the original understanding of the person interviewed. Did they know what would happen to the findings? Have they given permission for their name to be identified and if not what steps are possible to anonymise the data? The Data Protection Act research exemption is relevant here, because the exemption cannot be claimed if data subjects will not be anonymous when findings are published (See Section 33 of the Data Protection Act- A practical note for researchers (www.adls.ac.uk/wp-content/uploads/2011/04/Section-33-of-the-DPA-a-practical-note-for-researchers.pdf)).

What is the impact on other areas of participants' lives, such as their families and careers? Did they give permission for the material to be data archived or shared with other researchers? Political sensitivities may arise when findings are contrary to local or national policy. It may be important to publish critical findings about policies and organisations, but was this within the original remit of the research? Were participants aware that this could be a consequence of their participation? When working with commercial and government organisations, principal investigators should look carefully at the forms they are asked to sign concerning possible publication of the findings. Researchers should be particularly careful in publishing and using information about third parties.

2.2 Consent

What is informed consent?
Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion (see below) so that prospective participants can make an informed and free decision on their possible involvement. Information should be provided in a form that is comprehensible and accessible to participants, typically in written form (or in a form that participants can access after the end of the research interaction), and time should be allowed for the participants to consider their choices and to discuss their decision with others if appropriate. The consent forms should be signed off by the research participants to indicate consent.

Where participants are in a potentially vulnerable or dependent position (eg children) it is important to ensure that they have the time and opportunity to access support in their decision-making, for example by discussing their choice with a trusted adult. Where consent is sought from children it is normally good practice to secure permission from a

responsible adult in addition to child consent. Where participants are not literate verbal consent may be obtained, but this should wherever possible include a recorded written witness sign-off. In other circumstances, for example telephone interviews, this may not be possible. Where consent is not to be secured, a full statement justifying this should be submitted to the REC for review. In longitudinal research and data archiving it may be necessary to explain the need for (and limitations of) enduring consent (see Appendix C for a definition); it may also be necessary to re-negotiate consent during the lifetime of the research. If this is anticipated it is imperative to put in place procedures for maintaining contact with participants.

A primary objective is to conduct research openly and without deception. Deception (ie research that deceives or purposely misleads or misinforms the participants about the nature of the research) should only be used as a last resort when no other approach is possible and where it is crucial to the research design. However any departure from a consent approach should be fully justified and a protocol developed for full debriefing of participants. Any research potentially involving deception should be submitted to the REC to be reviewed. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them and to participants.

In some areas of research, particularly in facilitating biobank research, participants are asked to provide broad consent. This approach means that participants consent to a framework for future research of certain types, not just to consent for a particular project.

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

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

Research participants, however, may be given small monetary reimbursement for their time and expenses involved. Payment should not override the principles of freely given and fully informed consent. Participants should know before they start the research that they can withdraw from the study at any time without losing their payment. In some instances it may be justified to use techniques such as a free prize draw or book or gift vouchers to encourage survey responses. Respondents should not be required to do anything other than agree to participate or return a questionnaire to be eligible to a free prize draw; it should be clear that potential participants can enter the prize draw even if they don't answer the questions in the survey, and incentives should not be offered that require the respondent to spend money. If you are planning to use this approach the Market Research Society (https://www.mrs.org.uk/standards/downloads/2008-01-18%20Incentives%20and%20Free%20Prize%20Draws.pdf?SESSID=hbt5j57mhnb2vrs0pfsrs2hma0) has published useful guidelines on using free prize draws. Where children are involved, it is often appropriate to acknowledge their help with personal gifts, for example gift vouchers or gifts to participating schools. Incentives may be permissible, but anything which implies coercion is not.

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

Do participants have a right to withdraw consent?
In giving consent, participants have as mentioned above the right to withdraw consent as well as the right not to answer particular questions. All research should indicate the point at which data will have been anonymised and amalgamated and in certain circumstances cannot then be excluded. Some projects give a date after which participants cannot withdraw consent or ask for data destruction. If data are to be archived and shared, participants need as far as possible to give specific consent. The researcher should take into account the long-term use, including the potential for data linkage and preservation of data when obtaining consent. In some cases it may not be appropriate to archive data, but this should be discussed with an appropriate ESRC data service provider, for example the UK Data Service.

What if it is not possible to obtain informed consent?
Informed consent may be impracticable or meaningless in some research, such as research on crowd behaviour, or may be contrary to the research design, as is sometimes the case in psychological experiments where fully informed consent would compromise the objective of the research. In some circumstances (such as when users of illegal drugs and illegal groups are involved) written consent might also create unnecessary risks for research participants. Even in this last case a researcher should seek informed consent where possible to secure the trust and confidence of those involved, but care must be taken to ensure than consent processes (eg asking for written signatures) do not pose risks to participants. Such circumstances may encourage the researcher to seek valid consent from participants, which ensures they are capable of understanding the potential risks involved within the research. 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.

Covert research may be undertaken when it may provide unique forms of evidence that are crucial to the research objectives and methodology or where overt observation might alter the phenomenon being studied. The broad principle should be that covert research should not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance which cannot be uncovered in other ways are likely to be discovered. Normally, social scientists should ensure that research participants are aware of and consent to arrangements made with regard to the management and security of data, the preservation of anonymity, and any risk that might arise during or beyond the project itself, and how these might be minimised or avoided. Disciplinary professional ethics codes may be helpful here. Where the research design is

such that valid consent cannot be obtained from participants before data is gathered, REC review of the protocol should take place at the highest level. Wherever practically possible participants should be fully debriefed about the true aims and objectives of the research and given the opportunity to withdraw their data from the study (eg experimental studies involving deception). Researchers should also ensure they have received the relevant permission from gatekeepers where necessary to undertake the research, for example from the relevant public sector organisation to undertake research on public sector property.

How do you obtain consent from potentially vulnerable people?
In cases where research involves potentially vulnerable groups, for example children, older persons or adults with learning disabilities (for those who fall under the remit of the Mental Capacity Act 2005/ Adults with Incapacity (Scotland) Act 2000 see below), every effort should be made to secure actively given informed consent from individual participants. Passive assent, including group assent (with consent given by a gatekeeper) should be avoided wherever possible, and every effort should be made to develop methods of seeking consent that are appropriate to the groups being studied, using expert advice, support and training where necessary.

In the case of research on children, one cannot expect parents alone to provide 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). Researchers should consider whether mature children can confirm consent without adult approval, for example there may be circumstances where seeking consent from parents could jeopardise the research (for example, in research into teenage sexuality or alcohol use). In such circumstances, researchers will need to regard the potential risk to the principal participants of the research as a priority.

How do you obtain consent from participants who fall under the Mental Capacity Act 2005/ Adults with Incapacity (Scotland) Act 2000?
In the case of research with adults who lack capacity to make a decision under the terms of the Mental Capacity Act 2005 (http://www.legislation.gov.uk/ukpga/2005/9/contents) and Adults with Incapacity (Scotland) Act 2000 (http://www.legislation.gov.uk/asp/2000/4/contents)**,** these projects must be reviewed by a 'recognised' REC or Scotland 'A' REC (Code of practice Mental Capacity Act 2005 (www.opsi.gov.uk/acts/acts2005/related/ukpgacop_20050009_en.pdf) and Adults with Incapacity (Scotland) Act 2000 (http://www.scotland.gov.uk/Publications/2010/10/20153801/0)).

The Mental Capacity Act states that researchers should assume that a person has capacity to make a decision; unless there is proof that they do not have capacity to make a specific decision, and that a potential participant must receive support to try to help them make their own decision. The potential participant has the right to disagree with the decisions that others (such as relatives or carers) might make.

If it is established that an adult does not have the capacity to decide whether to participate, the Mental Capacity Act 2005 requires that the researcher must consult with a specified consultee as set out in the Guidance to the Act (2008). If possible, this should be a personal consultee. The researcher should take reasonable steps to identify someone

who knows the person well who lacks capacity to make a decision, but is not a professional or paid care worker; this does not include family members receiving some of the person's pension or other benefits as a payment towards their share of the household expenses. The guidance states that it should be someone whom the person who lacks capacity to make a decision would trust with important decisions about their welfare. Thus, a personal consultee could be a family member or close friend of the person.

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

2.3 Medical research

The Adults with Incapacity (Scotland) Act (http://www.legislation.gov.uk/asp/2000/4/contents) states that any medical research or treatment should benefit the individual and such benefit will not be reasonably achieved without the intervention. The past and present wishes of the individual should be taken into account (by any methods of communication), and consent should be obtained by the closest relative or person with relevant powers (eg welfare attorney).

What happens when research involves tissue samples (including blood)?
UK research involving human tissue (including blood) is subject to the Human Tissue Act 2004, or The Human Tissue (Scotland) Act 2006, and should adhere to the Codes of Practice issued by the Human Tissue Authority. Ethics review should be obtained from a REC operating to the standards set out in the governance arrangements issued by the UK Health Departments or other ethics committees for clinical trials of investigational medicinal products recognised by the United Kingdom Ethics Committee Authority (UKECA).

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

What happens when research is undertaken with medical clinicians?
Initially, a light-touch review by the RO's REC should identify those projects that need to be reviewed by an NHS REC (through HRA (http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/)) regardless of the level of risk. Such projects will involve any of the following groups: NHS patients and service users and their families (including carers and past patients, if identified through NHS records). Research involving NHS and social care staff who are recruited as research participants by virtue of their professional role may require NHS REC review only if they raise significant ethical issues. Please see the HRA approval decision tool (http://www.hra-decisiontools.org.uk/ethics/).

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

2.4 Internet-mediated research

Why should internet research receive full ethics review?
In a fast developing area RECs may need to involve an independent expert in assessing research proposals that break new ground. Internet research can take place in a range of settings, for example email, chat rooms, web pages, social media and various forms of 'instant messaging'. These can pose specific ethical dilemmas.

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

Researchers, research participants and reviewers of research ethics will often encounter new or unfamiliar ethics questions and dilemmas. There is a growing literature on ethics in online research. A good starting point is the Association of Internet Researchers 2012 (http://aoir.org/ethics/) report and the BPS 'Ethics Guidelines for Internet-mediated Research' 2013 (www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf).

2.5 Research governance

The RCUK Policy and Guidelines on Governance of Good Research Conduct (http://www.rcuk.ac.uk/Publications/researchers/grc/) is a requirement of all Research Councils, and provides guidelines on necessary provisions. The UK Research Integrity Office Code of Practice for Research (http://www.ukrio.org/publications/) and the European Code of Conduct for Research Integrity (www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf) are reference tools for ROs to use when revising their codes of practice for research, complementing existing guidance on research conduct, such as that provided by Research Councils UK, the Wellcome Trust and the Council for Science and Technology. The UK

Research Integrity Office Code of Practice for Research also includes a one-page recommended checklist for researchers: a non-technical checklist summarising the key points of good practice in research, based upon the more detailed standards provided in the Code. Use of the benchmarks contained in the Code can assist ROs in fulfilling the requirements of regulatory, funding and other relevant bodies. The UKRIO checklist (http://www.ukrio.org/publications/code-of-practice-for-research/) may be used by RECs in addition to their own REC forms.

Appendix A: Example research ethics initial checklist

An ethics checklist should be completed for every research project. It is used to identify whether a full application for ethics review needs to be submitted. Below is an example of an ethics checklist for reference only. Research Organisations (ROs) will have their own checklist and procedures in place for submitting proposals to their Research Ethics Committees.

Before completing a checklist please refer to the appropriate RO's 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 judgment in determining the ethics review required.

An appropriate checklist should be completed before potential participants are approached to take part in any research.

Project details: Project title				
Applicant details: Name of researcher (applicant)	Role:			
Contact address				
Email		Telephone		
For students only				
Module name and number or MA/MPhil course and department				
Supervisor's or module leader's name:				
Research ethics initial checklist Please answer each question by ticking the appropriate box:				
			Yes	No
Research that may need to be reviewed by NHS Research Ethics Committee or another external ethics committee (if yes, please give brief details as an annex)				
Will the study involve recruitment of patients or staff through the NHS or the use of NHS data or premises and/or equipment?				
Does the study involve participants age 16 or over who are unable to give informed consent? (eg people with learning disabilities: see Mental Capacity Act 2005/ Adults with Incapacity (Scotland) Act 2000. All research that falls under the auspices MCA/AWI should be reviewed by a recognised and appropriate REC operating under GAfREC or Scotland 'A' REC).				
Research that may need a full review				
Does the research involve other potentially vulnerable groups: children, those with cognitive impairment, or those in unequal relationships? (eg your own students)				
Will the study require the co-operation of a gatekeeper for initial				

access to the groups or individuals to be recruited? (eg employees, students at school, members of self- help group, residents of nursing home?)			
Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non- public places, use of deception in experimental studies)			
Will the study involve discussion of sensitive or potentially sensitive topics? (eg sexual activity, drug use, personal lives)			
Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind?			
Will tissue samples (including blood or saliva) be obtained from participants?			
Is pain or discomfort likely to result from the study?			
Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?			
Will the study involve prolonged or repetitive testing?			
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?			
Is there a possibility that the safety of the researcher may be in question? (eg lone working in international research)			
Does the research involve members of the public in a research capacity (participant research)?			
Will the research take place outside the UK?			
Will the research involve internet participants or other visual/vocal methods where participants may be identified?			
Will research involve the sharing of data or confidential information beyond the initial consent given?			
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?			
Principal investigator:			
Signed:	Date:		
Supervisor or module leader (where appropriate):			
Signed:	Date:		

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

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

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

Please note that it is your responsibility to follow the RO'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 Faculty/School Research Ethics Officer and may require a new application for ethics review.

Points to consider when planning research

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

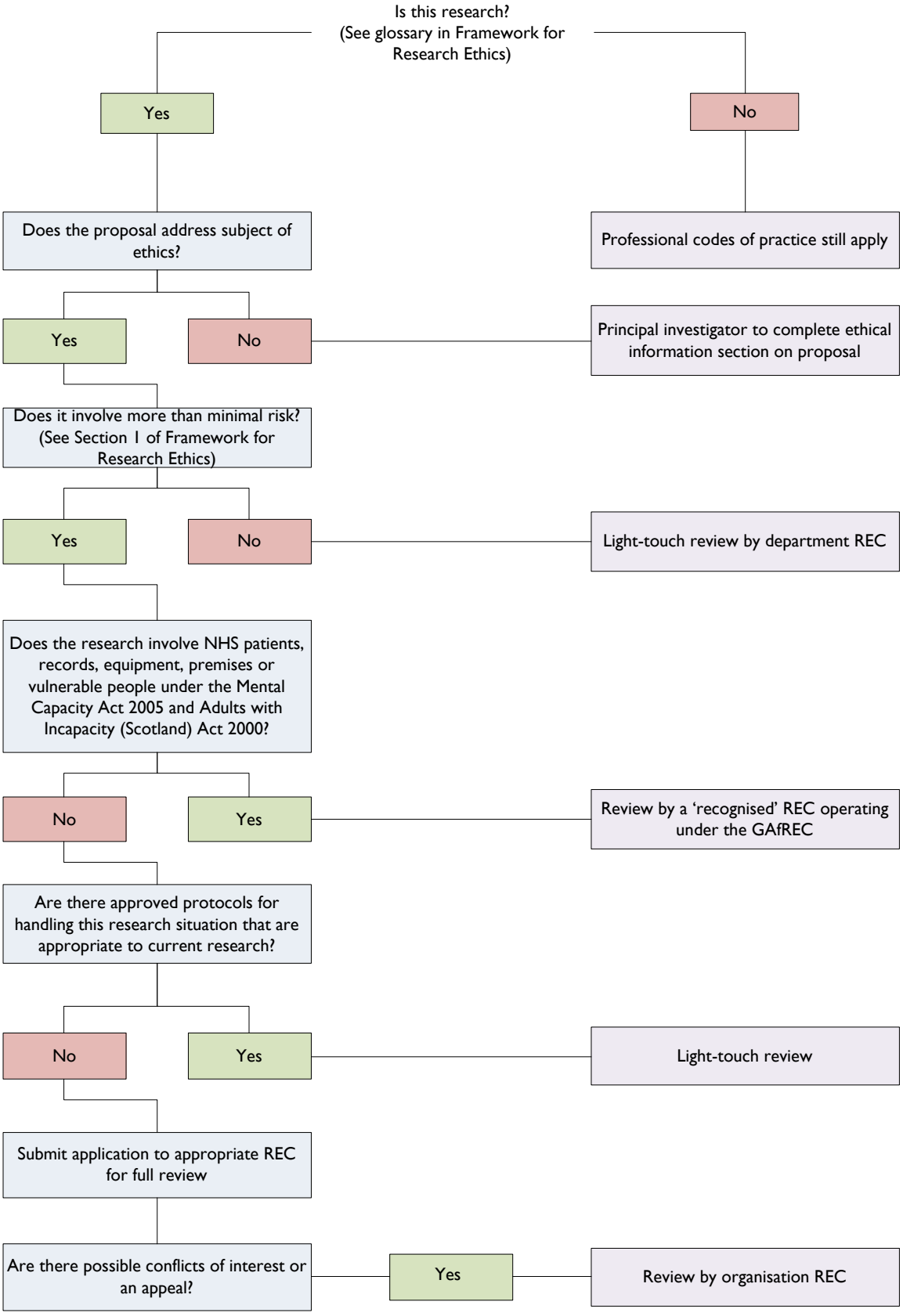
Further information on the issues raised in this list can be found in the main body of the framework as well as in ethics guidelines from Learned Societies and subject-specific guides. Please see Appendix D for links to websites that may be useful.

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

- Have you considered risks to:
    - the research team
    - the participants eg harm, deception, impact of outcomes
    - the data collected eg storage, considerations of privacy, quality
    - the ROs, collaborators, project partners and funders involved
    - anyone else be put at risk as a consequence of this research
- What might these risks be?
- How can these risks be addressed?
- How will you protect your data at the research site and away from the research site?
- Details and recruitment of participants:
    - What types of people will be recruited? Eg students, children, people with learning disabilities, elderly
    - How will the competence of participants to give informed consent be determined?

    - How, where, and by whom participants will be identified, approached, and recruited?
    - Will any unequal relationships exist between anyone involved in the recruitment and the potential participants?
    - Are there any benefits to participants?
    - Is there a need for participants to be de-briefed? By whom?
- What information will participants be given about the research?
- Who will benefit from this research?
- Have you considered anonymity and confidentiality?
- How will you store your collected data?
- How will data be disposed of and after how long?
- Are there any conflicts of interest in undertaking this research, eg financial reward for outcomes?
- Will you be collecting information through a third party?
- Have you considered consent?
    - If using secondary data, does the consent from the primary data cover further analysis?
    - Can participants opt out?
    - Does your information sheet (or equivalent) contain all the information participants need?
    - If your research changes, how will consent be renegotiated?
- Have you considered ethics within your plans for dissemination/impact?
- Are you conducting research outside the UK? Are there any additional issues that need to be considered as a result? eg local customs, local 'gatekeepers', political sensitivities?
- Which Ethics Committee is most appropriate for your research?
- Have you considered the time you need to gain ethics review?
- Have you considered what legal requirements your project will need to abide by? Eg Data Protection Act, Freedom of Information Act, Human Rights Act
- How will the ethics aspects of the project be monitored throughout its course?
- Is there an approved research ethics protocol that would be appropriate to use?
- How will unforeseen or adverse events in the course of research be managed? Eg do you have procedures to deal with any disclosures from vulnerable participants?
- Have you considered data management and curation? What measures have been taken to ensure confidentiality, privacy and data protection during and beyond the end of the project and to encourage data sharing and linkage? See the ESRC Research Data Policy.

Appendix B: Example flowchart of review process



Appendix C: Key terms glossary

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

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

Biobank (research tissue bank (http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/)): A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project.

Biosocial Research: The interdisciplinary interplay between biology, experiences and behaviours over the course of life. This encompasses multi-disciplinary science from the fields of biological, medical and social sciences.

Broad consent: has been seen as essential to facilitating biobank research. Participants are asked to consent to the use of samples and data within a biobank, at the time of collection rather than to a specific project or types of research. Broad consent means consenting to a framework for future research of certain types. Included in this framework is ethics review of each specific research project by an independent ethics committee as well as strategies to update regularly the biobank donor and ongoing withdrawal opportunities. If anything in the framework changes, the participant should re-consent.

Controlled data: are data which may be identifiable and thus potentially disclosive but to which access may be granted to users who have been accredited and their data usage has been approved by a relevant Data Access Committee. Data service providers may provide details of their policies regarding access to controlled data, for example the UK Data Service (http://ukdataservice.ac.uk/get-data/data-access-policy/controlled-data.aspx).

Data Custodian (Data Controller): is a person who determines the purposes for which and manner in which any personal data are to be processed in line with the Data Protection Act (https://ico.org.uk//for-organisations/guide-to-data-protection/).

Data Depositor/Data Producer: A data depositor/data producer is an individual or organisation who is named on a license as having sufficient responsibility to grant particular rights on behalf of a data collection. The depositor/producer may be the principal investigator, creator or the copyright owner of a data collection, but does not have to be.

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

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

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

ESRC data service providers: Organisations funded by ESRC to coordinate with data owners to provide access to data. This may be purchased, created or deposited for re-use (eg the UK Data Service (http://www.ukdataservice.ac.uk/)) or obtained and linked for specific approved projects (eg the Administrative Data Research Network (http://www.adrn.ac.uk/)). ESRC data service providers may also provide user support, training and strategic data related advice.

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

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

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

Freely-given informed consent: Informed consent entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement. Typically, the information should be provided in written form, time should be allowed for the participants to consider their choices and the forms should be signed off by the research participants to indicate consent. Where participants are not literate, verbal consent may be obtained but this should wherever possible be witnessed and

recorded. In other circumstances, for example telephone interviews, written or witnessed consent may not be possible, but verbal consent should be secured. Where consent is not to be secured, a full statement justifying this should be submitted to the REC for review. In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent. The primary objective is to conduct research openly and without deception. Deception (i.e. when participants are intentionally not fully informed or are misinformed about the purpose of the research for methodological reasons) should only be used as a last resort when no other approach is possible. Any research involving deception should be submitted to the REC for review. This principle also requires that research staff need to be made fully aware of the proposed research and its potential risks to them.

Lay member (of a REC): This person should have no affiliation to the RO apart from membership of the REC and may provide the perspective of the research participant to the REC.

Light-touch review: All ESRC-funded research should undergo at least a light-touch review. Light-touch reviews identify those projects where the potential for risk of harm to participants and others affected by the proposed research is minimal. In many cases this is the only ethics review necessary. An RO ethics checklist (see Appendix A for an example), should be completed for all social science research projects. RECs need to confirm that only a light-touch review is justified.

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

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

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

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

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

Research project lifecycle: includes the planning stage, the period of funding for the project and all activities that relate to the project once funding has ended. The research lifecycle also includes knowledge exchange and impact realisation activities, the dissemination process and the archiving, future use, sharing and linking of data.

Transparency in research ethics: The full, accurate, and open disclosure of relevant information is always important. Where the research involves new and innovative methodologies which raise distinctive considerations (eg online research), this is especially important.

Valid consent: Consent is valid if it meets three conditions: participant has capacity to make a decision; the process is free from coercion; and the consent is informed. For consent to be 'valid' the participant must be capable of understanding all the potential risks involved. Where this may be in doubt, the Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000 may apply (see Appendix D).

Appendix D: Useful links including professional ethics codes and relevant legislation

Requirements for ESRC-funded research

- Research Councils UK (RCUK) Policy and Guidelines on Governance of Good Research Conduct (2013) www.rcuk.ac.uk/publications/researchers/grc
- The Concordat to support research integrity (2012) www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx
- ESRC Research Data Policy (2015) www.esrc.ac.uk/about-esrc/information/data-policy.aspx
- ESRC Postgraduate Funding Guide (2014) www.esrc.ac.uk/funding-and-guidance/postgraduates/esrc-students/index.aspx
- ESRC Research Funding Guide (2014) www.esrc.ac.uk/funding-and-guidance/applicants/research-funding-guide.aspx
- ESRC Administrative Data Research Network – Protecting Privacy (2015) http://www.adrn.ac.uk/protecting-privacy
- UK Data Service advice on managing and sharing data (2014) http://ukdataservice.ac.uk/manage-data.aspx

Professional ethics codes and guidelines

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- HRA guidance for applicants and research community www.hra.nhs.uk/research-community/
- HRA decision tool (MRC/HRA): www.hra-decisiontools.org.uk/ethics
- HRA Application process Flowchart www.hra.nhs.uk/documents/2014/05/rec-application-process-flowchart-v6-0-19-may-2014.pdf
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- Social Care Research Ethics Committee www.screc.org.uk
- Wellcome Trust Biobank Ethics and Governance Framework www.wellcome.ac.uk/about-us/publications/reports/biomedical- ethics/wtd003284.htm

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- Information Commissioner's Office (2014). Data Controllers and data processors: what the difference is and what the governance implications are https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf
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- Disclosure Scotland www.disclosurescotland.co.uk/index.htm
- Access Northern Ireland www.dojni.gov.uk/accessni
- Freedom of Information Act 2000 www.legislation.gov.uk/ukpga/2000/36/contents
- JISC FOI and Research Data http://webarchive.nationalarchives.gov.uk/20140702233839/http://www.jisc.ac.uk/publications/programmerelated/2010/foiresearchdata.aspx#downloads
- Information Commissioner's Office. How to access information from a public body https://ico.org.uk/for-the-public/official-information/
- Information Commissioner's Office. Guide to freedom of information https://ico.org.uk/for-organisations/guide-to-freedom-of-information/
- The National Archives. Making a freedom of information request http://apps.nationalarchives.gov.uk/foi/requests.htm

- Freedom of Information (Scotland) Act 2002 www.legislation.gov.uk/asp/2002/13/contents
- Health and Social Care Act 2008 www.legislation.gov.uk/ukpga/2008/14/contents
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- Human Tissue Act 2004 www.legislation.gov.uk/ukpga/2004/30/contents
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Appendix E: Example of ethical information in ESRC proposal

Proposals submitted to the ESRC should provide a full ethics statement that confirms that proper consideration has been given to any ethics issues which the proposal raises. All ESRC-funded research should be approved by at least a light-touch ethics review.

The ESRC does not require the ethics review to be completed prior to submission of a research proposal. However, a proposal should state what the applicant considers to be the possible ethical implications of the research, what measures will be taken for ongoing review of ethics issues throughout the project lifecycle, what ethics review will be required for their proposed research and how it will be obtained. If an ethics review is required at a later stage in the project, this should be discussed and funding arrangements agreed in advance with the ESRC. At a minimum we expect that ethics review will be completed prior to the stage in the project that the research will be undertaken.

During review, peer-reviewers and other introducers will be asked to consider the ethical information section in the proposal. If they disagree with the proposed approach to ethics issues, or the statement does not adequately address ethics issues, this could lead to the rejection of a proposal, or the making of a conditional award based upon their assessment of the necessary ethical considerations within the proposal and the intended ethics review.

Example of a completed Ethical Information section on ESRC proposal

Super-diverse Streets: Economies and spaces of urban migration in UK Cities
The 'Super-diverse Streets' project, led by Dr Suzanne Hall, is a multidisciplinary, comparative analysis of 'super-diverse' high streets that aims to explore how urban retail economies and spaces are shaped by and shape migrant entrepreneurial practices. The project focuses on five high streets within the UK's most diverse cities, including London, Leicester, Manchester, Birmingham and Bradford. The overarching objective is to define and analyse the 'super-diverse' high street as a complex urban assemblage: to explore connections between the diverse origins and networks of the shop proprietors; their range of retail activities and practices; and the spatial infrastructure that supports and is altered by their endeavours. In developing a comparative evidence base, the research aims to input into policy on high street futures, and to contribute more broadly to understanding how migration transforms our streets and cities.

Ethical Considerations
This research project will be conducted with full compliance of research ethics norms, and more specifically the codes and practices established in the British Sociological Association's Statement of Ethical Practice and the LSE Research Ethics Policy. The research will involve human participants, commencing with a face-to-face/ door-to-door survey of the proprietors of each of the streets. In the second year of study, focus group workshops will be held with local authority officers and members, and trade associations and relevant local organisations associated with each street. As principal investigator I will take core responsibility to explain, in appropriate detail, what the research is about to participants. Every research participant will be given a one-page 'project information sheet' that outlines the purpose of the study, who is undertaking and financing the study, and

how it will be disseminated and used.

The project information sheet will include contact information should participants require additional information or wish to retract information or withdraw participation at any point and will also explain how anonymity and confidentially is afforded. Where necessary, the project information sheet will be translated, although it is anticipated that English will be the lingua franca. Participation in the research will be voluntary, and informed consent will be discussed with all participants. However, it is anticipated, particularly in the street surveys, that verbal as opposed to signed consent, will be more readily obtainable.

The first stage of data collection involves a socio-economic and spatial survey of a multi-ethnic street in each respective city. Each shop unit is given a tracking code to relate the GIS spatial position to the survey material. Personal identifiers are removed and the anonymity of participants will be secured through both research unit codes and pseudonyms. The raw data of each street survey will be collated in password protected computers and accessed by the principal investigator and the two research assistants. The data will then be systematised and stored in two password-protected external storage drives, since the digital and visual data generates large storage requirements. Storage drives will be stored in the secure office of the principal investigator.

The second stage of data collection involves focus group workshops related to two of the selected streets. The workshops will be arranged with respective local authorities, traders and local organisations to understand how these streets are organized, managed and imagined. For this stage of research I will work alongside 'Social Life', a social enterprise created by the Young Foundation. We will establish a specific ethics protocol for this stage of research, drawing on Social Life's extensive expertise in working with local authorities, community organisations and frontline agencies, and submitting the protocol for review to the LSE Research Ethics Committee. Time has been allocated prior to the workshops, to meet with relevant authorities and associations to develop appropriate workshop forums, and to review approaches to participation, confidentiality and dissemination. Feedback on workshop findings will be offered to local authorities and associations through a summary report. More generally, participants will be able to view project information and findings on the 'Superdiverse streets' online project pages.

In sum, for all stages of research dependent on research participants, I will submit an Ethics Review Questionnaire for Researchers to the LSE Research Ethics Committee, which operates in accordance with the ESRC Research Ethics Framework.