



City, University of London
Senate Research Ethics Committee
Framework for Delegated Authority

SUMMARY OF CONTENTS

1. Introduction
2. Principles of research ethics
3. Aims of this document
4. Senate Research Ethics Committee
5. School/Department Research Ethics Committees
6. External researchers/approvals
7. Participant information sheets/informed consent
8. Advertisements/flyers

1. Introduction

This Framework for Delegated Authority applies to all research undertaken by staff and students (undergraduate, taught postgraduate and research), and all research carried out in City, University of London, or under the auspices of City, University of London, with the exception that the authority to approve research involving animals is not delegated to School/Departmental committees but is required to be reviewed by Senate Research Ethics Committee (“SREC”) in accordance with the [policy on animal research](#).

The Framework sets out the rules and regulations governing research involving human participants, materials and/or data not in the public domain under the auspice of City, University of London (“City” or “the institution”), and the requirements for approving research proposals by City’s Schools, Departments, Divisions and Centres under the Framework. (Henceforth references to Department(s) should be taken to include Division(s) and Centre(s).)

Following a review of existing procedures for addressing ethical issues in Schools/Departments, a system of delegated authority has been implemented across City, in order to develop a coherent and consistent approach. The system has been designed to take into account the varying concerns and needs of different Schools/Departments and the likelihood of harm to participants of the research carried out in the various subjects.

All Schools have delegated power of authority from SREC to review and approve research ethics applications and are expected to refer all research either to a committee within the School/Department (or to a committee within another School where appropriate) or to SREC for consideration. City does not insist on Schools

setting up local sub-committees of SREC where the volume of research is minimal, but policies and procedures to address research involving human participants, materials and/or data not in the public domain must be in place and agreed with SREC.

In Schools and Departments where local committees have been set up, these are required to follow City guidelines as well as nationally and internationally accepted practices.

The Framework for Delegated Authority has been developed to ensure that all research involving human participants undertaken by staff and students at City and under its auspices undergoes appropriate and proportional review. City expects its staff and students to seek to maintain the highest achievable standards in their research conduct and as part of this to consider the ethical implications of their research.

City derives its ethics policy from ethical considerations identified by various recognised bodies, including the World Medical Association's Declaration of Helsinki, the Economic and Social Research Council's (ESRC) Framework for Research Ethics, the Health Research Authority (HRA) and other relevant institutions and professional bodies.

2. Principles of research ethics

In addition to the scientific rigour of a project and the conduct of the researcher(s), projects should be ethical and in particular safeguard any participants and/or their data, and the researcher(s). Ethical issues are many and varied and may be quite complex. It is recognised that there are differences between disciplines, but all research should be guided by the principle that the risk of harm to the participants should be minimised, and as far as possible the benefit to the participants and/or society should be maximised.

City subscribes to the six key principles identified in ESRC's Framework for Research Ethics¹:

- Research should aim to maximise benefit for individuals and society and minimise risk and harm.
- The rights and dignity of individuals and groups should be respected.
- Wherever possible, participation should be voluntary and appropriately informed.
- Research should be conducted with integrity and transparency.
- Lines of responsibility and accountability should be clearly defined.
- Independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

¹ <http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/our-core-principles/>

It should be noted that while research ethics committees are not normally charged with reviewing the design and methodology of research projects, they must sometimes consider elements of these in order to assess the risks and benefits of a project. If a study design does not adequately attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is therefore no justification for inconveniencing people or potentially placing them at risk.

Research requiring external approval

Research involving NHS patients, research which falls under the Human Tissue Act, and research that involves participants who fall under the Mental Capacity Act must be reviewed and approved by an authorised HRA committee. Such projects will not require internal review, but a copy of the approval letter should be forwarded to the appropriate person(s) in the Department/School. Further details on what needs ethical approval by an HRA committee is available on their [website](#). Research involving prisoners, those on probation, the police and the courts system will need approval from the Ministry of Justice, the National Offender Management Service, the Courts, the Police and Prison Governors as appropriate. Researchers should familiarise themselves with the appropriate requirements. The [Offender Health Research Network](#) is a good starting point.

3. Aims of this document

This document sets out the formal agreement between SREC and each of the School/Department committees on:

- a) The code of research ethics principles that the School/Department committee uses for guidance (e.g. the ESRC Framework for Research Ethics, British Psychological Society Code etc.). This would cover such matters as the standard governing informed consent and the procedures for obtaining and documenting it.
- b) The procedures for scrutinising research ethics.
- c) The type of projects for which responsibility is delegated.
- d) The type of projects (and risks) for which referral to SREC is required.
- e) The minimum requirements for information sheets and consent forms.
- f) The formal and systematic reporting to SREC of all ethical decisions taken by delegated authority.

4. Senate Research Ethics Committee

SREC is ultimately responsible for research ethics across City and for overseeing adherence by local committees in Schools and Departments to the policies and procedures set out in this document. SREC reports directly to Senate.

SREC operates, with authority granted by Senate, to grant ethical clearance for research projects conducted by staff and students that require such consideration under the following terms of reference:

1. To consider the ethical implications of all research, experiments, investigations and procedures involving human participants, or animal subjects carried out in the institution or under the auspices of City.
2. To consider the ethical implications arising from research projects collecting, using and/or storing personal data carried out in the institution or under the auspices of City.
3. In connection with the above, to approve statements of practice for routine and emergency clinical procedures and other research, experiments, investigations and procedures routinely undertaken by appropriate departments of City.
4. To set standards, propose and review policy on the ethical conduct of research throughout City.
5. To approve School/Departmental delegation frameworks and procedures relating to research ethics.
6. To receive from individual members of academic staff, students, local Research Ethics Committees, Boards of Studies, or committees of Senate, proposals for all other research, experiments, investigations and procedures falling within its terms of reference and to allow, refer back or disallow such proposals, specifying where necessary any conditions subject to which proposals may be allowed.
7. To receive and advise on research proposals for the use of the name of the institution in connection with all aspects of research involving human participants, personal data or animal.
8. In carrying out its responsibilities, to seek and take account of all necessary advice from sources within and without City.
9. To report to Senate at least once annually on the research, experiments, investigations and procedures which have been allowed by the Committee through the Chair of the Committee.
10. To receive minutes and reports from Departmental/School Research Ethics Committees and to carry out spot checks on the effectiveness of procedures and standards adopted by the local committees.
11. To approve requests from external researchers wishing to recruit staff and students from City for participation in research projects.
12. To submit a copy of the minutes of each meeting to Academic Governance Committee.

5. School/Department Research Ethics Committees

All research involving human participants, materials and/or data not in the public domain requires ethical consideration. Even if the research is low risk, issues such as data protection, confidentiality and anonymity need to be considered.

It is recognised that, as a result of differing disciplinary practices, the nature of scrutiny required for projects varies between areas of the institution. SREC

recommends that these expectations are clarified in policies so that researchers, in particular student researchers, wishing to engage research participants in another area can adapt to them and not waste time on applications that are later refused by the other School/Department. Groups which are likely to be at risk of over-research can also be made known both within the School concerned and to other areas of City in order that projects involving these groups are not put forward for review and later rejected by another School/Department.

Ethical review must take place before any research involving human participants or identifiable personal data is undertaken. City's indemnity insurance will not cover research without approval. Failure to obtain approval at the appropriate time may result in disciplinary procedures being instigated. It may also lead to a breach of funding conditions and/or to publication of the research findings being prevented.

The level of review should be proportionate to the level of risk to the participants/researcher(s). For instance, a survey which is not collecting any personal details and is not asking intrusive or sensitive questions can be signed off by a supervisor or Head of Department where this is the documented procedure. Issues which need to be considered in all projects involving human participants or identifiable personal data include:

- Anonymity
- Confidentiality
- Informed consent
- Safety of the participant
- Safety of the researcher(s)
- Data protection
- Transportation of data
- Storage of data (where and how long)
- Destruction of data
- Re-use of personal data
- Complaints procedures
- In the case of international research, local legislation and requirements

For potential higher risk research (see examples below) a more rigorous review is required. The procedural requirements for Schools and Departments with potential higher risk research are outlined below. The procedures for reviewing lower level risk projects are outlined in the agreements between SREC and School/Department committees.

Examples of potential higher risk projects

- A study that involves participants who are vulnerable (including children), unable to give informed consent or are in a dependent position (e.g. those in care homes, students, employees, colleagues).

- A study that involves participants taking part without their consent or knowledge at the time or a study involving deception.
- A research topic that is highly sensitive and might lead to disclosures from the participant concerning their own involvement in illegal activities or other activities that represent a risk to themselves or others.
- A study which could induce psychological stress, produce humiliation or cause harm beyond the risks encountered in normal life.
- A study that involves drugs, placebos or other substances to be administered to the participants or involves invasive, intrusive or potentially harmful procedures.
- A study that carries a risk of harm (physical, mental or otherwise) to the researcher(s).

Retrospective approval

Retrospective approval of research protocols cannot be given.

School/Department committees are responsible for

- Ensuring that there are effective mechanisms to bring any policy, guidelines or procedures determined with or through SREC or a School/Department committee to the attention of staff and students. These mechanisms need to make clear that it is an institutional requirement that the policies, guidelines and procedures are followed;
- Keeping ethical issues in research under review;
- Managing and monitoring the procedures in practice;
- Ensuring that appropriate records of applications, practices and decisions are made and kept;
- Reporting on an annual basis, using the template provided to all School/Department committees, to Senate Research Ethics Committee, including the title of projects considered, applicant/project owner, category (e.g. staff, undergraduate, taught postgraduate and research students), abstract (this includes externally approved protocols indemnified by City, e.g. HRA-approved research), types of risks or issues that have been considered over the reporting period;
- To submit a copy of the minutes of each meeting to Senate Research Ethics Committee
- Conducting a two-yearly review of ethical procedures and policy and reporting on this to Senate Research Ethics Committee.
- Keeping a record of approvals where the committee has signed off the sponsorship form for research involving human participants which is subject to approval by an external body and where City is the sponsor of the research and also indemnifies the researcher.

Constitution and membership

It is recommended that all research ethics committees should include representation from experts, non-experts and, where possible, an independent/lay member (someone from outside the School/Department or external to City). Student participation is also expected. To help ensure consistency and to ensure that issues are brought to the attention of SREC, it is recommended that the Secretary to SREC should be appointed as an ex-officio member to each of the School/Department committees, allowing for the Secretary to attend from time to time.

Terms of reference under which research ethics committees should operate

- a. To consider research proposals from both staff and students of the School/Department involving human participants, human material and data;
- b. To give written approval for such proposals in the form of minutes or to provide written information on why approval has not been given;
- c. To keep a record of all applications, deliberations and decisions;
- d. To consider revised submissions;
- e. To consider amendments, modifications and extensions to approved research protocols;
- f. To refer to SREC cases which cannot be satisfactorily resolved or about which there is uncertainty;
- g. To operate procedures no less rigorous than those suggested or required by the institution and relevant professional bodies.

Requirements for modifying an approved application

Applicants will need to notify the approving body of any changes to the research project which may raise new ethical implications or issues and in some cases apply for approval of a modification to the research. Applicants will need to notify the approving body if any of the following apply:

- Adding a new category of participants.
- Adding a new/changing research method.
- Asking for additional data from the existing participants.
- Change of researchers involved in the project.
- An extension of approval (approval is valid for three years; applicants can then seek extensions for one year at a time).

The correct form should be used, available from City research ethics webpages [link].

Adverse events/incidents and/or breach of protocol/confidentiality

At the time of formally approving research protocols, committees should notify the researcher(s) that they are required to inform the approving committee and the Secretary to Senate Research Ethics Committee of any adverse events/incidents and/or breach of protocol/confidentiality as soon as possible and no later than 5 days after the event. Safeguarding issues relating to children and vulnerable participants must be reported immediately, as must any untoward incidents that affect the personal safety of a participant or researcher. Safeguarding issues relating

to children also needs to be reported to City's safe guarding officer. The correct reporting form should be used, available from City's research ethics webpages [link]. This does not absolve the researcher from reporting the event to other institutions where required, such as the Police or Social Services.

Appeals

City has a documented formal appeals process [link], but the School/Department should as far as possible deal with any issues arising from refusal of approval through informal negotiation and agreement between the researcher and the committee responsible for reviewing the application.

City defines an appeal in this regard as a request from an applicant for a review of a decision, in relation to significant amendments requested to or rejection of a research ethics application by the relevant committee.

The School/Department REC must inform the applicant in writing of the reason(s) for requesting significant amendments to or the rejection of the research ethics application. The applicant should then be given the opportunity to respond to the committee's comments, or be allowed to resubmit a revised application. It is recommended that a meeting between the Chair of the committee, one or two members of the committee, the researcher and the Secretary to the committee is arranged to discuss the protocol in order to resolve the issues.

Only in cases where agreement cannot be reached between the researcher and the School/Department REC should the appeal be taken forward to SREC under the formal institutional process [link].

6. Recruiting students/staff at City as research participants

Recruiting where approval has been obtained externally or external researchers wishing to recruit City staff and/or students

If a study has been given approval from another REC, for example another institution or an NHS REC, or the researcher is external to City and wishes to recruit participants (staff and/or students) from City, the applicant would not normally need to go through the full review process within City but should follow the guidelines for [external researchers](#) which also apply to City staff/students who have obtained external approval. Permission from the relevant Dean(s) of School(s) and/or Head(s) of Department(s) and the Chair of SREC must be obtained before the recruitment of staff and/or students can begin.

Recruiting staff and/or students for internally approved projects

Permission from the relevant Dean(s) of School(s) and/or Head(s) of Department(s) must be obtained before the recruitment of staff and/or students can begin.

7. Participant information Sheet/Informed consent

Regardless of the level of risk associated with a research project, all participant information sheets and consent forms are normally expected to follow the standard City templates, unless a justified case can be made for not doing so. The templates contain the minimum information which should be provided to the participants. If the research is not low risk, additional information may be required. Further details can be found on City's research ethics webpages [\[link\]](#).

8. Advertisements/flyers

Regardless of the level of risk associated with a research project, all advertisements and/or flyers are normally expected to use the template provided on City's research ethics webpages [\[link\]](#).

Research & Enterprise
City, University of London
V5 October 2016