

UCL Research Ethics Framework

Research undertaken in accordance with ethical principles constitutes good practice and this framework should be read in conjunction with the following documents:

- i. Guidelines for responsible practice in research
- ii. Procedures for investigating and resolving allegations of misconduct in academic research
- iii. Policy and guidelines for conflicts of interest.
- iv. UCL Research Ethics Committee: constitution and terms of reference; guidelines
- v. UCL animals ethical review process (under the Animals (Scientific Procedures) Act 1986)
- vi. UCL Museums and Heritage Committee, constitution and terms of reference
- vii. Policy, principles and procedures for the care and treatment of human remains at UCL

1. Introduction

- 1.1. UCL is committed to maintaining the integrity and probity of academic research and therefore regards it as fundamental that research should be conducted according to ethical guidelines defined by the wider research community. UCL interprets ethical issues broadly and considers that they include, *inter alia*: relevant codes of practice; the involvement of human participants, tissue or data in research; the use of animals in research; research that may result in damage to the environment; the use of sensitive economic, social or personal data; and the acquisition, storage and disposal of historical artefacts.
- 1.2. These guidelines should be followed by all UCL staff and students undertaking academic research at any location, including honorary staff. They also apply to other individuals who conduct research on UCL premises and/or who collaborate in specific projects with UCL staff or students. It is the duty of all those to whom these guidelines apply to bring any ethical issues relating to a research proposal or an ongoing project in which a new methodological or other approach is followed, to the attention of appropriate internal and external regulatory bodies.
- 1.3. Approval to undertake academic research which includes one or more of the activities referred to in paragraph 1.1. above must be granted before any work is commenced. UCL considers that failure to gain appropriate consent before starting a project, non-compliance with conditions specified by an approval body and making changes to a research project without notifying the relevant approval body, amount to research misconduct (please see UCL's *Procedures for investigating and resolving allegations of misconduct in academic research*) and may lead to appropriate disciplinary action.
- 1.4. All research undertaken at UCL and/or by UCL staff (including honorary staff) and students should conform to commonly agreed standards of good practice, such as: those defined in the Declaration of Helsinki; and publications produced by (i) Research Councils UK (RCUK) and its constituent research councils, (ii) other funding bodies, for example,

members of the Association of Medical Research Charities, (iii) and other national and international regulatory and governance bodies.

2. Research involving human subjects

- 2.1. All researchers who plan to undertake activity which will come under the remit of NHS research ethics committees should gain appropriate consent from such bodies before any work is carried out. All other academic research proposals which involve human subjects, including human tissues and storage of personal and sensitive information, should be considered by the UCL Research Ethics Committee.
- 2.2. UCL Research Ethics Committee provides guidance to researchers and responsible authorities to ensure that research involving persons is carried out safely, with considered consent and respect to the autonomy and privacy of the subjects and according to principles of distributive justice. All guidance which the Committee provides and decisions it makes are in accordance with the ethical principles set out in the Declaration of Helsinki, the guidelines of RCUK and the expectations of other relevant funding, statutory and regulatory bodies.
- 2.3. Any research which falls under the remit of the UCL Research Ethics Committee (and not under the remit of NHS-approved ethics committees), should first be approved by the UCL Research Ethics Committee before any work is commenced. If, in the course of a project approved by the UCL Research Ethics Committee, the method or nature of the research is revised, the project should be referred again to the UCL Research Ethics Committee for further consideration.
- 2.4. The UCL Research Ethics Committee is able to withhold approval from proposals within its scope and to set conditions with which research should comply. The UCL Research Ethics Committee also monitors any adverse effects in research subjects and undertakes regular reviews of research projects to which it grants approval (not less than once a year and more frequently if deemed appropriate).
- 2.5. Good practice dictates that the UCL Research Ethics Committee keeps appropriate records of all proposals submitted for consideration. Such records include information on whether the proposal was approved, whether there were any conditions associated with approval, the names and addresses of organisations approved to undertake the proposal, the financial sponsor, the name and qualifications of the research team, the research method and details of monitoring work undertaken.

3. Research involving animal subjects

- 3.1. Research using animals is rigorously defined and controlled by the Animals (Scientific Procedures) Act 1986 and is carried out under licences granted by the Home Secretary. All animal experimentation is therefore approved by the Home Office before it commences. UCL actively supports the '3Rs' (to 'Replace' animal use wherever possible, to 'Reduce' the number of animals used and to 'Refine' both procedures and

husbandry in order to minimise suffering and enhance welfare) and its internal procedures are committed to upholding this policy.

- 3.2. UCL compliance with the Animals (Scientific Procedures) Act 1986 is assured by the Certificate Holder and through UCL's ethical review process for research involving animals. This process is articulated through the Biological Services Management Group and the Biological Services Ethical Committee, both of which are chaired by the Certificate Holder. In line with Home Office requirements, this system ensures that new project licence applications are scrutinised prior to their submission to the Home Office and advice is made available on animal welfare and other matters. In addition, all staff (including honorary staff) and students undertaking experiments which involve animals and all other individuals who conduct such work on UCL premises, receive extensive training.
- 3.3. The Biological Services Management Group meets at least twice a year and is responsible for the management of biological services, including finance, planning, resource allocation and other management issues. The Biological Services Ethical Committee reports to the Biological Services Management Group and is charged with: (i) examining proposed applications for new project licences and amendments to existing licences; (ii) undertaking project reviews throughout their duration; (iii) promoting the development and uptake of reduction, replacement and refinement of alternatives to animal use where they exist and ensuring the availability of relevant sources; (iv) providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice and relevant legislation; (v) considering the care and accommodation standards applied to all animals; (vi) regularly reviewing UCL's managerial systems, procedures and protocols for the proper use of animals; (vii) advising on how all staff involved with animal use can be appropriately trained and how competence can be ensured; (viii) keeping appropriate records of all proposals submitted for consideration, licences granted by the Home Office and subsequent internal and external review activity. Researchers should ensure that their projects are considered by the Biological Services Ethical Committee before applying for a licence from the Home Office and bring relevant matters to the Committee's attention.
- 3.4. The Biological Services Ethical Committee keeps appropriate records of all proposals submitted for consideration, licences granted by the Home Office and subsequent internal and external review activity. Minutes are recorded and reported to the Biological Services Management Group. Such documentation is available for internal and external review and audit.

4. Research ethics and collections

- 4.1. UCL's Museums and Heritage Committee is charged with advising Council on matters of policy concerning the care and management of the UCL Museums and Collections and departmental collections. This includes advice on ethical issues concerning (i) the acquisition and disposal of cultural artefacts and specimens and (ii) the care and treatment of historic human remains at UCL. For example, it ensures that UCL complies with the Code of Ethics published by the Museums

Association, particularly with regard to the acquisition and disposal of artefacts and specimens.

- 4.2. UCL Council has approved a 'Policy, principles and procedures for the care and treatment of human remains at UCL', which complies with the statutory requirements of the Human Tissue Act (2004) in respect of human remains less than 100 years old and with the governmental advisory standards set out in the 'Guidance for the care of human remains in museums' (2005). The policy is subject to review at least every five years and substantive changes require the approval of Council.

5. Research which has the potential to cause damage to the environment

- 5.1. UCL takes action to militate against the possibility that research may cause damage to the environment by ensuring that its staff follow all relevant and legal health and safety protocols. UCL considers that failure to follow health and safety guidelines has the potential lead to significant negative environmental and other consequences. It therefore considers that breaking health and safety regulations amounts to research misconduct (please see UCL's *Procedures for investigating and resolving allegations of misconduct in academic research*).

6. Research conducted outside the UK

- 6.1. Researchers should bear in mind that they may face different civil, legal, financial and cultural conditions when working overseas and should ensure that they conform to any relevant regulations operating in the location in which they are undertaking their research. At the same time, all UCL staff (including honorary staff) and students are expected to conform to the UCL Research Ethics Framework wherever they conduct their research. UCL staff (including honorary staff) and students do not knowingly collaborate with an individual who refuses to conform to UCL's understanding of good practices in research. As such, they are expected to ensure that individuals external to UCL with whom they collaborate comply with this ethical code.
- 6.2. All relevant ethical review processes, where practicable, take place in the UK and in the host country.

7. Data Protection

- 7.1. The Data Protection Act protects information (personal data) about identifiable individuals ("data subjects") and enforces a set of standards for the processing of such information. Responsibility for implementation and enforcement of the Act is vested in the Data Protection Registrar.
- 7.2. UCL is registered with the Data Protection Registrar as a Data User and Computer Bureau, and as a consequence any member of staff or student of UCL using personal data for whatever purpose must comply with the provisions of the Act. There are eight principles of the Act which have to be applied by all users of personal data, and in outline these state that personal data shall:

- be collected and processed fairly and lawfully
 - only be held for specified lawful purposes
 - only be adequate and relevant and not excessive in relation to its purposes
 - be accurate and, where necessary, be kept up to date
 - be held no longer than is necessary for the stated purpose
 - be held and used in accordance with the rights of the data subjects under the Act
 - have appropriate security surrounding it
 - shall not be transferred outside the European Economic Area unless the country to which it is being transferred ensures adequate protection for the rights of data subjects.
- 7.3. All staff and students must ensure that any personal data, including research data, which they control are included in the structure of UCL registration. Departmental Data Protection Co-ordinators have copies of the department's registration details and should be consulted before new research is started, or before taking over established research from a colleague. The procedures for registering research projects can be found at: <http://www.ucl.ac.uk/efd/recordsoffice/data-protection/>.
- 7.4. The Registry will obtain indemnification from students in respect of data protection and an undertaking to act accordingly if research undertaken at UCL by the student during their programme of study falls within the scope of the Data Protection Act. All research involving the collection and/or storage of personal data which is not within the remit of NHS research ethics committees, should be approved by the UCL Research Ethics Committee, before the project is commenced (see paragraph 2.1. above).
- 7.5. Advice on data protection may be obtained from the UCL Data Protection Officer (extension 32589; e-mail: data-protection@ucl.ac.uk)

8. Review procedures and ethical consent

- 8.1. UCL's Research Strategy Committee (through a Working Group on Research Governance to which it has delegated the role) is charged with, *inter alia*, monitoring the activities of the various UCL research ethical committees and reviewing the ethical performance of research undertaken by its staff or students at any location and by other individuals on its premises. The UCL Research Ethics Committee, the Biological Services Management Group and the Museums and Heritage Committee submit annual reports to the Research Strategy Committee for its consideration. The Research Strategy Committee also conducts periodic audits of the work of these Committees, particularly with regard to the research projects to which they grant approval and any monitoring and follow-up activities, to ensure that they are consistent in their approach to ethical matters and conform to external expectations.
- 8.2. The Research Strategy Committee (through a Working Group on Research Governance to which it has delegated the role) is responsible for monitoring developments within the research community generally with regard to research ethical matters, disseminating relevant information and ensuring that UCL conforms appropriately.

Acknowledgements

This document is informed by the policies and publications of other institutions. UCL gratefully acknowledges the use of the following documents in particular:

ESRC, *Research ethics framework*;

OSI, *'Universal ethical code for scientists': Research Councils current policies and procedures upholding the provisions of this code*;

University of Manchester, *Guidelines on ethical practice*; and

University of Warwick, *Research code of conduct*.