



UCL RESEARCH ETHICS

Introduction

UCL is committed to ensuring the highest standards of integrity in all aspects of its research activities and expects that all those involved with research at UCL maintain a similar commitment.

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. UCL's review processes are intended to ensure this whilst remaining sensitive to the needs of researchers.

It is also generally accepted that funders, such as research councils, will not support, nor publications accept for publication, results of research that was not ethically approved.

The aim of ethical review is to protect participants, who are a valuable part of the research process and not merely a means of accessing data. However, ethical review also helps to protect the researcher. By obtaining ethical approval the researcher is demonstrating that (s)he has adhered to the accepted ethical standards of a genuine research study which could increase recruitment potential.

Information in this leaflet includes brief advice on:

- which ethics committee you should apply to
- the types of research which require ethics approval through the UCL REC and when research is exempt from the requirements to obtain this
- the UCL REC (and UCL IOE) ethical review process and how to apply

Detailed information and the application form may be found on the

UCL Research Ethics Committee website:

<http://ethics.grad.ucl.ac.uk/>

UCL Research Integrity Website:

www.ucl.ac.uk/research/integrity

→ UCL REC ethical review process

Ethical approval is required through the UCL REC if a specific research project is:

- a non-NHS study involving human participants and the collection and/ or study of data derived from living human participants undertaken by UCL staff or students on the UCL premises and/or by UCL staff or students elsewhere;
- a study involving NHS staff recruited as research participants by virtue of their professional role;
- a study on NHS premises, involving healthy volunteers not recruited as NHS patients and not subject to any legal requirements;
- a clinical trial conducted overseas;
- a 'mechanistic' study in which a drug is used to investigate a physiological process in healthy volunteers;
- a study involving a CE-marked medical device that has not been modified or is not being used for a new purpose.

UNLESS: the only involvement of human participants in particular research activities will be one or more of the categories listed on our exemptions page OR UCL staff are involved as co-researchers in a project led by a Principal Researcher from another UK institution and ethics approval has been granted by that institution.

TO NOTE: For Research Conducted Overseas

(to include the rest of Europe). The following rules apply *UNLESS the study is deemed to be exempt from the requirement to obtain UCL REC approval in which case only local ethics approval in the study country(ies) is required.*

1. All non-patient and patient studies solely conducted overseas require review by the UCL REC this includes clinical trials. Approval of these types of studies is conditional on the receipt of local ethical approval in the study country(ies).
2. All non-patient and patient studies conducted overseas and studies on healthy volunteers in the UK require review by the UCL REC this includes clinical trials. Approval of these types of studies is conditional on the receipt of local ethical approval in the study country(ies).

3. For studies conducted on NHS patients AND on patients overseas the following triple-review is required:

- Health Research Authority (HRA) review for the NHS patient element
- UCL REC review for the overseas element
- Local research/ethics permission in the study country(ies)

This is obligatory given that the HRA does not consider the ethical perspectives of the overseas elements of research and therefore it must also be reviewed by the UCL REC.

Ethical approval at UCL involves a two-stage process.

Completed applications are first submitted for departmental endorsement. Departmental endorsement can be via a departmental ethics/research committee or via the Head of Department.

Departmental endorsement ensures:

- knowledge by the Department of proposals being put forward by departmental staff and students
- compliance with the Data Protection Act
- completion of a formal signed Risk Assessment Form
- compliance with UCL's policy on the recruitment of staff with criminal convictions
- an opportunity for modification of the ethics application before it reaches the UCL Ethics Committee to expedite ethics approval

Departmental endorsement also offers the Department the opportunity to recommend that a research proposal be considered by the Committee Chair rather than the full Ethics Committee if the research involves minimum risk. For example research studies NOT involving:

- vulnerable groups
- intrusive interventions [including MRI]
- sensitive topics
- deception

...→ What types of research require ethical approval?

The following types of research are considered to involve MORE than minimal risk and require ethical approval:

- **research involving potentially vulnerable groups**, for example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.
- **Research involving those who lack capacity.** All research involving those who lack capacity, or who during the research project come to lack capacity, must be approved by an appropriate body (in most cases this is the NRES) operating under the Mental Capacity Act 2005.
- **research involving sensitive topics** – for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
- **research involving groups where permission of a gatekeeper is normally required for initial access to members.** This includes research involving gatekeepers such as adult professionals (e.g. 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 (e.g. the parent or husband of the participant) or a community leader.
- **research involving deception or which is conducted without participants' full and informed consent** at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable.
- **research involving access to records of personal or confidential information**, including genetic or other biological information, concerning identifiable individuals.
- **research which could induce psychological stress**, anxiety or humiliation or cause more than minimal pain.
- **research involving intrusive interventions or data collection methods** – for example, the administration of substances, vigorous physical exercise, or techniques such as hypnotism. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.
- **research where the safety of the researcher may be in question**, in particular those working in the field and locally employed research assistants working outside the UK.
- **research undertaken outside of the UK** where there may be issues of local practice and political sensitivities.

- **research involving respondents through the internet**, in particular where visual images are used, and where sensitive issues are discussed.
- **other research involving visual/vocal methods**, particularly where participants or other individuals may be identifiable.
- **research which may involve data sharing of confidential information beyond the initial consent given** – for example where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.
- research using administrative data or secure data. Researchers using these data sets will need to be approved by the body supplying the data and keep data in secure areas. Issues however may arise when data are linked and where it may be possible to identify participants.

Is my research EXEMPT from requiring ethical approval?

Within the definition of research, the following are not considered ‘research’ and would be exempt:

- Service evaluation
- Performance reviews
- Quality assurance/audit projects that do not involve access to or collection of private or sensitive data.
- Testing within normal education requirements
- Literary or artistic criticism

UCL Departmental Heads have final judgement as to whether a particular activity should be exempt from the requirement to obtain ethical approval, provided they have taken the criteria below into account.

The following types of research do not require ethical approval through the UCL REC unless approval is specifically required by an external funding body or other external body.

1. **Research involving information freely available in the public domain.** For example, published biographies, newspaper accounts of an individual’s activities and published minutes of a meeting whilst still personal data under the Data Protection Act would not require ethics review.
2. **Research involving anonymised records and data sets that exist in the public domain.** For example, datasets available through the Office for National Statistics or the UK Data Archive where appropriate permissions have already been obtained and it is not possible to identify individuals from the information provided.

3. **Studies of public behaviour that are purely observational** (non-invasive and non-interactive), unless the recorded observations identify individuals (names, photographs) which could place them at risk of harm, stigma or prosecution.
4. **Research involving the use of non-sensitive, completely anonymous educational tests, survey and interview procedure** when the participants are not defined as ‘vulnerable’ and participation will not induce undue psychological stress or anxiety.
5. **Research involving the use of educational tests, survey and interview procedures on human participants in the public arena** (e.g. elected or appointed public officials, candidates for public office, artists).
6. **Taste and food quality evaluation and consumer acceptance studies**, if the food consumed is (i) wholesome without additives or (ii) contains a food ingredient, agricultural, chemical or environmental contaminant, for a purpose and at a level declared safe by the relevant national food safety agency.

However, please note that whether or not research is subject to formal approval under the criteria listed above, it is always expected that UCL researchers will abide by their appropriate disciplinary ethical guidelines and UCL data protection requirements.

→ Which ethics committee should I apply to?

There are currently the following different application routes for UCL staff and students whose projects require research ethics approval:

1. **NHS Research Ethics Review** – any research that involves NHS patients and carers, invasive research involving prisoners or adults lacking capacity, a Clinical Trial of an Investigational Medicinal Product or human tissue. Please refer to HRA checklist: www.hra.nhs.uk/documents/2013/09/does-my-project-require-rec-review.pdf or to the UCL REC website at: www.ethics.grad.ucl.ac.uk/which-ethics-committee-apply-to.php for a full detailed listing of the types of studies that require approval via this route.
2. **Social Care Research Ethics Committee (SCREC)** – ethical approval is required through SCREC for social care research projects funded by the Department of Health www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee
3. **Ministry of Defence Research Ethics Committee (MoDREC)** – ethical approval is required through MODREC for research involving human participants either undertaken, funded or sponsored by MOD in order to meet nationally and internationally accepted ethical standards. www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees

4. **University Ethics Review** – research that involves human participants, their tissue and/or data but which does not fall into the above categories should apply to one of the following two ethics committees at UCL:

EITHER

UCL Research Ethics Committee – for all UCL staff and students

OR

UCL Institute of Education Research (IoE) Ethics Committee – for all IoE staff, students and visitors. The Institute maintains its own REC separate from the UCL REC. All research projects which collect or use data from human participants including secondary data analysis and systematic reviews are required to gain ethical approval before the project starts. This includes preliminary and pilot studies. For further details: www.ioe.ac.uk/about/policiesProcedures/41899.html

If you are unsure about the type of ethical review that is required please email: ethics@ucl.ac.uk for advice.

→ Contact Us

Please feel free to contact the Administrator of the UCL Research Ethics Committee about any issues relating to research ethics, or to discuss your application.

Address: UCL Research Ethics Committee, Academic Services, UCL 1-19 Torrington Place (9th Floor), London WC1E 7HB
Tel: 0203 108 8216 **Email:** ethics@ucl.ac.uk
Web: <http://ethics.grad.ucl.ac.uk/>

→ How to apply:

- Visit the UCL Ethics website at: <http://ethics.grad.ucl.ac.uk/>
- Check application **submission deadlines** and **meeting dates**.
- **Register your personal details** on the ethics database.
- **Formal Sponsorship Review for Clinical Trials Conducted in Developing Countries** (if required) – if your project is an interventional study in a developing country i.e. a drug, device or surgery trial then you will need to register your study within the new UCL Interventional Clinical Trials Portal.
- **Disclosure and Barring Service (DBS)** check (if required) – the DBS number needs to be quoted in your ethics application form.
- **Data Protection Registration** (if required) – the registration number needs to be quoted in your ethics application form.
- **Risk Assessment** (if required) – if the research places you as the researcher at any risk greater than that which you would encounter in your daily life then a project risk assessment form will need to be completed.
- **Insurance** – the insurance for all UCL studies is provided by a commercial insurer. For a majority of studies the cover is automatic. However, for a minority of clinical research studies the insurer requires prior notification of the project before cover can be provided.
- **Download and complete the ethics application form**, ensuring that both the Principal Researcher and Head of Department have signed the form. The Head of Department should also indicate whether the application is being submitted for Chair's action or full Committee review based on the criteria of minimal risk.
- **Submit your application** with the relevant number of copies to the Administrator of the Ethics Committee at the address shown below by the appropriate submission deadline.

UCL Research Ethics Committee website:

<http://ethics.grad.ucl.ac.uk/>

UCL Research Integrity Website:

www.ucl.ac.uk/research/integrity