

## ETHICAL APPROVAL PROCESS AT UCL

## HOW TO APPLY

## 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 and the use of criminal record clearance;
- an opportunity for modification of the ethics application before it reaches the UCL Ethics Committee (if alterations are deemed necessary and desirable) to expedite ethics approval.

Departmental endorsement also offers the Department the opportunity to recommend that an application be considered by the Committee Chair rather than the full Ethics Committee. A recommendation for Chair's action is appropriate if the research involves minimum risk as defined below:

- applications where there are no contentious issues such as genetic research or research on illegal substances;
- applications where no invasive or traumatic procedures are involved including the administration of pharmacological agents;
- applications where participants are not children or vulnerable adults;
- applications that are unlikely to put the researchers at risk.

- Visit the UCL Ethics website at: [www.ucl.ac.uk/gradschool/ethics](http://www.ucl.ac.uk/gradschool/ethics)
- Check application submission deadlines and meeting dates.
- Register your personal details on the ethics database.
- Criminal Record Check (if required) – If the research includes access to children or contact with vulnerable adults, it is a requirement by law, for both students and staff researchers to undergo criminal record checks. It can take a month or more to arrange and complete the check. The Criminal Record Check Disclosure Number needs to be quoted in the ethics application form.
- Data Protection Registration (if required). The registration number needs to be quoted in your ethics application form.
- 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 on the form 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.

## CONTACT US

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

## ADDRESS

UCL Research  
Ethics Committee

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# RESEARCH ETHICS AT UCL

*The UCL Research Ethics Committee was established in recognition of the need for a system of ethical review for Non-NHS research involving human participants, particularly for social science research.*

This need was driven by the requirements of funding organisations that projects receive appropriate ethical approval before funds are released.

Funding bodies such as the Wellcome Trust, the MRC, the ESRC and the National Institutes of Health in the USA provide funding for research projects, conditional upon ethical review of those research projects having taken place.

Information in this leaflet includes brief advice on:

- what types of research require ethical approval
- whether a particular research project requires approval
- whether research is exempt from requiring ethical approval
- NHS Research Ethics Committees
- ethical review process at UCL
- how to apply

Detailed information and the application form may be found on the UCL Research Ethics Committee website: [www.ucl.ac.uk/gradschool/ethics](http://www.ucl.ac.uk/gradschool/ethics)

## WHAT TYPES OF RESEARCH REQUIRE ETHICAL APPROVAL?

The following research is considered to involve **MORE than minimal risk** and requires ethical approval:

- research involving vulnerable groups, for example, children or young people, older persons, people with mental health problems, people with learning disabilities or prisoners.
- research involving sensitive topics - for example participants' sexual behaviour or orientation, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic group.
- research involving groups where permission of a "gatekeeper" is normally required for initial access to members - for example, ethnic or cultural groups, native peoples or indigenous communities.
- research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out.
- research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
- research which could induce psychological stress, anxiety or humiliation, or cause more than minimal pain.

- research involving intrusive interventions - for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy, where participants would not normally encounter such interventions, which may cause them to reveal information which causes concern in the course of their everyday lives.

### HOW DO I KNOW IF MY RESEARCH REQUIRES ETHICAL APPROVAL?

All Non-NHS research proposals involving living human participants and the collection and/or study of data derived from living human participants undertaken by UCL staff or students within the geographical boundaries of UCL or elsewhere, requires ethical approval by the Committee. This is to ensure that the research conforms with general ethical principles and standards.

If the only involvement of human participants in particular research activities will be in one or more of categories (a) – (f) defined overleaf, then the research will be exempt from ethics approval, unless approval is specifically required by an external funding body or other external body.

## IS MY RESEARCH EXEMPT FROM REQUIRING ETHICAL APPROVAL?

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

In accordance with the following criteria, UCL Departmental Heads have final judgement as to whether a particular activity should be exempt from the requirement for approval by the Committee, providing they have taken the criteria below into account.

The following types of research **do not** require ethical approval:

**However, the exemptions below do not apply to research involving vulnerable groups as defined earlier.**

- (a) Research involving the collection or study of existing data, documents or records that are publicly available.
- (b) Research involving anonymised records and/or data sets that exist in the public domain.
- (c) Research involving the use of educational tests, survey procedures, interview procedures or observation of public behaviour, unless information obtained is recorded in such a manner that human participants can be identified and any disclosure of the human participants' responses outside the research could reasonably place the participants at greater risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or reputation.
- (d) Research involving the use of educational tests, survey procedures, interview procedures or observation of public behaviour that is not exempt under paragraph (c), if the human participants are elected or appointed public officials or candidates for public office.
- (e) Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level known to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe by the appropriate government regulators.
- (f) Service evaluation and audit:

Ethical approval is not required for an audit or service evaluation. Please see our website for guidance on the policy regarding such studies.

## NHS RESEARCH ETHICS COMMITTEES (RECs)

The Committee is not responsible for considering the ethics of research which falls under the remit of Department of Health approved ethics committees which abide by Governance Arrangements for NHS Research Ethics Committees (GfREC), para 3.1, as detailed below.

### The remit of an NHS REC

Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
- individuals identified as potential research participants because of their status as relatives or carers or patients and users of the NHS as defined above.
- access to data, organs or other bodily material of past and present NHS patients.
- the recently dead in NHS premises.
- fetal material and IVF involving NHS patients.
- the use of, or potential access to, NHS premises or facilities.
- NHS staff - recruited as research participants by virtue of their professional role.

Further details and information on how to apply is available from the National Research Ethics Service (NRES): [www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk) but please also contact the Joint UCLH / UCL Biomedical Research Unit: <http://www.ucl.ac.uk/joint-rd-unit/about-us> who can give the appropriate advice.