

Ethical approval is required by Research Ethics Committees falling within the UK Health Departments' Research Ethics Service if a specific research project involves:

- potential research participants identified from, or because of, their past or present use of NHS healthcare (UK-wide), Adult social care (England, Wales and Northern Ireland), Children's social care (Wales and Northern Ireland) and services provided under contract with the private or voluntary sectors including participants recruited through these services as healthy controls.
- potential research participants identified because of their status as relatives or carers of past or present users of these services.
- collection of tissue (i.e. any material consisting of or including human cells) or information from users of these services; or
- use of previously collected tissue or information from which individual past or present users of these services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available without consent where this could breach confidentiality.
- Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people).
- health-related research involving prisoners in the custody of the National Offender Management Service, Scottish Prison Service and Northern Ireland Prison Service.
- social care research projects funded by the Department of Health.
- patients (or information about patients) who are cared for in private and voluntary sector nursing homes (in England, Wales and Northern Ireland) and/or residents (or information about residents) of residential care homes (in Northern Ireland only).
- exposure to ionising radiation.
- medical devices that are not CE-marked (i.e. not compliant with European Directives) or CE-marked medical devices that have been modified or are being used for a new purpose;

- investigational medicinal products;
- practising midwives conducting a clinical trial; or
- protected information from the Human Fertilisation and Embryology Authority Register.
- people who lack (or lose) the capacity to give informed consent to take part (or to keep taking part) in the research.

Further details and information on how to apply is available from NRES: www.nres.nhs.uk but please also contact the Joint Research Office: www.ucl.ac.uk/jro who can give the appropriate advice.

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
- compliance with UCL's Risk Assessment procedures and insurance arrangements
- 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

Expedited Review by the Committee Chair

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

How to apply

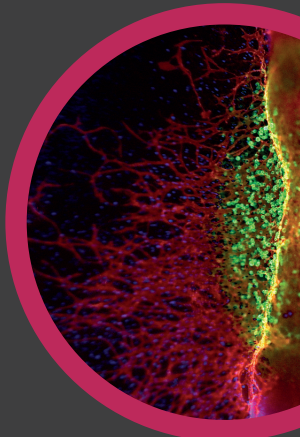
- Visit the UCL Ethics website at: www.ucl.ac.uk/gradschool/ethics
- Check **application submission deadlines** and **meeting dates**.
- **Register your personal details** on the ethics database.
- **Disclosure and Barring Service (DBS)** check (if required) – if the research includes access to children or contact with vulnerable adults it is a requirement by law for students as well as staff researchers to undergo DBS checks. The DBS 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.
- **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 the 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.

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, Graduate School, North Cloisters, Wilkins Building UCL, Gower Street, London WC1E 6BT Tel: **020 3108 4312** Email: ethics@ucl.ac.uk



Research ethics at UCL



In order for research to result in benefit with a minimal 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 generally accepted that funders such as Research Councils will not provide financial support for research that does not have ethical approval. Many publications will also no longer accept for publication results of research that was not ethically approved.

www.ucl.ac.uk/gradschool/ethics

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:

- the types of research which require ethics approval and when research is exempt from the requirements to obtain this
- the UCL REC ethical review process and how to apply
- Research Ethics Committees falling within the remit of the National Research Ethics Service (NRES) part of the Health Research Authority (HRA)

Detailed information and the application form may be found on the UCL Research Ethics Committee website:

www.ucl.ac.uk/gradschool/ethics

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.

*Please note that for studies conducted overseas, ethical approval from both a UK and a local institution is required.

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 Heads of Department 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.

- **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 would not be considered 'personal data' or sensitive personal data requiring ethics review.
- **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.
- **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.
- **Research involving the use of non-sensitive, completely anonymous educational tests, survey and interview procedures** when the participants are not defined as 'vulnerable' and participation will not induce undue psychological stress or anxiety.

- **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).
- **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.

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.

Miss Jay Stone, Institute of Ophthalmology
Research Images as Art Competition

[www.ucl.ac.uk/
gradschool/ethics](http://www.ucl.ac.uk/gradschool/ethics)