

Ethical Review Process FAQs

- ***Why does the University have ethical review?***

A number of funders now require evidence that projects have been subjected to independent ethical review. This requires a clear and consistent system for independent ethical review of research projects in any discipline.

In order to assure continuity of other research funding and meet the requirements for consistence and independence, a university-wide ethical review process was established.

- ***What are the principles on which the University ethical review process is based?***

The two principles are: (a) The principal investigator or supervisor (for PGR student projects) takes full responsibility for the ethical conduct of the research and (b) The University takes responsibility for the ethical review procedures.

Notwithstanding a review by the ERC, the PI/supervisor shall remain responsible for observing good practice. Any decision of the ERC shall not detract in any way from the ultimate responsibility that the PI/supervisor must have for all research which he or she carries out or is responsible for supervising.

- ***To whom does the new University ethical review process apply?***

The obligation for University ethical review applies to all University members of staff and all supervisors of University registered postgraduate research (PGR) students carrying out research in the name of the University or using University premises or facilities, including all visiting researchers and members in honorary positions.

Undergraduate and taught master's student projects are not included in the institutional ethical review system.

Please note that those PGR students registered before 1st September 2008 are not subject to the institutional ethical review system and should refer to their Department/School/College for further advice.

- ***What is the duration of the ethical approval granted by the University ERCs?***

Ethical approval will be granted for the duration of the research project or for 5 years, whichever is the lesser, and is binding on the applicant researchers.

- ***When will the ERCs hold full physical meetings?***

All meetings will be held 2-4pm.

Humanities and Social Sciences ERC

25th January 2011

19th April 2011

19th July 2011

18th October 2011

Science, Technology, Engineering and Mathematics ERC

18th January 2011

21st April 2011

21st July 2011

20th October 2011

(N.B. Should there be no agenda items for discussion, a meeting will not be convened)

- ***I have been awarded funding for a project that requires NRES (formerly COREC) approval via the NHS REC, do I need to go through the university ethical review?***

You still need to complete the online Self Assessment Form, but then will not be subject to any further ethical review via the University system. Rather than submitting an Application for Ethical Review (AER), it is sufficient that the relevant recognised NHS research ethics committee formally approves such research proposal. Researchers shall act in accordance with the ethical approval issued by that ethics committee. Should any proposed changes in the research be made, the procedures of the relevant body that gave approval must be followed.

- **Whilst a Self-Assessment form is still required, submission of an application for ethical review (AER) to the University ethical review committee is not required for research projects that require ethical review under the National Research Ethics Services (NRES) process. What are those projects that go down the NRES route?**

Ethical review and approval via the NRES system is required in the following circumstances:

Clinical and non-clinical research involving NHS patients (living or dead)

Research involving access to data, organs or other bodily material of past and present NHS patients

Exemption from the licensing requirements established by the Human Tissue Act 2004 to store Relevant Material (whether coming from NHS patients or healthy volunteers)

Exemption from consent requirements to use anonymised tissue from the living as regulated by the HTA 2004

Research involving the collection or use of NHS patient data

Research involving NHS staff or carers
Research using NHS facilities or premises
Studies involving healthy volunteers as part of Phase I clinical trials
Research involving gene therapy
Clinical research that involves xenotransplantation
Research on prisoners in the UK
Research involving ionising radiation
Research involving participants aged 16 years or over who lack the capacity to give informed consent (see Mental Capacity Act 2005)

▪ ***Having obtained ethical approval from an ERC for my ESRC funded project what happens next?***

According to ESRC rules, for proposals which have been awarded funding, the administering institution has to provide written confirmation that the required ethical approval has been received. This confirmation of ethics approval is included in the 'Start Certificate' return made to the Council by Finance Office. The secretariat to the Ethical Review Committee will inform Finance Office of this approval and the latter will include this statement in the starting certificate and sends it to ESRC.

For ESRC funded projects, funds will not flow until ethical approval has been confirmed. Therefore, if an Application for Ethical Review is required, funds will not be released until this has been reviewed and approved by the relevant Ethical Review Committee.

▪ ***Is University ethical review required when submitting a Tender or Application for funding?***

Principal Investigators are NOT required to undergo University ethical review prior to the submission of bids in response to tenders unless specifically required by the conditions of tender. The University ethical review is only required AFTER funding is awarded and not at application for funding or tender stage. It is recommended that wording on the new ethics system is included in the tender bid proposal or cover letter to cover any eventual review after funding is awarded:

"All research carried out by the University of Birmingham is subject to ethical review, either by our internal review processes, or by any relevant external ethics review body such as the NHS National Research Ethics System. In the event that the ethical review requires any material changes to the proposed work, we shall contact you and discuss how these may be accommodated within the project.

- **What ethical review and approvals are required for social care research projects?**

Research involving social care practitioners, social care clients and resources is governed by the Department of Health's Research Governance Framework (2nd ed, 2005). This document prescribes that no such social care research may start until:

- a formal Research Sponsor is identified,
- ethical approval is confirmed by an appropriate research ethics committee, and
- formal permission is given by the relevant care organisation.

The University's online ethics self-assessment form should be completed for all new research projects, including those involving social care.

If the self-assessment form indicates that further ethical review is required, an application for ethical review form should be submitted to one of the University Ethical Review Committees for independent ethical review.

In certain cases, ethical approval may be required from the [Social Care Research Ethics Committee \(SCREC\)](#) rather than from the University ERC. For further clarification on this, please contact the University's Research Ethics Team.

Please also be aware that social care research involving NHS patients or their data (i.e., recruited by virtue of being NHS patients), NHS staff or NHS facilities must have a favourable opinion from the relevant NHS REC and not from the University ERC.

Visit our Research Governance pages for more information about University Sponsorship for social care research.

- ***When and how should Criminal Records Bureau (CRB) checks be carried out?***

The Criminal Records Bureau (CRB), an executive agency of the Home Office provides access to criminal record and other relevant information to organisations in England and Wales.

If as part of your research you will be working with children or vulnerable adults, you should request that the University obtains a CRB check on your behalf. An individual cannot apply for a CRB check directly.

Further information about CRB checks can be found at <http://www.crb.gov.uk>. If required, please contact Sally Steele in HR to arrange for the appropriate level of CRB check to be carried out.

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- ***What training does the University offer in relation to research ethics?***

There are currently two courses available for the benefit of University researchers:

Ethics 1: Good Research Practice

Ethics 2: Working with Human Subjects

These two courses run through WebCT modules and take about 40 minutes to complete and can be accessed anytime by anyone with University user ID and Password.

In order to access the course please email Ayaaz Tarajia with your username, requesting access to the courses via WebCT.

These are part of online resources provided by the University's Academic Practice and Organisational Development (APOD) unit and specially aimed at young researchers. Further information may be found here.

- ***How do I lodge an appeal against the University's ethical review process?***

Appeals may be made against the University's ethical review process, but not against the outcome of an ethical review.

Appeals should only be made once the ethical review process is complete. Any appeal must be received in writing within 28 days of the date of the decision letter from the relevant Ethical Review Committee.

Any appeals will be considered by the University's Ethical Review Group. In order to lodge an appeal, please forward a concise summary of the issues involved to Mrs Susan Cottam at s.l.cottam@bham.ac.uk.

The University will endeavor to reply to appeals within 60 days.

If your question is not answered above, please contact ethics-queries@contacts.bham.ac.uk.

If your question is not answered by the FAQ list, please direct it to the Research Ethics Officer.