

## Research Ethics Review and Approval Procedures

November 2021

Increased demands for greater public scrutiny and accountability have meant that studies and teaching activities involving human participants, human tissues or data, or of a potentially socially/politically sensitive nature are expected to be formally reviewed by individuals who are independent of the research. Ethics review and approval procedures are designed to monitor the implementation of the University's Code of Practice in individual research studies and to ensure that the dignity, rights, safety and well-being of participants are given primary consideration.

### 1. Procedures for all students and researchers at the University

- 1.1. Each academic department<sup>1</sup> in the University is responsible for the ethics review of all research conducted in their department. Research conducted by members of staff and postgraduate research students may also be reviewed by the University Ethics Committee (UREC) in addition to Departmental Review.
- 1.2. Departments are required to appoint a Departmental **Research Ethics Officer** (REO) who represents their School on the University Research Ethics Committee and who is responsible for ensuring that appropriate procedures for research ethics review are in place and followed. Schools should establish Departmental Ethics Committees (DREC) to contribute to these duties.
- 1.3. Where deemed appropriate by the University Ethics Committee, a number of Schools may be approved to operate with a shared Departmental Research Ethics Officer and/or Committee.

### 2. For undergraduates and taught postgraduates, the procedures include three elements:

- i A procedure for identifying whether an application for further ethics approval needs to be made. This is done through a screening checklist (**Form RE1**) submitted to the local REO.
- ii A procedure for considering applications for further ethics approval. These should be made in writing (**Form RE2(D)**) to the Departmental Research Ethics Officer and considered within a specified time period. (There may be case where the REO considers that University level clearance is needed, in particular if the answer is 'yes' to certain questions in Section 2 of the RE1 checklist, in which case you will be advised to use Form RE2(U)).
- iii A way of maintaining appropriate records of decisions and of providing written notification to applicants of the decision made (**Form RE3(D)**).

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<sup>1</sup> In this document Department is used for consistency of terminology but it may refer to a Department, School, Faculty etc that is given the authority to undertake research, depending on the organisational structure in force.

- 2.1. Basic prototypes for each of these **ethics review forms** are provided online. Students should then complete forms appropriate to the department in which they are registered to conduct their research.
3. **For staff, visiting researchers and research students (this includes staff who are registered for a research degree at the University):** all those within these categories are required to seek ethical clearance via the online EFIT system for **any** research activity. You will be guided through an initial ethical screening and then the system will advise you what to do which may include being asked to complete a Form RE2(U). This form will be reviewed by an REO before being forwarded to UREC for consideration. In all cases, the EFIT system will issue you with a uniquely coded EFIT certificate that will outline your ethical clearance and the parameters within which you may conduct your research. In some cases, ethical clearance will be declined and you will be directed to have a discussion with your REO in the first instance.
  - 3.1. You should allow plenty of time for your research ethical clearance and whilst some applications may result in auto approval, others that require UREC approval may take at least 2 weeks.
  - 3.2. Staff or research students whose research involves recruitment of patients, carers or staff through the NHS will need to obtain ethics approval from a recognised NHS Research Ethics Committee (see below). An application to the University Committee will still need to be made and a copy of the approval or any other letter from the NHS Research Ethics Committee should be sent to the Secretary of the University Research Ethics Committee when requested.
4. Whatever the levels of research ethics review, all researchers are expected to give careful consideration to the issue of informed consent. Guidance is provided in relation to both **participant information sheets** and formal **consent forms**. **Indemnity forms** are also available where an outside organisation requires a statement of the insurance cover provided by the University.

## 5. Procedures for external researchers

- 5.1. Following completion of Form RE1 and consideration at Departmental level, external researchers are required to obtain any further ethics approval deemed necessary from the University Research Ethics Committee before recruiting University students or staff to their research. The procedure is much the same as it is for staff and research students at the University. An application for research ethics review should be made on Form RE2(U). External researchers are also expected to give careful consideration to both participant information sheets and formal consent forms.
- 5.2. A complete copy of the application (completed Form RE2(U) plus supporting documents) should be sent to the deadline for applications is midday two weeks before the Committee meets. Alternatively, multiple copies of the application plus the original copy (completed form plus supporting documents) should be sent by midday 11 days before the Committee meets.

## 6. Procedures for ethical clearance of teaching activities

- 5.1. Where a teaching activity is being planned that may involve human participants, human tissues or data, or potentially socially/politically sensitive nature then the University requires the same ethical clearance to be applied for in advance. This is

done via the online EFIT system which will guide the applicant as to whether or not an RE2(U) is required.

## **7. External Research Ethics Committees**

- 7.1. Researchers at the University who wish to recruit participants through another organisation may be asked to submit their proposal for ethics review by that organisation's Ethics Committee.
- 7.2. This is most likely when researchers wish to carry out research in the NHS (including patients, staff, carers or a study on NHS premises) or Social Services and is governed by the requirements of the Department of Health. NHS Local Research Ethics Committees (LRECs) have been established by Health Authorities throughout the country and some require that researchers gain approval from their own institution before making an application to them.
- 7.3. The Central Office for Research Ethics Committees (COREC), works on behalf of the Department of Health in England and co-ordinates the development of operational systems for Local and Multi-Centre Research Ethics Committees (LRECs and MRECs), on behalf of the NHS in England.
- 7.4. Ethical clearance requests that involve human tissues will require clearance by a national ethics The Human Tissue Regulations provide that, where ethical approval is required for research involving human tissue in England, Wales or Northern Ireland, it must be given by an application made through the Health Authority Integrated Research Application System (IRAS) <https://www.myresearchproject.org.uk/>. Following the granting of ethical clearance through IRAS your local Designated Officer will advise how to submit this to UREC for University approval.

## **8. Request for Ethics Review**

- 8.1. Notwithstanding the procedures for ethics review described above, a researcher and/or supervisor or a third party may request on submission of form RE1 or during an EFIT submission that the ethical clearance is considered by the Departmental Ethics Committee instead of by the Departmental Research Ethics Officer.