

## Research Ethics Review and Approval Procedures

Increased demands for greater public scrutiny and accountability have meant that studies involving human participants 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 Research Ethics Committee (UREC) in addition to Departmental Review.
- 1.2. Departments are required to appoint a **Departmental Research Ethics Officer** 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 Research Ethics Committees (DREC) to contribute to these duties.
- 1.3. Where deemed appropriate by the University Research 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:

- 2.1. A procedure for identifying whether an application for further ethics approval needs to be made. This is done through a screening checklist (**Form RE1**) which includes a common set of core questions, supplemented where necessary by further questions appropriate to the research carried out in the School.
- 2.2. 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.
- 2.3. A way of maintaining appropriate records of decisions and of providing written notification to applicants of the decision made (**Form RE3(D)**).
- 2.4. Basic prototypes for each of these **ethics review forms** are provided. 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, where an application for further research ethics approval has been identified as being necessary following consideration of **Form RE1** at Departmental level, this should be made on **Form**

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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.

**RE2(U)**. Once approved by your Departmental Research Ethics Officer/Committee, a complete copy of the application (completed **Form RE2(U)** plus supporting documents) should be sent to the Secretary to the University Research Ethics Committee, Academic Quality and Standards Unit, Eagle House. 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 received by midday 11 days before the Committee meets.

- 3.1. All applications to the University Research Ethics Committee should first be reviewed through Departmental procedures; the Committee will consider applications only after they have been signed off by the Departmental Research Ethics Officer. Staff or 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, normally beforehand (see 3.2), and whether or not this is the case 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.
  - 3.2. Please note that although the Committee will do its utmost to respond to applicants within a week of the meeting at which it was discussed (**using Form RE3(U)**), in some cases it can take two weeks for the reply to be written. Therefore, please allow two weeks from the date of the Committee meeting as a worse case scenario.
  - 3.3. 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.
4. **Procedures for external researchers**
- 4.1. 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.
  - 4.2. 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.
5. **External Research Ethics Committees**
- 5.1. 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 Research Ethics Committee.
  - 5.2. 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.

5.3. 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.

**6. Request for Ethics Review**

6.1. Notwithstanding the procedures for ethics review described above, a researcher and/or supervisor or a third party may request on submission of form RE1 that it is considered by the Departmental Research Ethics Committee instead of by the Departmental Research Ethics Officer.