

## Research Ethics Review and Approval Procedures

July 2022

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 College'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. For staff and visiting researchers

- 1.1. A procedure for identifying whether an application for further ethics approval needs to be made. This is done through a screening checklist (**Form RE1**) submitted to the College Ethics Panel (CEP).
- 1.2. A procedure for considering applications for further ethics approval. These should be made in writing (**Form RE2(U)**) to the CEP and considered within a specified time period.
- 1.3. You should allow plenty of time for your research ethical clearance and whilst some applications may result in relatively quick approval, others that require further CEP approval may take several weeks.
- 1.4. Those whose research involves recruitment of patients, carers or staff through the NHS will need to obtain ethics approval from a recognised NHS Research Ethics Panel (see below). An application to the CEP will still need to be made and a copy of the approval or any other letter from the NHS Research Ethics Panel should be sent to the CEP when requested.

### 2. Consideration of informed consent

- 2.1. 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**.

### 3. Procedures for external researchers

- 3.1. Following completion of Form RE1, external researchers are required to obtain any further ethics approval deemed necessary (eg. a completed ethics approval form from their home institution) from the CEP before recruiting the Colleges' students or staff to their research. The procedure is much the same as it is for staff at the College. A Form RE2(U) should be completed, as needed. External researchers are also expected to give careful consideration to both participant information sheets and formal consent forms.

3.2. A complete copy of the application (completed Form RE2(U) plus supporting documents) should be sent to the CEP, as needed.

#### **4. Procedures for ethical clearance of teaching activities**

4.1. Where a teaching activity is being planned that may involve human participants, human tissues or data, or potentially socially/politically sensitive nature then the College requires the same ethical clearance to be applied for in advance. This is done via Form RE1 which will guide the applicant as to whether or not an RE2(U) is required.

#### **5. External Research Ethics Panels**

5.1. Researchers at the College who wish to recruit participants through another organisation may be asked to submit their proposal for ethics review by that organisation's Ethics Panel.

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 Panels (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 Panels (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 Panels (LRECs and MRECs), on behalf of the NHS in England.

5.4. Ethical clearance requests that involve human tissues will require clearance by a national ethics Panel. 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 CEP for College approval.

#### **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 the ethical clearance is considered by the College Ethics Panel instead of by a supervisor or a designated departmental level research ethics person.

#### **Acknowledgement**

This Research Ethics Review and Approval Procedures has been adapted from Regent College's partner, the University of Bolton:

[https://www.bolton.ac.uk/assets/Uploads/Ethics\\_approval\\_procedures\\_Nov\\_2021.pdf](https://www.bolton.ac.uk/assets/Uploads/Ethics_approval_procedures_Nov_2021.pdf)