

## 1.0 Projects which require application to NHS Research Ethics Committees – Independent Peer Review

Some projects also require NHS Research Ethics Committee [REC] approval. (The submission to an LREC can only occur after the scrutiny and approval process within the University has been completed. The University, through the student project supervisor, is the research sponsor of all staff and student projects and the failure to adhere to the guidelines for University approval will be taken seriously. Scrutiny will be undertaken on behalf of the University by the Faculty of Health and Faculty of Sciences.

Supervisors and staff submitting projects to NHS RECs must take into account the extended timescale involved in gaining this approval. It will necessitate forward planning. Consideration by an NHS REC may take up to sixty working days and, as changes may be required, it is wise to allow three months from the date of submission to the NHS REC following the completion of the internal University approval process which may also take between 12 – 16 weeks. Supervisors of students' research projects must support them through the process.

Reference should also be made to the [flow chart](#) (PDF, file size: 5.49KB) outlining the internal University procedures for projects intended to be submitted for NHS Research Ethics Committee approval.

**Please note** that there are minor details concerning the approval process contained in the Faculty guidelines which are different from the main University guidelines. These are for the purpose of further clarification of the process for projects which will receive ethical approval by the relevant NHS REC.

### 1.1 Projects Requiring NHS REC Approval

The first stage in the University ethical scrutiny procedure is to determine whether the research project requires NHS REC approval.

National Health guidelines require you to seek the approval of an NHS REC if the research sponsored by Staffordshire University involves:

- NHS patients, i.e. persons recruited through their past or present treatment by the NHS. This includes NHS patients treated under contract in the private sector.
- Access to records of past or present NHS patients
- The use of or potential access to NHS premises or facilities, including staff working in the NHS
- Research projects where the researcher is an employee of the NHS

This includes the following types of study:

- Pilot Studies that involve patients, patient information or NHS staff or facilities
- New research studies involving patients
- New analysis of data sets or samples not entirely anonymised

If there is doubt about whether or not a project should be categorized as research rather than education, audit or service evaluation, guidelines are available from the National Patient Safety Agency in the leaflet 'Defining Research' <http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allid=355>. You may also wish to contact the Chair of the Health and Sciences Faculty Ethics Committee for advice.

### **Clinical Trials**

You should also note that if your project is a clinical trial you should provide details of the individual project to the Finance Department where a register will be established for notification to the Insurers.

## **1.2 Independent Peer Review**

As a result of changes in Research Governance coming out of the Department of Health all research projects which will require NHS Research Ethics Committee approval must provide evidence of Independent Peer Review of their Scientific Merit. This is in addition to the reforms that have occurred in the area of Ethical Review and is seen as central to the process of approval for any piece of research in the Health and Social Care sector. Below is a detailed account of the process for the Peer Review which is required prior to ethical approval by the University. The Independent Peer Review Panel located in the Faculty of Health will undertake the work associated with this process

It should be noted that there are differences in the approach dependent on the nature of the study and the source of funding/review. Peer review should be appropriate to the nature of the research being undertaken. It is essential that where Research Projects are being undertaken within the NHS you should review the most recent advice emerging from the National Research Ethics Service ([www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk)) and in particular discuss your proposal and seek advice from the relevant Research & Development Department within your Trust.

- The peer review process for student projects which require NHS Research Ethics Committee approval involves review within the University by senior researchers who have no prior connection with the project.
- Where the project is a response to a bid to an outside funding body such as the various research councils, the European Union or charitable trusts, for example the Wellcome Foundation, independent review may be carried out by these organisations. However, evidence of such a process must be supplied to the Faculty Independent Peer Review Panel.

Staff and student projects are reviewed by internal reviewers but if such specialist knowledge is unavailable within the University, the project will require external review. The 'Status of Study' section on the IPR form should then include the names of up to three possible peer reviewers who have the subject expertise to comment on the scientific merit of the proposals.

### 1.3 Process for Independent Peer Review Approval

- Three hard copies of the Independent Peer Review form (not the standard University Application for Ethical Approval) with self addressed envelope and one electronic copy should be submitted to the Faculty of Health/Faculty of Sciences Independent Peer Review Panel. This should occur two weeks before the date of the Faculty Independent Peer Review Panel (IPR) (refer to dates as scheduled on the Independent Peer Review and Ethics Panel Timetable) and at least 12 to 16 weeks before the project is due to be submitted for NHS REC consideration. **Please make sure that all the appropriate signatures are included on the form.**
- There is a checklist which should be followed and it is essential that you tick all the appropriate sections to ensure that the process has been completed accurately. Your forms will be returned if this is incomplete.
- It may be appropriate to complete a separate Risk Assessment Form as well as the Peer Review form. Where this is the case it must be attached to the main form.
- The Faculty will forward the form to the IPR Panel.
- Applicants are invited to attend the IPR Panel meeting. Please telephone the Faculty Office to confirm your time of attendance.
- If projects are approved subject to amendments the applicants and supervisor[s] will receive a letter from the Chair of the IPR Panel to this effect indicating the points that require clarification. The project should be amended and two copies of the IPR form with self addressed envelope and one electronic copy re-submitted to the IPR Panel for approval. Please include a detailed commentary explaining how you have dealt with each point raised.
- If projects are not approved because they contain major flaws the applicant and supervisor[s]/mentors will receive a letter from the Chair of the IPR Panel detailing the issues to be addressed. The project must be substantially revised and three copies of the IPR form with self addressed envelope and one electronic copy re-submitted to the Panel for approval. Please include a detailed commentary explaining how you have dealt with each point raised.
- The IPR Panel may choose to defer a decision about a project and refer it to the University Academic Ethics Sub-Committee for consideration. The applicant and supervisor will receive a letter from the Chair of this Sub-Committee informing them of the result of the University's considerations.
- Once projects are approved, the Independent Peer Review Panel form will then be submitted by the Faculty to the Chair of the University Academic Ethics Sub-Committee for his authorisation of the project and for Insurance and Indemnity. When the project has received final authorisation, researchers will be notified in writing that the project has been approved, normally within three weeks of the final approval by the Chair of the IPR Panel. **No external project submission should take place until you have received authorisation.**

- Once you have received approval from the University, action can then be taken to make arrangements for them to be submitted for NHS REC approval
- If issues of scientific merit, which were not previously anticipated, arise after approval has been granted, it is the responsibility of project supervisors for all supervised research, or in other cases the staff responsible for the research, to inform the Faculty IPR Panel and seek guidance on the consideration to be given to their projects to take account of the new methodological and/or ethical issues. Researchers should also follow relevant NHS guidelines about this matter.
- Similarly all 'adverse' events which occur during the conduct of research projects must be reported to the University through the Chair of the IPR Panel. NHS reporting requirements for adverse and untoward events must always be followed.
- Researchers must also follow NHS requirements for progress and completion reports.
- Proposals submitted on IPR forms will specify the resources available to ensure completion. Submission documentation should also include a letter signed by an appropriate Trust Officer or Research Centre Director which indicates that the researcher will have access to the NHS resources necessary to complete the project. The status of the project should be made clear, including whether this is a student project, a staff project, a pilot study or a full intervention study.
- Student and pilot projects will normally be assessed by the IPR Panel. Where the members of the Panel feel they do not have the capacity to review the study because of methodology/subject matter issues, a reviewer from elsewhere within the University will be sought prior to looking beyond the institution. The reports from the reviewers will be addressed to the Chair of the IPR Panel and copies will be circulated to the Panel members.

#### **1.4 Possible Peer Review Decisions**

- Approval - Proceed without any revision. Project may be submitted for appropriate University signatures and then to either the Local Research Ethics Committee.
- Approval Subject to Amendments - Amendments required. Revise project and resubmit for Chair's action.
- Deferred - Major scientific flaws and subject to major overhaul or abandonment.

#### **1.5. LREC Approval Procedures**

It may be helpful to note that following the completion of the University approval process and the submission of the NHS ethical approval form (IRAS Form) researchers and supervisors submitting to an NHS REC may be invited to attend the REC meeting at which their submission is being considered to answer questions and defend their proposal.