Staffordshire University

Academic Ethics Sub-Committee

An Introduction and Guidance to the Research Ethics Approval Process

This document describes procedures for the ethical approval of research projects carried out by staff and students of Staffordshire University. The University takes the view that such consideration is at the foundation of a sound research methodology and expects that at undergraduate, postgraduate level and in staff research these principles are given their due weight in the formulation of projects. It is assumed that Faculties, via those who supervise students or staff, will include reference to and discussion of research ethics when preparing researchers for their work. Reference should also be made to the University's **Code of Conduct for Research**, which covers a range of other issues which researchers will need to consider when designing and carrying out research projects. Ethics approval procedures may also need to be followed when undertaking enterprise or consultancy work, or when setting up other kinds of projects for student assessment; you should consult the Chair of your Faculty Ethics Committee for advice on this issue if necessary.

In principle then ethics approval may be required for any piece of work that implicates the involvement of others (human or animal) or has the capacity to interfere with or make a difference to their lives. 'Others' commonly refers to participants in the research, but could also refer to others affected by it e.g. at risk of physical or mental harm. This is without reference to the length of the piece of work, or the level at which it is undertaken. It is acknowledged that there are sometimes difficulties in drawing a clear line between research requiring/not requiring ethical consideration, but if in doubt researchers are advised to err on the side of caution and go through the ethical approval route.

Where there are no ethical implications the researcher should sign a **disclaimer.** The form to be used is included in the set of approval forms that accompany this document. All disclaimers should be stored in the appropriate Faculty office in such a way that records can be easily subject to audit if required. As is the case for examination scripts and other coursework assessments, disclaimers should be retained for a period which extends to one year after students graduate. Disclaimers for staff projects should be kept until one year after project completion, subject to any external requirements for the retention of documentation, and thereafter on a sample basis.

Some Guidance on When Ethical Approval is Required

The development of a sound research methodology includes consideration of ethical principles. It requires the identification of ethical implications and issues arising and will involve action to address them. Signing the disclaimer implies that these principles have been reviewed in relation to the proposed work and no issues have been found to apply to the research proposal. In these cases research may then proceed. In general any proposal which involves human or animal participants, their 'products' (e.g. body samples, written records, etc), has a direct impact on individuals, (e.g. research that will evaluate imposed changes to people's working environment) or uses contemporary material that may implicate living subjects or organisations, will need ethical approval, and cannot be 'disclaimed'. For these

projects the University requires all students, staff and supervisors to apply for Ethical Approval using the fast track approval form or, if appropriate, the full ethical approval application form.

Basic Ethical Principles

In preparation for submitting a research project for ethics approval, whether by the fast-track or full approval process, the researcher (with supervisory input if the researcher is a student) should consider the following basic ethical principles.

- Participants' interests and /or rights
- Informed Consent – i.e. the need to inform participants of the aims and procedures of the research and obtain their agreement to take part on the basis of this information
- Deception – i.e. the need to avoid deception in informing participants about the research, or to justify the need for deception if necessary
- Debriefing – i.e. the need to provide participants with additional information to support them after taking part in the research, and/or to provide true information if deception was necessary originally
- Withdrawal from Investigation – i.e. the need to inform participants of their right to withdraw from the research at any stage, including during or at the end of their involvement
- Confidentiality – i.e. the need to reassure participants that information they provide will not be disclosed to others other than within the context of the research, or at a minimum will be made anonymous
- Participant and researcher safety and risk – i.e. the need to avoid harm or potential harm.
- Possible impact of work on others

Various professional groups have their own ethical guidelines and many of these are easily available on the Internet and can be consulted and/or downloaded. Some of the most useful are those published by the British Psychological Society and these may be consulted by those needing guidance.

Procedures for the Ethical Approval of Research Projects

Researchers should note at the outset of any application for research ethics approval that the part of the research for which ethical approval is sought must not take place until such approval is given.

A summary of the required processes is provided in the flow diagrams which accompany this document, and all forms referred to in this document are also available from the University Research Ethics website, at www.staffs.ac.uk/???

1. Researchers who have identified within their project issues that require ethical approval should first complete a draft of the University **Fast Track Ethical Approval Form –** Staff or Student version as appropriate. Students should seek the advice of their supervisor, and staff should consult their research mentor and /or other appropriate colleagues if appropriate.

2. Where this process indicates no significant ethical implications requiring a full ethics submission, the Fast Track Ethical Approval Form should be completed Where significant

ethical implications are indicated the researcher should complete and submit the **Full Application for Ethical Approval of a Research Project** form. Supervisors should note, however, that there may be sound pedagogic reasons why they may wish their students to complete the Full Application even when it is acceptable to use the fast track approach.

3. For undergraduate and postgraduate students the Fast Track Ethical Approval Form must be signed by the student, their supervisor, and one other member of academic staff. The form should then be stored in the appropriate Faculty Office in such a way that records can be easily subject to audit if required, and for a time period as indicated above for disclaimers. For staff, their own signature is sufficient, but a copy of the form should also be sent to the Chair of the Faculty Ethics Panel.

4. In order to facilitate progress and avoid delay for undergraduate and taught postgraduate student projects, the Student Fast Track Ethical Approval Form allows the possibility that ethical approval may be granted in principle, subject to later submission to the supervisor for final approval of key documents such as consent forms, information sheets and questionnaires. **Students and supervisors should note that the part of the research for which ethical approval is sought must not take place until this final approval is given.**

5. Where significant ethical implications are indicated the researcher should complete and submit the **Full Application for Ethical Approval of a Research Project** form to the relevant Faculty Ethics Panel – see below. In addition to requiring the completion of this form, some researchers may also be required to submit a Risk Assessment Form. Where this is the case it must be submitted attached to the main form, and the Faculty is required to retain a copy of the Risk Assessment.

6. Applications should be submitted for approval as early as possible. All projects must be signed off from an ethics perspective before that part of the work for which approval is being sought begins. Where external funding is sought ethical approval must be gained before the application leaves the University. Faculty Ethics Panels should post information about dates of meetings at the start of each academic year.

7. If projects are approved research may proceed. The applicant and supervisor[s] will receive a letter to this effect. The approval letter will indicate the timescale within which the research must commence in order for ethical approval to be valid. Projects which do not begin within specified timescales must begin the approval process again and submit a further application for ethical approval.

8. If projects are approved subject to amendments the applicant and supervisor[s] will receive a letter to this effect that indicates the minor points that require clarification. The project should be amended and re-submitted to the appropriate Faculty Ethics Panel for approval.

9. If projects are not approved because they contain major flaws the applicant and supervisor[s] will receive a letter from the appropriate Faculty Ethics Panel, detailing the issues to be addressed. The project must be substantially revised and re-submitted to the Faculty Ethics Panel for approval.

10. Faculty Ethics Panels 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 informing them of the result of the University's considerations.

11. The accompanying documents include copies of the forms on which researchers should be given feedback as to the status of their project after consideration, as described in 8-11

above. **That part of the research project for which ethics approval is sought should not begin until approval has been given.**

12. If projects which initially have been judged not to have ethical implications change and do subsequently have ethical dimensions it is the responsibility of project supervisors for all supervised research, or in other cases the staff responsible for the research, to ensure that ethical scrutiny procedures are invoked and followed through. If projects approved by the fast track process subsequently develop additional non-routine ethical dimensions, as indicated by the questions on the Fast Track Ethical Approval Form, then a Full Application should subsequently be made to the Faculty Ethics Panel.

13. All adverse events occurring during the conduct of research projects must be reported to the Faculty Ethics Panel, or in the case of Fast Track approval to the supervisor (student projects) or Chair of the Faculty Ethics Panel
(staff projects). It is likely that the occurrence of adverse effects on projects originally approved by fast track procedures will trigger the need to make a Full Application for ethics approval if the research is to proceed.

14. Faculty Ethics Panels should be notified when research projects are completed. In the case of fast-track approval, supervisors (student projects) or the Chair of the Faculty Ethics Panel (staff projects) should be notified.

15. It is recommended that copies of signed approval forms be included in the Appendices of student dissertation/ project reports.

16. For projects requiring external NHS LREC approval, either the Full Application for Ethical Approval of a Research Project or the COREC Form must be completed. Applicants should refer to the document '**Procedures for Research Projects which Require Approval from NHS Research Ethics Committees'.** All applications in this category must be sent to the Faculty Ethics Panel in the Faculty of Health and Sciences for approval.

These procedures are summarised in four flowcharts, one for students, one for SURF students, one for staff for projects which will not require NHS Local Research Ethics committee approval, and a further flowchart which indicates the procedures to be followed for the health and social care related projects which will require external approval from an NHS LREC.

Checklist of Additional Issues to be Considered when completing Ethics Approval Forms

- At the outset you should consider where the research is located in relation to any hazard or difficulty that may arise in relation to:
    - Facilities
    - Safety
    - Other institutions – is permission necessary, has approval been sought from them?
    - Other interested parties?

- Purpose of Research : project must be supported by:

- Academic/scientific rationale
- Background to project
- Review of existing work
- Aims
- Specific hypotheses to be tested

- Risk Assessment

In planning your work you should ask and explicitly define any special ethical considerations.

- Details of them – justifications
- Potential hazards e.g. in relation to the physical environment for research
- Potential inconvenience to participants
- Explicit information that will be given to participants

You may need to conduct a specific risk assessment and append this to your proposal.

- Description of Procedures

Your project application should cover the following issues

- Design of project
- What procedures will be followed
- How participants will contribute
- Will project test hypotheses?

- Participants:

You should consider how they are:

- Recruited
- Numbers
- Age
- Gender
- State of Health
- Groups requiring justification, e.g. children, elderly, those with a mental or physical impairment

You must also consider how the participants will be treated including details about:

- How participants will be informed
- How consent is obtained and recorded – Is it written, Is it from a parent/guardian?

The above should be summarised on an information sheet for participants

You must also ascertain whether or not you need Criminal Records Bureau clearance in order to proceed with your research. If so this must be obtained before you begin data collection or other research activities which require this clearance

- Information and Data

Data obtained will be covered by the Data Protection Act therefore you must explain:

- What data will be obtained
- How will confidentiality be maintained
- Security and access to data
- Analysis
- Storing of data and disclosure

- Legal Issues

Consider if you need :

- To obtain/seek indemnification
- To Include risk assessment with your application for approval

Ethics Approval Committees

Academic Ethics Sub-Committee (AESC) is a sub-committee of Quality Development Committee. It meets three times year and is responsible for the setting and dissemination of policy around research ethics approval, the review and monitoring of practice, and the organisation of awareness training. A Sub-Committee of AESC is responsible for Research Governance issues, which need to be followed by projects which require NHS approval.

Routine ethics approval work is now devolved to Faculties. Each Faculty convenes a **Faculty Ethics Panel**. Meetings are scheduled as needed, but should be built into the Faculty's annual calendar in relation to the regimes for preparing and agreeing research projects. Where a large volume of work is involved, Faculty Ethics Panels may devolve responsibility to Programme Area (or Subject Area) Ethics Panels,
and monitor their activity on an annual basis. Faculty Ethics Panels may refer specific proposals to AESC where issues arise that they feel unable to assess. Faculty Ethics Panels are required to provide an annual report to AESC summarising the ethics approval work carried out and highlighting any issues that have arisen. Ethics approval work in Faculties may be subject to audit by AESC.

From 2005/6 an additional Ethics Panel will be located within the Academic Development Institute to receive proposals from non-Faculty staff. Also from 2005/6 there is an expectation that students on Staffordshire University awards in partner institutions will work within approved ethics guidelines, either those of the partner institution (which must be approved by the University) or our own. Ethics Panels in partner institutions should, where possible, be set up, and should report annually to either SURF Quality Committee or Academic Collaboration Sub-Committee. These committees should provide an annual summary of any issues in need of consideration to AESC. It is acknowledged that these systems will take a while to embed, and Faculty Ethics Panels may wish to support their collaborative awards in the interim by providing advice and receiving proposals. Advice and training will be offered to International Programme Advisers and Link Tutors.