

## 1. Introduction

- 1.1 The University's Ethical Review policy applies to everyone carrying out research under the auspices of Staffordshire University, whether within or outside University premises or facilities. This includes, but is not limited to, undergraduate and postgraduate students; staff members; visiting researchers; and individuals holding honorary posts.
- 1.2 The University Research Ethics Policy is designed to complement the National Health Service (NHS) ethics review system. The University's Ethics Review Procedures do not, therefore, duplicate the functions, or overlap with the remit, of the NHS ethics review system.
- 1.3 Any queries regarding the applicability of this policy should be referred to the Chair of the University's Research Ethics Committee.
- 1.4 For the purpose of this policy, 'research' includes all investigation undertaken in order to acquire knowledge and understanding, across the full range of academic disciplines and also incorporates research undertaken within, or on behalf of, professional support departments (REF, 2011. P. 43). This includes:

- work of educational value designed to improve understanding of the research process;
- work of relevance to commerce, industry;
- work of relevance to the public and voluntary sectors;
- scholarship supporting the intellectual infrastructure of subjects and disciplines (such as dictionaries, scholarly editions, catalogues, and contributions to research databases);
- the invention, design and generation of ideas, images, performances and artefacts, where these lead to new or substantially improved understanding; and
- the experimental use of existing knowledge to develop, design and construct new or substantially improved materials, devices, products and processes.

This definition of research excludes:

- the production of student assessments which do not require original research (e.g. the critical analysis and evaluation of existing published material including text books and academic journals);
- the development of teaching materials that do not embody original research;
- routine audit and evaluation, within the established management procedures of organisations.

- 1.5 Types of research activity covered by this policy include, but are not limited to:
- Undergraduate and postgraduate taught dissertations or projects;
  - Postgraduate research degrees;

- Research that is funded in whole or in part by Staffordshire University or an external organisation;
- Work undertaken by a member of staff under the auspices of Staffordshire University; for example:
  - Non-funded research
  - Consultancy activity
  - Work undertaken in the capacity of an expert witness
- Institutional Research conducted or commissioned by Staffordshire University (e.g. Market Research).

## 2. Ethical Principles

2.1 Research ethics at Staffordshire University is underpinned by the following commonly agreed principles of ethical research (Association of Research Ethics Committees, 2013, p. 5):

- **Autonomy** - Individuals participating in the research must be made aware of the purpose of the research and be free to take part without coercion or penalty for non-participation. Individuals should be able to withdraw at any time without being required to give a reason and without threat of any adverse consequences arising from their withdrawal.
- **Beneficence** – The research must be worthwhile and provide a reasonable opportunity for securing beneficial outcomes which outweigh any associated risks. The research methodology must be sound, ensuring the best results are obtained.
- **Non-maleficence** – Any possible harm must be avoided by robust precautions.
- **Confidentiality** – Personal data must remain unknown to all but the research team (unless the participant agrees otherwise, or in cases where there is an overriding public interest, or where participants wish their voices to be heard and identified).
- **Integrity** – The researcher must acknowledge any actual or potential conflicts of interest, and undertake their research in a manner that recognises standards of research integrity.

2.2 The University's policy and procedures for the ethical review of research proposals have been informed by the following expectations (Association of Research Ethics Committees, 2013, p. 6):

- **Independence** – The ethical review of research projects must include reviewers who are not connected to the research and are free to reach an independent judgement, unimpeded by potential conflicts of interest.
- **Competence** – Ethical review decisions should be informed by relevant expertise and be made by competent reviewers who are fully conversant with the University's Research Ethics Policy and its associated procedures.

- **Facilitation** – The ethical review process should be efficient and effective. The process should protect the interests of those potentially affected by the research, whilst not presenting unnecessary or unreasonable barriers to the conduct of good research.
- **Openness** – The ethical review process should be transparent and accountable, with clear lines of responsibility. Details of the research ethics review process should be published and made available to the public.

### 3. Research Requiring Ethical Approval (Proportionate or Full Ethical Review)

- 3.1 The need to consider the ethical implications of a proposed piece of research is not dependent on the length of a piece of work or the academic level at which it is being undertaken.
- 3.2 Ethical approval is required prior to the commencement of all:
- Research that involves human or animal participants. This includes direct participants in the research, but also includes others affected by it e.g. at risk of physical or mental harm.
  - Research that does not directly involve human and animal participants but does raise other ethical issues due to the potential social or environmental implications of the study.
  - Research which re-uses previously collected personal data which is sensitive in nature, or enables the identification of individuals.
- 3.3 Ethical approval is **not** normally required when:
- The research will only employ information freely available in the public domain. This includes: published biographies, newspaper articles, and published minutes of meetings.
  - The research will only draw upon anonymised records and data sets that already exist in the public domain. (e.g. published by the Office of National Statistics).
- 3.4 It is acknowledged that there are sometimes difficulties in establishing a clear line between research requiring and not requiring ethical approval. Where these situations arise, researchers are advised to adopt a precautionary approach and follow the ethical approval procedure, or seek further advice from the Chair of the appropriate Faculty Research Ethics Committee.

### 4. Responsibilities

- 4.1 Responsibility for maintaining ethical conduct lies, in the first instance, with the individual researcher. All researchers must ensure that their research is conducted in accordance with the University's Research Ethics Policy and its associated procedures.
- 4.2 Associate Deans for Scholarship Enterprise and Research and Heads of School, Service or Research Institute are responsible for the conduct of the research in their areas. They are therefore responsible for ensuring that researchers have access to

the appropriate ethics review procedures. They are responsible for ensuring that all research-active staff and students are familiar with the content of the University's Research Ethics Policy.

- 4.3 Each Faculty is responsible for identifying staff members responsible for the storage of documentation arising from the operation of University and Faculty Research Ethics procedures.

## **5. University Research Ethics Sub-Committee**

- 5.1 The University Research Ethics Sub-Committee is responsible for monitoring and reviewing University policies and procedures governing the ethical scrutiny and conduct of research and for recommending proposals for their development and enhancement.
- 5.2 The Sub-Committee will be responsible for considering appeals against Faculty Research Ethics Committee decisions and will consider complex ethical review applications referred to it by Faculty Research Ethics Committees.
- 5.3 The terms of reference and composition of the Research Ethics Sub-Committee will be published on the University's Research Ethics Website.
- 5.4 The terms of reference and composition will be confirmed at the commencement of each academic year, with proposed changes being submitted for approval by the University's Academic Board.

## **6. Faculty Research Ethics Committees**

- 6.1 Each University Faculty will have a formally convened Faculty Research Ethics Committee.
- 6.2 The terms of reference of Faculty Research Ethics Committees will include, as a minimum:
  - i. To consider applications for full ethical review.
  - ii. To inform the University Research Ethics Sub-Committee of high-risk projects identified and under review.
  - iii. To refer cases to the University Research Ethics Sub-Committee where necessary.
  - iv. To provide advice and guidance on any matters relating to the ethical scrutiny and conduct of research.
  - v. To act as the vehicle for the dissemination of good practice in matters related to the ethical scrutiny and conduct of research.
- 6.3 The composition of each Committee should include a minimum of five members, including at least one lay member.

## 7. Lay Members

- 7.1 Voluntary lay member appointments to the University and Faculty Research Ethics Committee will be approved by the Chair of the University Research Ethics Committee.
- 7.2 Lay Members are normally appointed by the University for three years and can be renewed for a further three year term.
- 7.3 Lay member appointments are unpaid. The University will reimburse reasonable expenses incurred during the performance of the role.
- 7.4 In order to ensure impartiality, they will normally not have had close involvement with the University during the last five years. For example as a member of staff; a member of the Board of Governors; a student; or a near relative of a member of staff. They will not be personally associated with the sponsorship of students; involved in assessing; or involved closely with student placements.

## 8. Ethical Review Level 1: Ethics Disclaimer

- 8.1 Where the proposed research raises **no ethical risk** the researcher should complete a Staffordshire University Ethics Disclaimer (available on the Research Ethics Website).
- 8.2 An Ethics Disclaimer form is not required where an assessment task allocated to a student falls outside the definition of research as outlined in section 1.4.

## 9. Ethical Review Level 2: Proportionate Review

- 9.1 The Proportionate Review process may be used where the proposed research raises only **minimal ethical risk**. This research must: focus on minimally sensitive topics; entail minimal intrusion or disruption to others; and involve participants who would not be considered vulnerable in the context of the research. This may include (ESRC, 2012, p. 8)
  - Research that involves the use of an anonymous, self-completion questionnaire, or the completion of a standard survey that has no ethical implications and addresses an uncontentious topic (e.g. a transport survey).
  - The use of unlinked or aggregated human data, which when collected, was subject to relevant Research Ethics Committee approval.
  - Research that replicates a previous study previously approved by a Faculty Research Ethics Committee.
- 9.2 **Undergraduate research:** The completed form should be signed by the student, their supervisor and one other member of academic staff with no direct connection with the student or his/her research.
- 9.3 **Postgraduate research:** The completed form should be signed by the student, their supervisor and one member of the Faculty Research Ethics Committee with no direct connection with the student or his/her research.
- 9.4 **Staff research:** The researcher and one member of the Faculty Research Ethics Committee must sign the completed form. The Faculty Research Ethics Committee

Member should be located within another School and have no connection with the research being undertaken.

- 9.5 Where significant ethical implications are identified through the completion of the proportionate review process, the researcher must complete the full ethical review process.

## **10. Ethical Review Level 3: Full Ethical Review**

- 10.1 Full ethical review will be used for research involving **above minimal risk** and therefore necessitating a more thorough ethical review prior to approval. This will include (ESRC, 2012, p. 8):

- Research involving vulnerable groups. This includes: children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.
- Research involving sensitive topics. This includes: participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
- Research involving groups where permission of a gatekeeper is normally required for initial access to members, for example, ethnic or cultural groups, native peoples or indigenous communities.
- Research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out.
- Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
- Research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain.
- Research involving intrusive interventions. This includes: the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy which may cause participants to reveal information which could cause concern, in the course of their everyday life.

- 10.2 The application for full ethical review must be considered by at least two members of the Faculty Research Ethics Committee. Where the two reviewers are unable to reach an agreed judgment the application should be referred to a full meeting of the Faculty Research Ethics Committee. Where the Committee is unable to reach a judgement the application should be referred to the University Research Ethics Sub-Committee.

- 10.3 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.

## **11. NHS Research - Independent Peer Review (IPR)**

- 11.1 All research projects which require NHS Research Ethics Committee approval must provide evidence of Independent Peer Review of their Scientific Merit.

- 11.2 Relevant projects will be considered by the Independent Peer Review Panel located within the Faculty of Health Sciences. The panel will be formally constituted as a sub-Committee of the Faculty of Health Sciences Research Ethics Committee.
- 11.3 Peer review should be appropriate to the nature of the research being undertaken and the source of funding/review. Researchers should review the current advice and guidance published by the National Research Ethics Service ([www.nres.nhs.uk](http://www.nres.nhs.uk)) and seek advice regarding their proposal from the relevant Research & Development Department within their Trust.
- 11.4 Projects will normally be reviewed by senior researchers at Staffordshire University who have no prior connection with the project. Where senior researchers with the requisite specialist knowledge are unavailable within the University, the project will be subject to external review.
- 11.5 Where a project is approved subject to amendments the applicant and supervisor[s] will receive a letter from the Chair of the IPR Panel to this effect indicating the points that require clarification. A revised IPR form responding to the points raised should be re-submitted to the IPR Panel for approval.
- 11.6 Where a project is not approved because it contains 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 the IPR form should be re-submitted to the Panel for consideration.
- 11.7 The IPR Panel may choose to defer a decision about a project and refer it to the Faculty Ethics Committee and in turn the University Research Ethics Sub-Committee for consideration outlining the issues that they can't decide on.
- 11.8 On securing Independent Peer Review Panel approval, the IPR form will be submitted for consideration by the Faculty of Health Sciences Research Ethics Committee. The Faculty Committee will be responsible for forwarding approved forms to the Chair of the University Academic Ethics Sub-Committee for his authorisation of the project and for insurance and indemnity.
- 11.9 When the project has received final authorisation, the researcher(s) 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.
- 11.10 No external project submission should take place until authorisation has been received.
- 11.11 On receipt of final authorisation, the researcher will submit the research ethics application to the NHS Research Ethics Committee, in accordance with NHS procedures.
- 11.12 The researcher is responsible for informing his/her Faculty Research Ethics Committee of the outcome of the NHS Research Ethics application.

## **12. Non-Compliance with Ethical Review Procedures**

- 12.1 The University expects that all research carried out in its name complies with the requirements and expectations of this policy and associated procedures. Where a researcher is suspected to be in breach of this Policy, the University may take action in accordance with its staff or student disciplinary procedures.

12.2 **The individual researcher will NOT be covered by the University's insurance if a favourable ethical review was not secured prior to the commencement of the research activity.** This means that should a participant make a claim regarding the research, then the student or staff member would be personally liable.

### **13. Appeals**

13.1 A researcher may appeal against a Faculty Ethics Committee decision on the following grounds:

- i. There existed material circumstances relating to the application of which the Faculty Research Ethics Committee was unaware.
- ii. Procedural irregularities occurred during the review process, resulting in reasonable doubt that the Committee would have reached the same conclusion regarding the application had the irregularities not taken place.
- iii. There is demonstrable evidence of prejudice, bias, or inadequate review.

13.2 **Stage 1:** Where a researcher is dissatisfied with the decision reached by a Faculty Ethics Committee the researcher may request that the Faculty Committee review its decision. When requesting the review, the researcher, must clearly articulate the reason for the request, including the provision of additional information not originally made available.

13.3 **Stage2:** Should the outcome of the review be contested by the researcher, he or she can submit an appeal to the University Research Ethics Sub-Committee.

13.4 If a researcher wishes to appeal to the University Research Ethics Committee, he or she should notify the Officer to the University Committee within ten days of receiving the Faculty Research Ethics Committee appeal decision.

13.5 An appeal should be submitted in writing and provide the following information:

- i. The title of the research proposal
- ii. The title of the Faculty Research Ethics Committee to which the ethical review application was submitted.
- iii. The reason for the appeal.
- iv. Any documentary evidence to support the appeal.

13.6 Appeals will be considered by a panel drawn from members of the University Research Ethics Sub-Committee. All panel members will be independent, having no previous involvement in the ethical review process leading up to the appeal.

13.7 The researcher and the Faculty chair will be informed in writing of the Committee's decision.

### **14. Retention and Storage of Ethical Review Documentation**

14.1 All documentation arising from the ethical review procedures (including disclaimer, proportionate and full ethical review forms) will be stored centrally by the appropriate Faculty or Service in such a way that records can be easily subject to audit when required.

- 14.2 Minutes from University and Faculty Research Ethics Committees should be held electronically in perpetuity.
- 14.3 Faculty's will retain disclaimer, proportionate review and full ethical review documentation for nine years, subject to any external requirements for the retention of documentation. Faculty and University Ethics Committees may further extend this retention period on a case-by-case basis.
- 14.4 All documentation should be stored in such a way as to ensure that individual documents can be easily located and audited by the University.

## **15. Annual Faculty Reports**

- 15.1 The Chair of each Faculty Research Ethics Committee will provide an annual report to the University Research Ethics Committee in respect of ethical issues in non-clinical research i.e. research not reviewed by an NHS ethics committee.
- 15.2 Reports to the University Research Ethics Committee will include the following:
- The current Committee membership.
  - Details of any suggested changes to the approved Faculty procedures.
  - The number of applications considered by Proportionate Review and Full Ethical Review; the decisions taken (approved, referred); and any particular difficulties encountered or action taken.
  - Any issues for consideration by the University Research Ethics Committee.
- 15.3 The University Research Ethics Sub-Committee will consider the annual reports, offer advice and recommendations as appropriate, and report to the University Quality Committee and Research and Advanced Scholarship Committee on any major policy issues or outstanding difficulties.

## **16. Audit of Ethical Review Procedures**

- 16.1 The Quality Enhancement Service will develop an annual Ethical Review Audit schedule for consideration by the University Research Ethics Sub-Committee. The proposed schedule will be considered at the first meeting of the Sub-Committee in each academic year. The schedule will ensure that all University Faculties receive an Ethical Review Audit over a two year period.
- 16.2 Audits will be conducted by a member of the University Research Ethics Committee, independent from the Faculty being audited.
- 16.3 An audit checklist will be produced by the auditor and approved by the Chair of the University Research Ethics Sub-Committee. The approved checklist will be circulated to the relevant University Faculty one week prior to the conduct of the audit.
- 16.4 A report detailing the findings of the audit will be submitted for consideration by the University Research Ethics Sub-Committee and the relevant Faculty Research Ethics Committee.

- 16.5 The Faculty Research Ethics Committee (to whom the audit report relates) will produce a formal response and action plan detailing the corrective and preventative action that will be taken by the Faculty to address any issues or non-conformance identified by the audit. The formal response will be submitted to the Chair of the University Research Ethics Committee within 20 working days of receiving the audit report.
- 16.6 The Faculty audit response and action plan will be submitted to, and considered by, the University Research Ethics Sub-Committee.
- 16.7 The University Research Ethics Sub-Committee will be responsible for monitoring the completion of the Faculty Action plan and for disseminating any recommendations or good practice identified by the audit to other areas of the University.

## **17. Collaborative Provision**

- 17.1 Arrangements for the ethical review of research proposals will be considered during the initial development and approval of collaborative provision. The proposals put forward for approval will clarify whether research proposals will be considered in accordance with University or partner ethical review policy and procedures.
- 17.2 Where research proposals will be considered in accordance with the partner's ethical review policy and/or procedures, a copy of the policy, procedure and associated documentation should be made available to the University Research Ethics Committee.
- 17.3 The operation of research ethics policies and procedures (University or partner) will be audited by Staffordshire University in accordance with section 16 of this policy.

## **18. References**

REF (2011) Assessment Framework and Guidance on Submissions.  
([http://www.ref.ac.uk/media/ref/content/pub/assessmentframeworkandguidanceonsubmissions/02\\_11.pdf](http://www.ref.ac.uk/media/ref/content/pub/assessmentframeworkandguidanceonsubmissions/02_11.pdf)), 23 May 2012.

The Association of Research Ethics (2013) A Framework of Policies and Procedures for University Research Ethics Committee.

ESRC (2012) ESRC Framework for Research Ethics  
([http://www.esrc.ac.uk/images/framework-for-research-ethics-09-12\\_tcm8-4586.pdf](http://www.esrc.ac.uk/images/framework-for-research-ethics-09-12_tcm8-4586.pdf))

**Approved by Staffordshire University's Academic Board on 26<sup>th</sup> November 2014**

**This policy will be reviewed in November 2016**