Staffordshire University Research Ethical Review Policy (Amended September 2019)

Contents

Staffordshire University Research Ethical Review Policy (Amended September 2019)

1. Introduction

1.1   The University's Research Ethical Review policy applies to everyone carrying out research at 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. In this policy, the term 'researcher' is used to describe any person doing research (as defined in section 1.5, below).

1.2   The University's Research Ethical Review Policy is designed to work alongside the National Health Service (NHS) ethics review system. The Policy does not duplicate or overlap with the functions of the NHS system.

1.3   Any queries regarding this policy, and who it applies to, should be referred to the Chair of the University's Research Ethics Committee.

1.4   This Research Ethical Review Policy applies to all academic subjects and disciplines. It also includes any research undertaken by professional support departments. Before any research (as defined below) is undertaken, the appropriate level of ethical approval must be secured, in line with this policy. The different levels of approval required, and the procedure that must be followed, are outlined in section 3.

1.5   For the purpose of this policy, 'research' includes all investigation undertaken in to gain knowledge and understanding. This includes:
- work of educational value designed to improve understanding of the research process;
- work of relevance to commerce and 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.

1.6   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 in the name 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).

1.7 This Research Ethical Review Policy should be read and followed alongside [Staffordshire University Code of Practice for Research](#)

2. Ethical Principles

2.1 Research ethics at Staffordshire University is based on the following principles of ethical research (adapted from the 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 being pressured to do so. Individuals should be able to withdraw at any time without being required to give a reason and without threat due to their withdrawal.

- **Beneficence** – The research must be worthwhile and provide a reasonable opportunity for securing beneficial outcomes. These outcomes should outweigh any potential 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 anonymous to anyone except 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 Applications for ethical approval will be considered by members of the Panel of Ethics Reviewers (as outlined in section 3, below), in line with this Research Ethical Review Policy. Appendix C provides a detailed description of the approval process.

2.3 The University's policy and procedures for the review of applications for ethical approval of research proposals have been informed by the following expectations (adapted from 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. The reviewers must be free to reach an independent judgement and are not affected by potential conflicts of interest.

- **Competence** – Ethical review decisions should be informed by relevant expertise and be made by competent reviewers. Reviewers must be fully aware of the University's Research Ethical Review 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

3.1 All research requires ethical approval. However, depending on the nature of the research you are planning to do, different levels of approval are needed. There are three levels of ethical approval:

- Disclaimer
- proportionate review
- full ethics

Staff and students should refer to the 'routes to ethical approval: a summary guide', below (appendix A) for guidance on what level of approval they require. The process for approval is described in detail in appendix C, at the end of the document.

All research projects which require NHS Research Ethics Committee approval must provide evidence of Independent Peer Review of their Scientific Merit (see Appendix C)

3.2 The researcher must consider the ethical implications of any proposed piece of research, before the research starts. This is regardless of the length of a piece of work or the academic level at which it is being undertaken.

3.3 Ethical approval is required before starting any:

- Research that involves human or animal[1] 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.
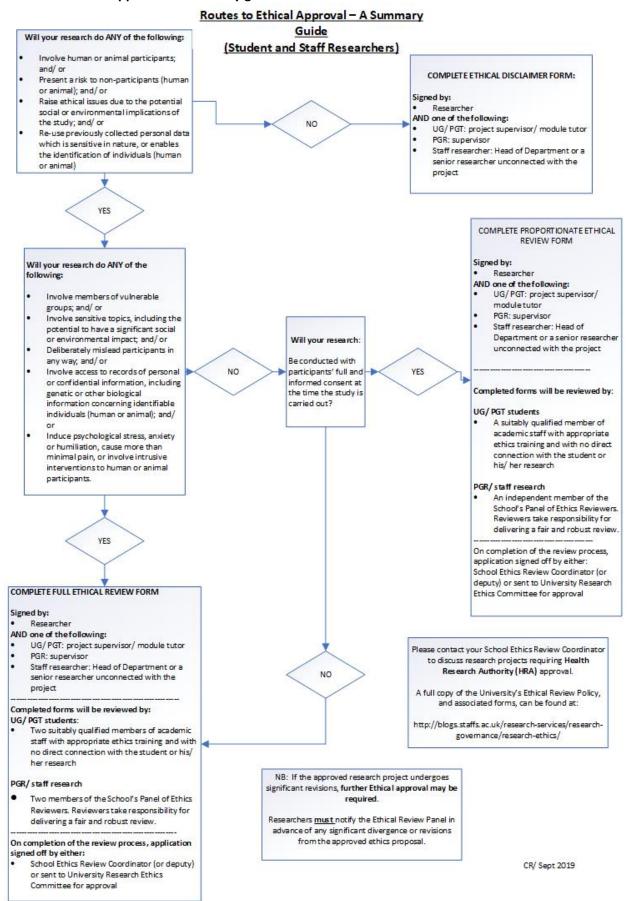
In these cases, you must complete either a **proportionate** or **full research ethical review** (please see the flow chart below)

3.4 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).

  In these cases, you should complete a **disclaimer** form (please see the flown chart below)

3.5 It can sometimes be difficult to do decide whether a piece of research does or does not need ethical approval. Where this situation does arise, researchers should follow the ethical approval procedure, or seek further advice from their School's Research Ethical Review Coordinator. If in any doubt over whether research does need approval, researchers should take extra care and should apply for ethical approval before starting any research. If there is any doubt over whether approval is required for a undergraduate or postgraduate taught research project, the proposal should be referred to the School's Ethical Review panel.

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[1] For this policy, animals are defined as 'All vertebrates and any other species of the kingdom Animalia demonstrated to be sentient', where sentience is defined as 'the ability of an animal not only to attempt to escape from an adverse environment, but also to learn to take informed decisions based on its environment and, if treated adversely, to demonstrate adverse physiological changes and behavioural suffering'.
Taken from Understanding Animal Research's response to the 2018 Draft Animal Welfare Bill Enquiry, available at http://www.understandinganimalresearch.org.uk/news/policy-issues/uars-response-to-the-draft-animal-welfare-bill-inquiry/, accessed 10Apr19.

Routes to Ethical Approval: A summary guide

Routes to Ethical Approval – A Summary Guide (Student and Staff Researchers)

Will your research do ANY of the following:

- Involve human or animal participants; and/ or
- Present a risk to non-participants (human or animal); and/ or
- Raise ethical issues due to the potential social or environmental implications of the study; and/ or
- Re-use previously collected personal data which is sensitive in nature, or enables the identification of individuals (human or animal)

NO →

COMPLETE ETHICAL DISCLAIMER FORM:

Signed by:
- Researcher

AND one of the following:
- UG/ PGT: project supervisor/ module tutor
- PGR: supervisor
- Staff researcher: Head of Department or a senior researcher unconnected with the project

YES ↓

Will your research do ANY of the following:

- Involve members of vulnerable groups; and/ or
- Involve sensitive topics, including the potential to have a significant social or environmental impact; and/ or
- Deliberately mislead participants in any way; and/ or
- Involve access to records of personal or confidential information, including genetic or other biological information concerning identifiable individuals (human or animal); and/ or
- Induce psychological stress, anxiety or humiliation, cause more than minimal pain, or involve intrusive interventions to human or animal participants.

NO →

Will your research:

Be conducted with participants' full and informed consent at the time the study is carried out?

YES →

COMPLETE PROPORTIONATE ETHICAL REVIEW FORM

Signed by:
- Researcher

AND one of the following:
- UG/ PGT: project supervisor/ module tutor
- PGR: supervisor
- Staff researcher: Head of Department or a senior researcher unconnected with the project

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Completed forms will be reviewed by:

UG/ PGT students
- A suitably qualified member of academic staff with appropriate ethics training and with no direct connection with the student or his/ her research

PGR/ staff research
- An independent member of the School's Panel of Ethics Reviewers. Reviewers take responsibility for delivering a fair and robust review.

On completion of the review process, application signed off by either: School Ethics Review Coordinator (or deputy) or sent to University Research Ethics Committee for approval

YES ↓

COMPLETE FULL ETHICAL REVIEW FORM

Signed by:
- Researcher

AND one of the following:
- UG/ PGT: project supervisor/ module tutor
- PGR: supervisor
- Staff researcher: Head of Department or a senior researcher unconnected with the project

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Completed forms will be reviewed by:
UG/ PGT students:
- Two suitably qualified members of academic staff with appropriate ethics training and with no direct connection with the student or his/ her research

PGR/ staff research
- Two members of the School's Panel of Ethics Reviewers. Reviewers take responsibility for delivering a fair and robust review.

On completion of the review process, application signed off by either:
- School Ethics Review Coordinator (or deputy) or sent to University Research Ethics Committee for approval

NO ←

Please contact your School Ethics Review Coordinator to discuss research projects requiring **Health Research Authority (HRA)** approval.

A full copy of the University's Ethical Review Policy, and associated forms, can be found at:

http://blogs.staffs.ac.uk/research-services/research-governance/research-ethics/

NB: If the approved research project undergoes significant revisions, **further Ethical approval may be required.**

Researchers **must** notify the Ethical Review Panel in advance of any significant divergence or revisions from the approved ethics proposal.

CR/ Sept 2019

4. Responsibilities

4.1   Responsibility for maintaining ethical conduct lies with the individual researcher. All researchers must ensure that their research is conducted in accordance with the University's Research Ethical Review Policy and its associated procedures.

4.2   Heads of academic departments and University services are responsible for the conduct of the research in their areas. They are therefore responsible for ensuring that researchers have access to the appropriate research ethical review procedures and that all research-active staff and students are familiar with the content of the University's Research Ethical Review Policy.

4.3   Each School is responsible for identifying staff members responsible for the storage of documentation arising from the operation of University and School Research Ethical Review procedures.

5. University Research Ethics Committee

5.1 Central oversight for Ethics across the University is provided by the University Research Ethics Committee (UREC). This Committee reports directly to the University Research, Innovation and Impact Committee, which reports to the University's Academic Board. (Please refer to appendix B showing the governance structure of research ethical review at the University.)

5.2 The University's Research Ethics Committee is responsible for monitoring and reviewing University ethics policies and procedures. This includes all policies and procedures governing the ethical scrutiny and conduct of research. Where required, the Committee will recommend proposals for their development and enhancement.

5.3 The University Research Ethics Committee will consider complex ethical review applications referred to it by Ethical Review Coordinators. This includes where the school wish to seek further advice or where a decision cannot be made by the school. The Committee is responsible for considering any appeals against ethical review decisions.

5.4 The Chair of the University Research Ethics Committee is nominated by the Deputy Vice Chancellor. The School Ethics Coordinator for each school sits on the University Research Ethics Committee. School Ethics Coordinators are responsible for giving ultimate approval of any full ethics or proportionate review applications (for staff and PGR) in their school. The University Research Ethics Committee therefore provides central governance of the research ethical review process in all schools.

5.5   The terms of reference and membership of the Research Ethics Committee will be published on the University's Research Ethics Website.

5.6   The terms of reference and membership will be confirmed at the start of each academic year. Any proposed changes must be approved by the University's Academic Board.

6. Panel of Research Ethics Reviewers and Research Ethical Review Coordinators

6.1   Each School will have a Panel of Ethics Reviewers. This panel is not a formal ethics committee which meets on a regular basis but is drawn from a group of experienced researchers who will be responsible for reviewing applications in their respective subject areas for proportionate or full research ethical review submitted by **postgraduate research students** and **staff researchers** within their school.

6.2   Ethical approval for undergraduate and postgraduate taught dissertations and fieldwork applications will be handled in schools by the course teams and will not normally be referred to the Panel of Ethics Reviewers. However, in complex cases, these applications can be referred to the Panel.

6.3 Where an application for ethical approval is submitted for research being conducted by staff within a central university service, this should be submitted to the ethics@staffs.ac.uk email inbox. The Chair of the University Research Ethics Sub Committee will determine which School's Panel of Ethics Reviewers is the most appropriate to review and approve the application.

6.4 Schools will be responsible for ensuring that all Panel members maintain a comprehensive understanding of the University's Research Ethical Review Policy and associated procedures.

6.5 Consistency of Research Ethical Review will be ensured by regular training sessions provided by Research Innovation and Impact Services (RIIS) and delivered by experienced ethics reviewers, normally members of the University Research Ethics Committee. These sessions will be mandatory for members of the Panel of Ethics Reviewers. All academic staff are also required to complete the mandatory online ethics training.

6.6 Members of the Panel of Ethics Reviewers will be supported by an Ethics Handbook, produced by the University Research Ethics Committee and provided to all reviewers. This Handbook will contain discipline specific information, as well as generic advice on reviewing applications for ethical approval. Any member of the Panel of Ethics Reviewers should be encouraged to seek support from their School Research Ethical Review Coordinator if they are unsure of any aspect of the work they are reviewing.

6.7 Each School will appoint an Ethics Review Coordinator to facilitate and oversee the effective operation of research ethical review processes within the School. The Coordinator should be a member of academic staff with appropriate research experience and will become a member of the University Research Ethics Committee

6.8 School Ethics Review Coordinators will:

    i. Ensure the efficient and equitable allocation of applications for research ethical review across the Panel of Ethics Reviewers.

    ii. Inform the University Research Ethics Committee of high-risk projects identified and under review.

    iii. Refer cases to the University Research Ethics Committee where a decision cannot be made based on the review process (for example when there is a substantial disagreement between the reviewers).

    iv. Provide advice and guidance on any matters relating to the ethical scrutiny and conduct of research.

    v. Disseminate good practice in matters related to the ethical scrutiny and conduct of research within the School.

    vi. Work with Heads of Department to compile an annual research ethics report for submission to the University Research Ethics Committee. (see section 15).

7. Lay Members

7.1 Membership of the University's Research Ethics Committee will include one lay member. Appointments 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 one further three-year term.

Lay member appointments are unpaid. The University will reimburse reasonable expenses incurred during the performance of the role.

7.3 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. Non-Compliance with Ethics Review Procedures

8.1   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.

8.2   **The individual researcher will NOT be covered by the University's insurance and indemnity procedures if ethical approval was not secured before the research activity started.** This means that should a participant in the research make a claim regarding the research, then the student or staff member would be personally liable.

8.3   The University will use the following mechanisms to verify that the correct ethical procedure had been followed for all research activity:

   a. There will be mandatory ethics training for all academics. It will be the responsibility of Schools and Services to ensure all their staff have completed the ethics training. All members of the panel of ethical reviewers will also receive face to face training from a member of the University Research Ethics Committee.
   b. There will be regular re-training and reminders about the need to complete ethics for all research, delivered at both University and School levels. Ethics and current research activity will be added as an agenda item to all regular meetings between RIIS and school SMTs.
   c. There will be an annual audit of a proportion of publications in the University's repository (STORE) to ensure that the have appropriate ethical approval. This audit will be undertaken centrally by RIIS and reported to the University Research Ethics Committee. A summary of the report will, in turn, be presented to the Research & Innovation Committee. This annual audit will be supplemented by regular spot check audits of publications in STORE, to be undertaken by RIIS and reported to the University Research Ethics Committee.
       This audit of publications will be in addition to comprehensive audit of School's ethical review procedures, as detailed in section 11, below.

9. Appeals

9.1   A researcher may appeal against an ethics review decision on the following grounds:

   i.   There existed material circumstances relating to the application of which the reviewers were unaware.
   ii.   Procedural irregularities occurred during the review process, resulting in reasonable doubt that the reviewers 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.

9.2   Where a researcher is dissatisfied with the outcome of the research ethics review decision reached by the School, he or she can submit an appeal to the University Research Ethics Committee.

        If a researcher wishes to appeal, he or she should notify the secretary to the University Committee within ten days of receiving the School's decision

        When requesting the review of the original decision, the researcher, must clearly articulate the reason for the request, and may include in the request additional information not originally made available.

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

       i.   The title of the research proposal

      ii.   The University School to which the research ethical review application was submitted.

     iii.   The reason for the appeal.

     iv.   Any documentary evidence to support the appeal.

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

9.5   The researcher and the School's Research Ethical Review Coordinator will be informed in writing of the Committee's decision.

10. Annual School Reports

10.1   School Ethics Review Coordinators will work with Heads of Department to 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). Heads of Department will be responsible for making data relating to ethics review processes within their department available to the Coordinator.

10.2   Reports to the University Research Ethics Committee will include the following:

- The current membership of the School's Panel of Ethics Reviewers.

- Details of any suggested changes to the approved School procedures.

- The number of applications considered by Proportionate and Full Research 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.

10.3   The University Research Ethics Committee will consider the annual reports, offer advice and recommendations as appropriate, and report to the University Research, Innovation and Impact Committee on any major policy issues or outstanding difficulties.

11. Audit of Ethics Review Procedures

11.1   Audits of Ethical Review procedures in the Schools will be undertaken annually. Research Innovation and Impact Services will develop an annual Ethics Review Audit schedule, which will be approved by the University Research Ethics Committee. At least two Schools will be audited per academic year and the schedule will ensure that all University Schools receive an Ethics Review Audit over a three-year period. The proposed schedule will be considered at the first meeting of the University Research Ethics Committee in each academic year

11.2   The Audit will review and identify any issues with the quality and appropriateness of ethical review undertaken in the school and identify issues of non-compliance or deviation with the ethical review policy.

11.3   Audits will be conducted by a member of the University Research Ethics Committee, independent from the School being audited. Audits will be undertaken using the audit checklist developed and approved by the University Research Ethics Committee. The approved checklist will be circulated to the relevant University School one month prior to the conduct of the audit.

11.4   A report detailing the findings of the audit will be submitted for consideration by the University Research Ethics Committee. In addition to this report, any issues of insufficient ethical review or non-compliance with the ethical review policy will be reported at the earliest available opportunity by the auditor to the Chair of the Ethics Committee. If, in the opinion of

the Chair, any issues raised represent a serious breach of the ethical review policy, these must be reported immediately to the Deputy Vice Chancellor.

11.5   The School Ethics Review Coordinator of the audited school will produce a formal response and action plan detailing the corrective and preventative action that will be taken by the School to address any issues or non-conformance identified by the audit. This action plan will be reviewed by the School Academic Committee and a formal response will be submitted by the Dean to the Chair of the University Research Ethics Committee within 20 working days of receiving the audit report.

11.6   The School audit response and action plan will be submitted to, and considered by, the University Research Ethics Committee.

11.7   The University Research Ethics Committee will be responsible for monitoring the completion of the School Action plan and for disseminating any recommendations or good practice identified by the audit to other areas of the University. The Committee may instigate follow up audits of the School to ensure compliance with the ethical review policy and procedures.

12. Collaborative Provision

12.1   Where the research undertaken is part of a collaborative partnership, arrangements for the research ethical review of 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's or partner's research ethical review policy and procedures.

12.2   Where research proposals will be considered in accordance with the partner's research ethical review policy and/or procedures, a copy of the policy, procedure and associated documentation must be made available to the University Research Ethics Committee.

12.3   The operation of research ethical review policies and procedures (University or partner) may be audited by Staffordshire University in accordance with section 11 of this policy.

13. References

13.1   REF (2019) Guidance on Submissions (https://www.ref.ac.uk/publications/guidance-on-submissions-201901/)

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

13.3   ESRC (2016) ESRC Framework for Research Ethics (https://www.gla.ac.uk/media/media_326706_en.pdf)

APPENDIX A: Governance of Research Ethical Review

Governance of Ethical Review

APPENDIX B: Processes for Ethical Approval

The below section summarises the processes for the differing levels of ethical approval (disclaimer, proportionate review and full ethics).

Research Ethical Review Level 1: Ethics Disclaimer

14.1   Where the proposed research raises **no ethical risk** the researcher should complete a Staffordshire University Research Ethics Disclaimer (available on the Research Ethics Website).

14.2   An Ethics Disclaimer form may be used when the research will **NOT**:

- Involve human or animal participants; and/or
- Present a risk to non-participants (human or animal); and/or
- Raise ethical issues due to the potential social or environmental implications of the study; and/or
- Re-use previously collected personal data which is sensitive in nature, or enables the identification of individuals (human or animal)

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.

14.3   For **undergraduate and postgraduate taught students**, the ethics disclaimer form should be signed by the student and their supervisor/ module tutor and should be submitted to the **relevant module leaders to note. These disclaimers will be stored electronically in the school by the course teams. Students should be notified of receipt of their ethics disclaimer by the module leader and informed that, should their project deviate from the information provided, they must seek ethical approval through either a proportionate of full research ethical review.**

14.4   For **postgraduate research** the ethics disclaimer form should be signed by the researcher and their supervisor. The disclaimer form should be submitted to the central research ethics administrators in RIIS (via the ethics@staffs.ac.uk email inbox). The researcher will receive confirmation of the receipt of their disclaimer from RIIS and will be informed that, **should their project deviate from the information provided, they must seek ethical approval through either a proportionate of full research ethical review. RIIS will store the disclaimer form electronically.**

14.5   For **staff research** the ethics disclaimer form should be signed by the researcher countersigned by the head of department or a senior researcher unconnected to the project. The disclaimer form should be submitted to the central research ethics administrators in RIIS (via the ethics@staffs.ac.uk email inbox). The researcher will receive confirmation of the receipt of their disclaimer from RIIS and will be informed that, **should their project deviate from the information provided, they must seek ethical approval through either a proportionate of full research ethical review. RIIS will store the disclaimer form electronically**

Research Ethical Review Level 2: Proportionate Review

15.1   The Proportionate Review process may be used where the proposed research raises only **minimal research 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 review and approval.

- Research that replicates a previous study previously approved in accordance with the University's Research Ethical review policy.

15.2 **Undergraduate and taught postgraduate research:** The completed form should be signed by the student and their supervisor. It should be submitted to the **relevant module leader who will arrange for it to be reviewed and approved by** one other member of academic staff with no direct connection with the student or his/her research. The course team may choose to convene an 'ad-hoc' ethics approval panel for the purposes of considering ethical applications submitted by a cohort of students (such as in preparation for a dissertation or final year project). The course team should aim to review the application within 21 working days of receipt, or within 21 working days of the publicised deadline for the submission of research ethical review forms. The student should be notified of the ethics approval by the module leader and permitted to commence the research. The student should be informed that **should their project deviates from the information provided, they must seek further ethics approval or approval of an amendment to the original research project. The form will be stored electronically in the school by the course teams.**

15.3 **Postgraduate research:** The completed form should be signed by the student and their supervisor. It should be submitted to the ethics@staffs.ac.uk email inbox where the central ethics administration team will arrange for it to be reviewed by one member of the School's Panel of Ethics Reviewers with no direct connection with the student or his/her research. RIIS will aim to provide the reviewers feedback to the student on their application within 21 working days of receipt of the application. The form should be signed off by the School Coordinator or deputy coordinator. The student should be notified of the ethics approval by RIIS and permitted to commence the research. The student should be informed that **should their project deviate from the information provided, they must seek further ethics approval or request approval of an amendment to the original project. RIIS will store the proportionate review form electronically.**

15.4 **Staff research:** The researcher must sign the completed form and arrange for it to be countersigned by the head of department or a senior researcher unconnected to the project. The form should then be submitted to the ethics@staffs.ac.uk email inbox where the central ethics administration team will arrange for it to be reviewed by one member of the School's Panel of Ethics Reviewers. The reviewer should be located within another research group or Department and have no connection with the research being undertaken. RIIS will aim to provide the reviewers feedback to the staff on their application within 21 working days of receipt of the application.

The form should be signed off by the School Coordinator or deputy coordinator. The member of staff should be notified of the ethics approval by RIIS and permitted to commence the research. They should be informed that **should their project deviate from the information provided, they must seek further ethics approval or request approval of an amendment to the original project. RIIS will store the proportionate review form electronically.**

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

Research Ethical Review Level 3: Full Research Ethical Review
16.1 Full research ethical review will be used for research involving **above minimal risk** and therefore necessitating a more thorough research 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.

16.2 **Undergraduate and taught postgraduate research:** The completed form should be signed by the student and their supervisor. It should be submitted to the **relevant module leader who will arrange for it to be reviewed and approved by** two other members of academic staff with no direct connection with the student or his/her research. The course team may choose to convene an 'ad-hoc' ethics approval panel for the purposes of considering ethics applications submitted by a cohort of students (such as in preparation for a dissertation or final year project). The course team should aim to review the application within 21 working days of receipt (or within 21 working days of the publicised deadline for the submission of ethics review forms.) The student should be notified of the ethics approval by the module leader and permitted to commence the research. The student should be informed that **should their project deviates from the information provided, they must seek further ethics approval or approval of an amendment to the original research project. The form will be stored electronically in the school by the course teams.**

16.3 **Postgraduate research:** The completed form should be signed by the student and their supervisor. It should be submitted to the ethics@staffs.ac.uk email inbox where the central ethics administration team will arrange for it to be reviewed by two member of the School's Panel of Ethics Reviewers with no direct connection with the student or his/her research. RIIS will aim to provide the reviewers feedback to the student on their application within 21 working days of receipt of the application. The form should be signed off by the School Coordinator or deputy coordinator. The student should be notified of the ethics approval by RIIS and permitted to commence the research. The student should be informed that **should their project deviate from the information provided, they must seek further ethics approval or request approval of an amendment to the original project. RIIS will store the proportionate review form electronically.**

16.4 **Staff research:** The researcher must sign the completed form and arrange for it to be countersigned by the head of department or a senior researcher unconnected to the project. The form should then be submitted to the ethics@staffs.ac.uk email inbox where the central ethics administration team will arrange for it to be reviewed by two members of the School's Panel of Ethics Reviewers. The reviewers should be located within another research group or Department and have no connection with the research being undertaken. RIIS will aim to provide the reviewers feedback to the staff on their application within 21 working days of receipt of the application.

The form should be signed off by the School Coordinator or deputy coordinator. The member of staff should be notified of the ethics approval by RIIS and permitted to commence the

research. They should be informed that **should their project deviate from the information provided, they must seek further ethics approval or request approval of an amendment to the original project. RIIS will store the proportionate review form electronically.**

16.5   For staff and postgraduate researchers, an application for full research ethical review must be considered by at least two members of the School's Panel of Ethics Reviewers. Where the two reviewers are unable to reach an agreed judgment, the application should be referred to the School's Ethics Review Coordinator. Where the three parties are unable to reach a consensus, the application should be referred to the University Research Ethics Committee.

16.6   Undergraduate and postgraduate taught applications that cannot be resolved within the school by the course team should be referred to the School Coordinator who may request review by the Panel of Ethics Reviewers and, if necessary, to the University Research Ethics Committee as appropriate.

16.7   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.

NHS Research - Independent Peer Review (IPR)

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

17.2   Relevant projects will be considered by the Independent Peer Review Panel on behalf of the University Research Ethics Committee.

17.3   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 Health Research Authority (http://www.hra.nhs.uk/) and seek advice regarding their proposal from the relevant Research & Development Department within their Trust.

17.4   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.

17.5   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.

17.6   Where a project is not approved 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.

17.7   The IPR Panel may choose to defer a decision about a project and refer it to the University Research Ethics Committee for consideration outlining the issues that they can't decide on.

17.8   On securing Independent Peer Review Panel approval, the IPR form will be submitted to the Chair of the University Research Ethics Committee (or their nominee) for authorisation of the project and for insurance and indemnity. The Chair will act as the sponsor of the project on behalf of the University.

17.9   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.

17.10   No external project submission should take place until authorisation has been received.

17.11 On receipt of final authorisation, the researcher will submit the research ethics application to the NHS Research Ethics Committee, in accordance with NHS procedures.

17.12 The researcher is responsible for informing his/her School Research Ethics Coordinator of the outcome of the NHS Research Ethics application.

APPENDIX C: Retention and Storage of Ethics Review Documentation

18.1   All documentation arising from the ethics review procedures (including disclaimer, proportionate and full ethics review forms) relating to **undergraduate or taught postgraduate research** will be stored centrally by the appropriate School or Service in such a way that records can be easily subject to audit when required.

18.2   All documentation arising from the ethics review procedures (including disclaimer, proportionate and full ethics review forms) relating to **postgraduate research or staff research** will be stored centrally by RIIS.

18.3   Minutes from the University's Research Ethics Committee will be held electronically in perpetuity.

18.4   Schools will retain disclaimer, proportionate review and full ethics review documentation for nine years, subject to any external requirements for the retention of documentation. The University Research Ethics Committee may further extend this retention period on a case-by-case basis.

18.5   All documentation should be stored in such a way as to ensure that individual documents can be easily located and audited by the University.

As per the University's research code of conduct, Staffordshire University considers that it is good practice for researchers to *"Make relevant primary data and research evidence accessible to others for reuse where appropriate and to safely store the data for reasonable periods after the completion of the research. Data should normally be preserved for at least 10 years."* This is a principal taken from the Common Principles on Data Policy adopted by Research Councils UK.

- For undergraduate and postgraduate taught dissertations and field work that is, in the opinion if the chief investigator (the supervisor), not publishable and is not likely to be published in the future, then under normal circumstances the consent form may be destroyed after the student has completed their project and been awarded their degree.
- If the chief investigator (the supervisor) deems that the data is publishable, or that it may be publishable in the future, then the data, including consent forms, should be stored in accordance with the university's data retention policy. In such circumstances, the supervisor takes responsibility for the data storage and handling.
- For postgraduate research and staff research, all data, including consent forms, should be stored in accordance with the university's data retention policy. The researcher themselves are responsible for data storage and handling, as well as for its appropriate disposal, which must be in accordance with University data policy.
- The above stipulations are superseded by any funding bodies requirements for a longer retention of data or consent forms.