RESEARCH ETHICS A red and white logo

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Full Ethical Review Form

Full ethical review must be used for research involving above minimal risk and therefore necessitating a more thorough ethical review prior to approval. Further guidance on projects which involve above minimal risk is provided within the University’s Ethical Review Policy. Relevant professional body ethical guidelines should be consulted when completing this form. Please seek guidance from the School Ethics Coordinator if you are uncertain about any ethical issues arising from this application. There is an obligation on the researcher and supervisor (if applicable) to bring to the attention of the School Ethics Coordinator any issues with ethical implications not identified by this form.

**PART A: TO BE COMPLETED BY RESEARCHER**

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| **NAME:** |  |
| **SCHOOL:** |  |
| **Contact email:** |  |

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| **Student/Course details (if applicable)** | |
| Student I.D. number |  |
| Name of supervisor/course leader |  |
| **Is your research:** |  |
| PhD/MPhil project |  |
| Taught postgraduate project/assignment |  |
| Undergraduate project/assignment |  |

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| **Project title:** |  | | |
| **Start date:** |  | **End date:** |  |

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| **Application Checklist: have the following document been included with your application?** | | |
|  | **Yes** | **N/A** |
| Participant information sheet(s) in language appropriate to the recipient |  |  |
| Participant consent form(s) in language appropriate to the recipient |  |  |
| Letter/s of invitation to participants in language appropriate to the recipient |  |  |
| Questionnaires (only attach questionnaires that have NOT been validated previously) |  |  |
| Health related projects only: Letters giving permission for access to participants or confirming that full LREC ethical approval is not required |  |  |
| Other relevant information (e.g. tests or product information) |  |  |

**PLEASE CHECK:**

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| **Will the research involve any of the following:** | **YES** | **N/A** |
| • NHS patients  • NHS staff or premises  • Confidential participant information  • Material consisting of or containing human cells/tissue\*  • Patients being cared for in private and/or voluntary sector nursing homes • Inmates or staff in prisons or secure settings  • Exposure to ionising radiation  • Medical devices that are not CE-marked or CE-marked medical devices that have been modified or are being used for a new purpose  • Investigational medicinal products  • Practising midwives conducting a clinical trial  • Protected information from the Human Fertilisation and Embryology Authority register  \* *Please refer to the Staffordshire University* [**Human Tissue Policy**](https://workvivo.staffs.ac.uk/file/505435)*for guidance* |  |  |
| Research that involves any of the above will need an IPR (Independent Peer Review) application INSTEAD of a full ethical review. Please contact the Chair if the IPR panel for advice. The HRA (Health Research Authority) provide a tool to help identify if projects need NHS REC approval: <http://www.hra-decisiontools.org.uk/ethics/index.html> | | |

**EXPORT CONTROL:**

Applicants are reminded to ensure they have checked their proposed research against the University's[**Export Control Policy**](https://workvivo.staffs.ac.uk/file/528453)in relation toresearch projects, material transfers, transnational education or IP licensing that concern:

1. work at post-graduate level and above in a ‘Relevant Discipline’ (nuclear engineering; viruses, pathogens, vaccines; chemicals with toxic properties; high strength materials; high specification electronics, computers, and telecommunications; automation; cryptography; optics and sonar; navigation; submersibles; aerospace; and space) and may involve the transfer of sensitive technology or other items out of the UK;

and/or

1. may involve any items that are subject to US export controls.

**Information can be obtained from** [**exportcontrols@staffs.ac.uk**](mailto:exportcontrols@staffs.ac.uk)

**Please describe your proposed research in full (provide a response in each section):**

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| 1. **Project Outline:**   Please provide a brief paragraph indicating answers to the following questions where relevant:  i) The aims and objectives of the project.  ii) Its rationale and justification.  iii) The research question or specific hypotheses to be tested.  iv) The background to the project.  v) Where the research is to be carried out.  vi) Names of other individuals or organisations involved in the project.  vii) Whether other approvals have been gained or are to be sought. |
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| 1. **Research Procedure:**   Please provide a summary of the procedures that will be followed when carrying out the research project under the following headings. |
| 1. The design of the project (including, where appropriate, issues of statistical power): |
| 1. The procedures to be followed: |
| 1. The participation of people or animals in the project: |
| 1. How the design of the project and the procedures followed are likely to assess the research question or test the hypothesis in question or establish some significant result: |
| 1. Availability of facilities/resources/equipment to enable the project to be carried out: |
| 1. Procedures that will be followed if any adverse event occurs: |

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| 1. **Participant Recruitment & Characteristics**   Please provide clear information regarding the recruitment of participants and their appropriateness to the project: (NB: Student researchers must also ascertain from their Supervisor whether or not they require a criminal record check through the Disclosure and Barring Service (DBS) in order to enable this project to proceed. If this is the case the application must make clear whether or not it has been undertaken. Any data collection or other activities requiring this clearance must not begin until it has been obtained.) |
| 1. The number of participants involved in the study (including the adequacy of the sample size for both qualitative and quantitative research) |
| 1. How participants will be identified, approached or recruited |
| 1. Whether there are any inclusion or exclusion criteria, together with their justification |
| 1. The age range of participants; the gender balance of participants; and the participants’ state of health |
| 1. Whether there is any inducement to participate in the study |
| 1. How participants will be informed about the right to withdraw from participation the study (and whether time limits will be established during which a participant can request for their data to be withdrawn from the study) |
| 1. Whether the project involves any special groups requiring some additional justification or permission (e.g. children and young people under 18 years of age, those with a learning disability or cognitive impairment, patients, people in custody, people engaged in illegal activities (e.g. drug taking), or individuals in a dependent or unequal relationship) |
| 1. Will informed consent be obtained from research participants? **Yes/No**   Please give details of who will obtain content and how this will be undertaken.  If no consent is to be sought, please provide your justification. |
| 1. **Information and Data**   Please provide answers to the following questions regarding the handling and storage of information and data |
| 1. How will research data be stored? (please refer to the SU [Research Data Storage Policy](https://workvivo.staffs.ac.uk/file/530741)) |
| b) How is protection given to the participants (e.g. by being made anonymous through coding and with a participant identifier code being kept separately and securely)? |
| 1. What assurance will be given to the participant about the confidentiality of this data and the security of its storage? |
| 1. Is assurance given to the participant that they cannot be identified from any publication or dissemination of the results of the project? |
| 1. Who will have access to this data, and for what purposes? |
| 1. How will the data be stored, for how long, and how will it be discarded? |

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| 1. **Risk, Harm and Other Ethical Considerations**   Please provide an estimate of the perceived benefits or outcomes of the project weighed against the possible harms caused to the participants. |
| Please identify any potential risks or hazards that might be caused to participants or the researcher, in addition to any discomfort, distress or inconvenience to them, together with any ethical problems or considerations that the researcher considers to be important or difficult in the proposed project. |
| Please explain how any potential risks or hazards will be dealt with, along with any justificatory statements. This information should highlight any remaining ethical considerations and to respond to them in a way which may assist the Research Ethics Committee in arriving at some judgement upon the proposal. |
| Has a risk assessment been completed for this project? Yes N/A |

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| 1. **Supporting Information**   Please attach the consent form, information sheet, and questionnaire/interview questions to this application. Further guidance on the design and content of consent forms and information sheets can be found on the University’s Research Ethics website. |

**RESEARCHER DECLARATION:**

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| I undertake to carry out the project described above in accordance with ethical principles as defined in the SU Code of Conduct for Research and Research Integrity. I have completed this application in good faith. I accept that providing false information constitutes misconduct and that I will consequently be subject to appropriate disciplinary procedures. | | | |
| **Signature:** |  | **Date:** |  |

**NB:** Any departure from the protocol for this research project may mean that the favourable decision made by the School Ethics Coordinator is no longer valid and a new ethics proposal will have to be submitted.

It is the responsibility of student researchers to discuss proposed changes to the agreed protocol with their project supervisor as soon as possible so that a revised/new ethics application can be submitted.

Research based on any revised/new protocol MUST not proceed unless and until the protocol has ethical approval.

**NEXT STEP:**

**STUDENTS: Please submit this form (and supporting documentation) for consideration by your Supervisor/Module Tutor.**

**STAFF: Please submit this form for consideration by your Head of Department of a Senior Researcher in the School. This form should then be forwarded to the Research Administrators in RIIS (ethics@staffs.ac.uk) who will arrange for it to be considered by two independent members of the School’s College of Ethical Reviewers.**

**PART B: TO BE COMPLETED BY SUPERVISOR/MODULE TUTOR (if student) OR HEAD OF DEPARTMENT/SENIOR RESEARCHER (if staff)**

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| I have examined this proposal and confirm that the rationale and methodology is appropriate and that it can proceed to the stage of ethical consideration. | | | |
| I have checked and approved the key documents required for this proposal (e.g. consent form, information sheet, questionnaire and interview schedule). | | | |
| **Name:** |  | **Date:** |  |
| **Signature:** |  |  |  |

**Please now submit this form to the research ethics administrators in RIIS at** [**ethics@staffs.ac.uk**](mailto:ethics@staffs.ac.uk)**.**

**PART C: TO BE COMPLETED BY THE SCHOOL ETHICS COORDINATOR**

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| This research proposal has been considered by two members of the School’s College of Ethical Reviewers and has been **APPROVED.** | |  | |
| This research proposal has been considered by two members of the School’s College of Ethical Reviewers. Significant issues have been identified and the form should be **REVISED AND RESUBMITTED** to address the issues identified. | |  | |
| **Signed:** |  | **Date:** |  |