

**School of Healthcare Sciences Research Ethics Committee**

**APPLICATION FOR ETHICAL REVIEW**

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| For Office Use Only |
| SREC Reference: [x] | Meeting/Review Date: [x] |

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| **SECTION 1. GENERAL INFORMATION** |
| Application Type: |  Staff  PGR student  PGT/Masters Student  Undergraduate |
| Research Project Title: |  |
| Short Title (where applicable):  |  |
| For Staff Projects |
| Name of Chief/Principal Investigator: |  |
| Contact details: |  |
| Other members of research team:  |  |
| For Student Projects |
| Name of Student: |  |
| Contact details: |  |
| Name of Supervisor(s): |  |
| Contact details: |  |
| Other members of research team: |  |
| **SECTION 2. SCREENING QUESTIONS** |
|  |  | **Yes** | **No** |
| [2.1 | Is the research project categorised as ‘Research’ (as defined in the Cardiff University [Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics) (Ethics Policy))?*If* ***no*** *(i.e. the research project is a Service Evaluation or Audit), the Committee is not required to conduct a review of the proposal but may choose to do so.* ***Please contact [the School Ethics Officer] to seek advice before proceeding with this application.*** *]* |  |  |
| [2.2 | Does the research project involve human participants, human material or human data (as defined in the [Ethics Policy](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics))?*If* ***no****, you are not required to submit the research proposal to this Committee.* ***Please do not continue with this application.]*** |  |  |
| [2.3 | Does the research project require review by an external ethics committee (refer to Appendix 1 of the [Ethics Policy](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics))? Please note that this includes all research projects involving participants who lack the capacity to consent. *If* ***yes****, the research project should be submitted to the relevant external ethics committee for review and does not fall within the remit of this Committee. Please contact the* *Research Governance Team* *for further advice.* ***Please do not continue with this application.]*** |  |  |
| [2.4 | Has the research project been ethically reviewed by another university or research institution (for example, where the Chief/Principal Investigator for the research project is based at another institution)?*If* ***yes,*** *please provide evidence of the review conducted (such as an outcome letter or communication) and the ethical review policy of the relevant institution or committee.* ***Please do not continue with this application.]*** |  |  |
| [2.5 | Does the research project only involve the use of information that is publicly and lawfully available e.g. census data and population statistics published by government departments. Note: research projects involving the use of Human Data obtained from social media (or similar internet forums) do not fall within this category. *If* ***yes****,* please seek advice from the [School Ethics Officer], providing details of the information and its source. ***The [School Ethics Officer] will determine whether you are required to proceed with the application.***]  |  |  |
| 2.6 | Does the research project fall within the scope of the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)? This Framework broadly applies to research taking place within, or involving, the health and social care systems. *If* ***yes****, you will need to apply to the* *Research Governance Team* *for Sponsorship using the Advanced Project Information Proforma (APIP) (available on the Cardiff University intranet)*. *The Research Governance Team will advise you on the approvals that are required for the research project after it has conducted a review of the APIP and supporting documentation.* ***Please do not continue with this application until you have sought advice from the Research Governance Team.*** |  |  |
| 2.7 | Does the research project involve the collection or use of Human Tissue (including, but not limited to, blood, saliva and bodily waste fluids)?*If* ***yes****, the research project should be submitted to the* *Human Tissue Act Compliance Team* *(HTACT) prior to submission to an ethics committee.* ***Please do not continue with this application until you have sought advice from HTACT.***  |  |  |
| 2.8 | Does the research project fall within the scope of the University’s [Security-sensitive Research Policy](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/security-sensitive-research)? This Policy broadly applies to research involving terrorism, extremism or radicalisation (or access to materials of such a nature). *If* ***yes****, you must register the research in accordance with the Policy and comply with the IT and security arrangements contained in the Policy.*  |  |  |
| 2.9 | Has the research project received appropriate peer/scientific review? (For student research projects, review by the research project supervisor is an acceptable form of scientific review)*If* ***no****, please obtain appropriate peer/scientific review before submitting the application to this Committee.*  |  |  |
| 2.10 | Have you and all other Cardiff University co-applicants/ /Supervisors/Members of the research team (as listed in Section 1) completed the University’s [Research Integrity Online Training Programme](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/training/research-integrity-online-training-programme)?*If* ***no****, please complete the training before submitting the application to this Committee.*  |  |  |
| If the research project involves the use of animals, please contact the Cardiff University Biological Standards Office bso@cardiff.ac.uk to seek further advice. |
| **SECTION 3. PROJECT SUMMARY** |
| 3.1 | Summarise the research project (including the purpose and its methodology) using language that would be understood by a lay person.  |
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| 3.2 | State the research question(s). |
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| 3.3 | Estimated start date. |
|  |
| 3.4 | Estimated end date (usually the end of data collection). |
|  |
| 3.5 | Is the research project funded? *If* ***yes****, please name the funding body.* |
|  |
| 3.6 | Are there any potential conflicts of interest? *If* ***yes****, please confirm the action you propose to take to address such conflicts.**Information and guidance on conflicts of interest is contained in the* [*Research Integrity Online Training Programme*](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/training/research-integrity-online-training-programme) *and the* [*Research Integrity and Governance Code of Practice*](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance)*.*  |
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| **SECTION 4. FULL REVIEW CRITERIA** |
| Your answers to the questions in this Section 4 will help the Committee determine whether your project requires full or proportionate review.If all ‘No’ boxes apply, your project may be considered for proportionate review.If a 'Yes' box applies, your project will proceed to full review [unless the School has approved a [Standard Operating Procedure] [Ethics Protocol] for that particular criterion. Where a [Standard Operating Procedure] [Ethics Protocol] applies, this is confirmed below. If you have complied with the [Standard Operating Procedure] [Ethics Protocol], your project may be considered for proportionate review.] *The School does not currently have any approved standard operating procedures or ethics protocols* |
|  | **Yes** | **No** |
| 4.1 | Will the research project be performed without the participants’ prior consent? |  |  |
| 4.2 | Does the research design include an element of deception, including covert research? |  |  |
| 4.3 | Will the research project involve children under the age of 18 or ‘at risk’ (vulnerable) adults or groups? *The* [*Cardiff University Safeguarding Children and Adults at Risk: Policy*](https://www.cardiff.ac.uk/public-information/policies-and-procedures/safeguarding) *and* [*Guidance*](https://www.cardiff.ac.uk/public-information/policies-and-procedures/safeguarding/activity-specific-guidance) *sets out examples of ‘at risk’ or ‘vulnerable’ adults.* |  |  |
| 4.4 | Does the research project include topics which may be considered highly sensitive for participants?*This includes sexual behaviour, illegal activities, political, religious or spiritual beliefs, race or ethnicity, experience of violence, abuse or exploitation, and mental health.* |  |  |
| 4.5 | Does the research project require access to records of a sensitive or confidential nature, including Special Category Data?*Special Category Data is defined in data protection legislation and currently includes information about an individual's: racial or ethnic origin; political opinions; religious beliefs; trade union membership; physical or mental health; sexual life or orientation; commission of offences or alleged offences; genetic data; and biometric data.*  |  |  |
| 4.6 | Is permission of a gatekeeper required for initial or continued access to participants? *This includes participants in custody and care settings, or research in communities where access to research participants is not possible without the permission of another adult, such as another family member or a community leader.* |  |  |
| 4.7 | Does the research project involve intrusive or invasive procedures?*This includes the administration of substances, vigorous physical exercise, procedures involving pain or more than mild discomfort to participants (including the risk of psychological distress, discomfort or anxiety to participants).* |  |  |
| 4.8 | Does the research project involve visual or audio recordings where participants may be identified? |  |  |
| 4.9 | Does the research project involve the collection or use of human tissue? |  |  |
| 4.10 | Does the research project involve more than a minimal risk of harm to the safety and wellbeing of participants and/or the Researchers?*Please answer this question based on your assessment of the risks involved in this project. Further information about possible harm or potential risks to participants/researchers must be provided in Section 7 of this form.*  |  |  |
| **SECTION 5. PARTICIPATION AND RECRUITMENT** |
| 5.1 | How will you identify and recruit participants to the research project?  |
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| 5.2 | How many participants are you aiming to recruit? *If applicable, please include a breakdown of participants by type and number.* |
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| 5.3 | What are the inclusion and exclusion criteria for participants? |
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| 5.4 | Will the research project involve participants that are Cardiff University staff or students or clients of the University (or the place in which you may otherwise work)? *If applicable, please provide details.* |
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| 5.5 | Please give details of where the study will be sited and if informal consent has been obtained to access these facilities/ participants? Evidence of consent is not required if using HCARE internal facilities.  |
| **SECTION 6. CONSENT PROCEDURES** |
| 6.1 | Will informed consent be obtained from participants? If so, how? *Please include who will be taking consent, how consent will be recorded, when participants will be provided with information about the research project, and how long potential participants will be given to decide whether to take part.* |
|  |
| 6.2 | Will participants be offered any incentives to take part in the research project? |
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| 6.3 | If a questionnaire is to be used, will you give participants the option of omitting questions they do not wish to answer? |
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| 6.4 | Will participants be informed that their participation is voluntary and that they may withdraw at any time and for any reason? |
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| **SECTION 7. POSSIBLE HARM TO PARTICIPANTS/RESEARCHERS** |
| 7.1 | Is there is a risk of the participants experiencing physical, emotional or psychological harm or distress*? If yes, please provide details of how ethical issues will be handled and how any risks will be minimised.* *Please consider whether the research project includes topics which could be considered as highly sensitive for participants.* |
|  |
| 7.2 | Is there a risk of the Researcher(s) experiencingphysical, emotional or psychological harm or distress? *If yes, please provide details of how ethical issues will be handled and how any risks will be minimised.* |
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| **SECTION 8. DATA MANAGEMENT, CONFIDENTIALITY AND DATA PROTECTION** |
| 8.1 | How, and by whom, will data be collected? |
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| 8.2 | Will you be accessing or collecting Personal Data (identifiable personal information) as part of the research project? *If yes, please confirm what data will be accessed and/or collected (including details of the information participants are asked to provide on a written consent form) and by who* |
|  |
| 8.3 | How long will you retain the Personal Data collected in connection with the research project? *Note for Staff/PGR/PGT projects: Consent Forms should be retained for the period specified in Section 2.9 ('Research Project Conduct') of the University's Research Records Retention Schedule. If other identifiable information is being collected, researchers must ensure that this is limited to the information necessary to achieve the relevant purpose (data minimisation) and that consideration is given to whether the information can be pseudonymised/anonymised (or otherwise removed) without affecting the integrity of the research data. In most cases, it will be reasonable to keep Personal Data for the period specified in the University’s Research Records Retention Schedule if retention is required to maintain the integrity of the research data and the steps above have been followed.**Note for UG projects: the retention period specified in the University’s Research Records Retention Schedule does not apply to UG projects unless the data is to be published. If there is no intention to publish, records and data should be retained until the end of the appeals process (students usually have 28 days from the date of their transcript/results to make an appeal).*  |
|  |
| 8.4 | What efforts will be made to anonymise the data collected (where possible)? |
|  |
| 8.5 | Are you proposing to utilise ‘public task’ as the lawful basis for processing Personal Data for the purposes of the research project (as recommended in the University’s [GDPR Guidance for Researchers](https://intranet.cardiff.ac.uk/intranet/students/documents/Guide-to-GDPR-and-Research.pdf))? *If no, please explain why and what alternative lawful basis you propose to use.*  |
|  |
| 8.6 | Have you utilised/incorporated into your Participant Information Sheet the following sections from the University's template Participant Information Sheet: *'What will happen to my Personal Data'* and *'What happens to the data at the end of the research project?'* *If* ***no****, please explain why this has not been used and how you have otherwise ensured that the relevant data protection/privacy information has been provided to participants.*  |
|  |
| 8.7 | For how long will the collected anonymised data be retained? *Note for Staff/PGR/PGT projects: Anonymised research data should be retained for the period specified in Section 2.9 ('Research Project Conduct') of the University's Research Records Retention Schedule.* *Note for UG projects: Unless there is an intention to publish (in which case the above retention period applies), anonymised research data should be retained until the end of the appeals process (students usually have 28 days from the date of their transcript/results to make an appeal).* |
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| 8.8 | Who will have access to the data? |
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| 8.9 | Will the data be shared in any way, for example through deposit in a data repository, with third parties, or a transcription service? |
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| **SECTION 9. OTHER ETHICAL CONSIDERATIONS** |
| Please outline any other ethical considerations raised by the research project and how you intend to address these. You are obliged to bring to the attention of the SREC any ethical issues not covered in this Ethics Review Application Proforma. |
| **SECTION 10. SUPPORTING DOCUMENTS** |
| I have attached the documents, as indicated in the table below, in support of this application.Please note that the documents listed below **MUST BE** provided where relevant to the research project, alongside any other documents relevant to recruitment, consent and participation. |
|  | **Yes** | **No** | **Version no.** (where applicable) |
| 1 | Research Project Protocol/Proposal |  |  |  |
| 2 | Recruitment Adverts/Invitation Letters |  |  |  |
| 3 | Participant Information Sheet |  |  |  |
| 4 | Consent Form |  |  |  |
| 5 | Data Collection Tools (e.g. questionnaires) |  |  |  |
| 6 | Other participant communications (e.g. debrief sheets)  |  |  |  |
| 7 | Evidence of Research Integrity training completion |  |  |  |

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| **SECTION 11. SIGNATURES AND DECLARATIONS** |
| General declaration I confirm that:1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I have the necessary skills, training and or/expertise to conduct the research project as proposed.
3. I am familiar with the University’s health and safety requirements and policies and that all relevant health and safety measures have been taken into account for the research project.
4. I am familiar with, and will comply with, the University’s [Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data](https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/integrity-and-governance/research-ethics) and the University’s [Research Integrity and Governance Code of Practice](https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics/research-integrity-and-governance).
5. The relevant equality and diversity considerations have been taken into account when designing the research project.
6. If the research project is approved, I undertake to adhere to the research project protocol, the terms of the full application as approved and any conditions set out by the Committee and any other body required to review and/or approve the research project.
7. I will notify the Committee and all other review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the Committee before implementing the amendment.
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| **FOR STAFF PROJECTS** |
| Signed: Chief/Principal Investigator |
| Print name: |
| Date: |
| **FOR STUDENT PROJECTS** |
| Signed: Student  | Signed: Supervisor |
| Print name: | Print name: |
| Date: | Date: |

**Please submit the completed application and supporting documents to** **HCAREethics@cardiff.ac.uk**

**Your electronic submission should contain wet-ink or electronic signatures of all relevant parties. Please note that if any information is missing, the application may be returned to you.**