**EC1 form**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Glasgow Caledonian University Research Ethics Approval Form (EC1 form)** | | | | |
| **All ethics applications should be submitted electronically to the correct email address and marked for the attention of the ethics chair for the committee[[1]](#footnote-1) (see below).** | | | | |
| **Committee** | **Chair of committee** | **Email address** | |  |
| GSBS | Professor Oonagh Walsh | [gsbsethics@gcu.ac.uk](mailto:gsbsethics@gcu.ac.uk) | |  |
| SCEBE | Dr Michael Tong | [scebe\_ethics@gcu.ac.uk](mailto:scebe_ethics@gcu.ac.uk) | |  |
| Nursing and community Health | Dr. Ben Parkinson | [HLSEthicsNursing@gcu.ac.uk](mailto:HLSEthicsNursing@gcu.ac.uk) | |  |
| [Psychology](http://www.gcu.ac.uk/hls/aboutus/ourdepartments/psychologysocialworkandalliedhealthsciences/) | Dr. Phil Dalgarno | [HLSEthicsPsychology@gcu.ac.uk](mailto:HLSEthicsPsychology@gcu.ac.uk) | |  |
| Life sciences | Dr. Les Wood | [HLSEthicsLifeSciences@gcu.ac.uk](mailto:HLSEthicsLifeSciences@gcu.ac.uk) | |  |
| Allied Health | Dr David Hamilton | [HLSEthicsAlliedHealth@gcu.ac.uk](mailto:HLSEthicsAlliedHealth@gcu.ac.uk) | |  |
| Social Work | Dr Heather Lynch | [HLSEthicsSocialWork@gcu.ac.uk](mailto:HLSEthicsSocialWork@gcu.ac.uk) | |  |
| **Study overview** | | | | |
| Study title: | | | | |
| Short title (optional): | | | | |
| Chief investigator (N.B. this should be the academic supervisor in student projects): | | | | |
| Email for the chief investigator: | | | | |
| Other staff involved: | | | | |
| Name of student undertaking the study (if applicable): | | | | |
| Level of study the student is undertaking (if applicable) (e.g. undergraduate, postgraduate, PhD): | | | | |
| GCU email for the student undertaking the study (if applicable): | | | | |
| **Study governance** | | | | |
| Study sponsor (e.g. GCU for student and/or staff projects): | | | | |
| Study start date: | | | | |
| Study end date: | | | | |
| Is the study research (N.B. use link to decide [http://www.hra-](http://www.hra-decisiontools.org.uk/research/)  [decisiontools.org.uk/research/](http://www.hra-decisiontools.org.uk/research/))? | | |  | |
| Is the study a clinical trial? | | |  | |
| Does the study include any invasive or biological procedures (e.g. taking blood/tissues)? | | |  | |
| Does the study involve the NHS (e.g. patients, staff, or both)? | | |  | |
| Does the study require NHS REC approval? | | |  | |
| Does the project involve using personal data? | | |  | |
| Has the chief investigator completed GDPR and data protection training? | | |  | |
| Has gatekeeper approval been given (if applicable)? | | |  | |
| Has this application been reviewed prior to submission (essential)? | | |  | |
| Who has reviewed this application (e.g. study team, peer, academic supervisor)? | | |  | |
| Has the study been prospectively registered (essential for clinical trials)? | | |  | |
| What is the prospective registration number (if applicable)? | | |  | |
| Does the chief investigator have up to date Good Clinical Practice training? | | |  | |
| Have students involved in the study received teaching on ethical research and consent (if applicable)? | | |  | |
| How will results of the study be disseminated? | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study design** | | | | | | | |
| **Answer all questions in this section by adding an X to either Yes, No, or N/A.** | | | | **Yes** | | **No** | **N/A** |
| Is there a robust rationale for the study? | | | |  | |  |  |
| Is there a clear study question(s)? | | | |  | |  |  |
| Can the methodology and study design answer the question(s)? | | | |  | |  |  |
| Are inclusion and exclusion criteria clearly stated? | | | |  | |  |  |
| Will the study only invite adult participants? | | | |  | |  |  |
| Does the study exclude potentially vulnerable people (e.g. people without capacity, prisoners, patients, and people with communication or learning difficulties). | | | |  | |  |  |
| Will participants receive a participant information sheet before starting the study? | | | |  | |  |  |
| Will participants be able to read and understand the participant information sheet? | | | |  | |  |  |
| Will the participant information sheet provide full details of the study and any potential risks involved? | | | |  | |  |  |
| Will participants be given the opportunity to ask questions and/or contact the study team if they want to know more about the study? | | | |  | |  |  |
| Will participants be told their participation is voluntary? | | | |  | |  |  |
| Will participants be told they can withdraw from the study at any time and without any penalty? | | | |  | |  |  |
| Will participants have to opt-in to the study (e.g. by contacting the study team or returning a survey)? | | | |  | |  |  |
| Will written informed consent be taken for every participant? | | | |  | |  |  |
| (N.B. anonymous online surveys can use implied consent) | | | |  | |  |  |
| With questionnaires/interviews, will participants be given the option to skip questions and/or take a break? | | | |  | |  |  |
| Will data collection methods be tested prior to use with participants (e.g. informal rehearsal with colleague/student)? | | | |  | |  |  |
| Will steps be taken to reduce the burden on participants (e.g. convenient appointments, expenses, and/or regular breaks)? | | | |  | |  |  |
| Will permission be secured to use existing/copyrighted data collection tools? | | | |  | |  |  |
| Will data management adhere to GCU policies ([information/data storage policies](https://www.connected.gcu.ac.uk/sites/InformationMatters/DataProtectionPrivacy/Documents/GuidanceResearchersV14.docx)), data protection legislation, and GDPR? | | | |  | |  |  |
| Will participants be told their participation is confidential and the situations where confidentially might have to be broken (e.g. disclosure of serious crimes and/or professional misconduct)? | | | |  | |  |  |
| Will steps be taken to maintain participant anonymity (e.g. pseudonyms)? | | | |  | |  |  |
| Will participants be told what data will be collected and how their data will be used (e.g. anonymous quotes)? | | | |  | |  |  |
| Will participants be told about the legal basis for processing data and who to contact if they have concerns about how their data has been handled? | | | |  | |  |  |
| Will participants be told about what will happen to their data after the study has finished? | | | |  | |  |  |
| Will participants receive debriefing and/or follow-up support after the study (e.g. links to useful services)? | | | |  | |  |  |
| Will participants be advised to contact their GP if any serious health concerns are highlighted during the study. | | | |  | |  |  |
| Will participants be told how to access a summary of the study findings once it is completed? | | | |  | |  |  |
| Will the study team be able to access emotional support and other assistance during the study to ensure their physical and emotional wellbeing? | | | |  | |  |  |
| Do the potential benefits of the study outweigh the possible risks associated with the study? | | | |  | |  |  |
| Will all serious adverse events that are related to the study and unexpected be documented and reported to the sponsor? | | | |  | |  |  |
| Does the study team and/or student have the necessary knowledge, skills, and competence to undertake the study? | | | |  | |  |  |
| Have study documents been approved by the study team and/or academic supervisor (e.g. accessibility, presentation, and accuracy)? | | | |  | |  |  |
| Have all ethical issues been disclosed in this application? | | | |  | |  |  |
| **Review the answers given to the study designs questions (1-33). If you have answered NO to any of the above questions, then please use the space below to give a rationale for your answer and any steps taken to mitigate possible negative consequences.** | | | | | | | |
|  | | | | | | | |
| **Risk assessment** (the risk assessment should consider possible harms to the participant(s), the researcher(s), wider society, GCU, and any risks associated with the use of personal data). | | | | | | | |
| **Risk(s)** | **Severity**  (e.g. low, medium, high) | **Likelihood**  (e.g. low, medium, high) | | | **Mitigation**  (e.g. what will you do to minimise harm?) | | |
|  |  |  | | |  | | |
|  |  |  | | |  | | |
|  |  |  | | |  | | |
|  |  |  | | |  | | |
| **Does this study have significant ethical concerns** (e.g. invasive/harmful procedures, potentially vulnerable participants, child participants, and/or deception of participants)? | | | | | | | |
| **Yes/No** (please delete as appropriate) | | | | | | | |
| **Safeguarding - the Chief Investigator or student should declare that they are aware of the University’s Policy and Procedures in relation to Safeguarding.** | | | | | | | |
| **I am aware of the University’s Policy and Procedures in relation to Safeguarding:**  **Yes/No (please delete as appropriate)** | | | | | | | |
| **Studies with NO significant ethical concerns should include:**  EC1 form  Protocol (2-3 sides of A4) (see separate guidance)  Participant information sheet(s) Consent Form(s)  Copies of data collection tools/interview guides  Adverts and/or recruitment emails Draft letter(s)  Proof of gatekeeper approval | | | **Studies with significant ethical concerns should include:**  EC1 form  Protocol (4-5 sides of A4) (see separate guidance)  Participant information sheet(s) Consent Form(s)  Copies of data collection tools/interview guides  Adverts and/or recruitment emails Draft letter(s)  Proof of gatekeeper approval | | | | |
| **Declaration**  The study team are familiar with the declaration of Helsinki and relevant professional body codes for research ethics (e.g. BPS). I can confirm the study abides with these guidelines.  The study team agrees to bring to the attention of the ethics committee any ethical issues not covered by the above document. | | | | | | | |
| **Chief investigator (this will be the supervisor for student projects)**  Name: Signature: Date: | | | | | | | |
| **Student carrying out the study (if applicable):**  Name: Signature:  Date: | | | | | | | |

1. The School of Health and Life Sciences has five subject-based ethics committees and each committee uses a separate email address. [↑](#footnote-ref-1)