**EC1 form**

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| **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 |  |
| SCEBE | Dr Michael Tong | scebe\_ethics@gcu.ac.uk |  |
| Nursing and community Health | Dr. Ben Parkinson | HLSEthicsNursing@gcu.ac.uk |  |
| [Psychology](http://www.gcu.ac.uk/hls/aboutus/ourdepartments/psychologysocialworkandalliedhealthsciences/) | Dr. Phil Dalgarno | HLSEthicsPsychology@gcu.ac.uk |  |
| Life sciences | Dr. Les Wood | HLSEthicsLifeSciences@gcu.ac.uk |  |
| Allied Health | Dr David Hamilton | HLSEthicsAlliedHealth@gcu.ac.uk |  |
| Social Work | Dr Heather Lynch | 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? |

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| **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.** |
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| **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?) |
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| **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 formProtocol (2-3 sides of A4) (see separate guidance)Participant information sheet(s) Consent Form(s)Copies of data collection tools/interview guidesAdverts and/or recruitment emails Draft letter(s)Proof of gatekeeper approval | **Studies with significant ethical concerns should include:**EC1 formProtocol (4-5 sides of A4) (see separate guidance)Participant information sheet(s) Consent Form(s)Copies of data collection tools/interview guidesAdverts 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)