**School Research Ethics Committee Review Form**

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**Research Ethics Committee (REC) Review Form**

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| This form should be completed by REC reviewer(s) and returned to the REC Chair (or designated person) via email. The form provides a guide for the reviewer(s) and is not intended to be prescriptive or to replace reviewer judgement. This form does not cover all possible ethical issues and it is possible the reviewer(s) may identify ethical issues not included in this form. REC reviewer(s) are encouraged to use this form and their judgement to reach a balanced decision about the ethical issues associated with a particular study. |
| **Name of applicant:** |
| **Name of the study:** |
| **Study ID:** | **School REC:** |
| **Date review received:** | **Date completed review sent to REC:** |
| **Reviewer Checklist** |
| **1. Is the application complete and ready for REC review?** [Applications should include high quality and clearly presented study documentation. Consider whether the application contains all the necessary documents (e.g. EC1 form, protocol, information sheet), whether the application is complete (e.g. does the protocol tell you everything you need to know), and whether the application is of sufficient quality for approval (e.g. spelling, presentation). **The ethical reviewer is not expected to proof read ethics applications and can decline to review the application if it is not of an acceptable standard.** Incomplete and/or low quality application will be returned to the applicant without a decision and will delay the approval process] |
| Reviewer comments … |
| **2. Is it clear who is involved in the study and their roles (e.g. chief investigator, collaborators, students)?** [The application should include the names and roles for all members of the study team. This may include students and/or people from other organisations] |
| Reviewer comments … |
| **3. Are the aims of the study clearly stated?** [It is unethical to recruit participants without clear study aims. The study aims should be clearly stated in the protocol and participant information sheet] |
| Reviewer comments … |
| **4. Is it clear where the study will take place (e.g. on campus, community venue, online)?** [It should be clear where the study will take place. Will participants/researchers have to travel and what are the risks associated with location?] |
| Reviewer comments … |
| **5. Does the study need internal/external approval and will this be secured before starting the study (e.g. gatekeeper, NHS ethics)?** [The chief investigator or academic supervisor is responsible for ensuring all necessary approvals are in place for the duration of the study. The application should explain what approvals are needed and provide evidence that these have or will be secured before the study starts] |
| Reviewer comments … |
| **6. Are the inclusion/exclusion criteria appropriate (NB: consider possible vulnerability and age of participants)?** [Are inclusion/exclusion criteria provided? Does the study specifically seek to recruit vulnerable participants (e.g. people without capacity, children, prisoners)? Studies specifically seeking to recruit vulnerable participants may need additional ethical scrutiny from a School or University REC] |
| Reviewer comments … |
| **7.** **Has the researcher read the University Safeguarding Policy?** The researcher should be aware of the commitment of Glasgow Caledonian University (GCU) to protect children, young people and adults at risk who are experiencing, or at risk of experiencing, harm and the reporting procedure for responding to concerns via the University Safeguarding Team. |
| Reviewer comments … |
| **8. Does the study have an appropriate recruitment plan?** [The study should clearly state how and where participants will be invited to participate in the study. Recruitment should be voluntary, without coercion, and on an opt-in basis] |
| Reviewer comments … |
| **9. Are study documents (e.g. participant information sheet, consent form) accessible enough for the intended audience (e.g. plain English)?** [Applications should include high quality documentation. Public facing documents (e.g. adverts, participant information sheets, and consent forms) should be accessible enough for the intended audience and provide all the information necessary for participants to make informed choices about the study] |
| Reviewer comments … |
| **10. Does the participant information sheet include enough information about the study (e.g. consent, risk-benefits, commitment, complaints, information security)?** [The participant information sheet should be given to potential participants before they give consent. Potential participants should be given the opportunity to ask questions (e.g. invited to email the researcher) and/or time to decide whether they wish to participate. Theparticipant information sheet needs to provide enough information about the study for potential participants to know what is involved with the study, what will be expected of them, and what their rights are (e.g. data protection, complaints)] |
| Reviewer comments … |
| **11. Does the study have appropriate informed consent arrangements (e.g. fully informed, voluntary, and reversible)?** [Gaining informed consent is a complex process involving the potential participant, the researcher, and potentially other people. The consent process does have to be indicated in some way, but can be proportionate and may vary between different studies (i.e. implied, verbal, and written consent). All consent processes should consider the nature of the study, capacity of the person, the information provided, the voluntary nature of consent, and be reversibility of the consent process] |
| Reviewer comments … |
| **12. Has a risk assessment been completed for the study and is there an acceptable risk-benefit ratio (i.e. the risks do not exceed the potential benefits)?** [All studies include some risk and there needs to be evidence of a risk assessment and what steps will be taken to mitigate the possible risks involved. The risk should not exceed the possible benefit from the study] |
| Reviewer comments … |
| **13. Does the application demonstrate how it meets data protection legislation and GCU information security requirements (e.g. password protection, data encryption, information security training, information/data management and storage)?** [Ethics applications should include detailed and comprehensive information about how data will be collected, handled, analysed, stored, reported, and destroyed. Data should be stored in authorised University storage and access available to and restricted to authorised individuals. All studies should comply with the relevant data protection legislation and GCU policies and procedures for data management] |
| Reviewer comments … |
| **14. Is it clear how the researcher(s) will respond to a participant who experiences deterioration in health and/or acute distress during the study (e.g. loss of capacity, suicidal ideation)?** [Researchers should anticipate and plan for situations where a participant may become unwell and/or distressed during the study and have a management plan in place to support the participant(s)] |
| Reviewer comments … |
| **15. Is it clear how the researcher(s) will escalate concerns if/when they are discovered during the study (e.g. unprofessional/criminal activity, identification of previously unknown health conditions)?** [Researchers should anticipate and plan for incidental findings or situations they discover information that needs to be shared with the participants and/or the authorities] |
| Reviewer comments … |
| **16. Is the level of ethical concern in this study acceptable for approval by the School Research Ethics Committee?** [The reviewer(s) need to consider whether the application can be approved by the school REC. School RECs can approve most studies, but should additional scrutiny by REIS may be required for studies involving major ethical concerns/dilemmas] |
| Reviewer comments … |
| **17. Additional comments (Use this space for ethical concerns not covered in the checklist)** [This form provides a guide for the reviewer(s) and is not intended to be prescriptive or to replace reviewer judgement. This form does not cover all possible ethical issues and it is possible the reviewer(s) may identify ethical issues not included in this form. This section can be used by the reviewer(s) to identify additional ethical issues that are not covered elsewhere on the form] |
| Reviewer comments … |
| **Reviewer decision (Delete as appropriate)** |
| * Approve (study able to start)
* Approve with conditions (provide conditions)
* Amend and resubmit (provide list of revisions in reviewer comments below)
* Not approved (study not appropriate in current format)
* Significant ethical concerns (refer to REIS)
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| **Reviewers comments and/or conditions for approval** [This space should be used to provide clarification or conditions for the approval] |
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| **Reviewer** |
| Name: | Conflict of interest declared with this review?Yes/No(delete as appropriate) |