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**Study Protocol for Ethics Applications**

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| **The protocol must use these headings (if applicable) and contain the information requested. Additional headings can be added if necessary and it is expected all potential ethical issues are disclosed. The protocol should be approximately 2-3 sides of A4 for studies with no significant ethical concerns and approximately 4-5 sides of A4 for studies with significant ethical concerns. The protocol structure aligns with the research ethics toolkit (Li, et al. 2016), which is a framework for protocol writers to use when applying for research ethics.**  **Reference:**  Li R.*, et al.* 2016. Incorporating ethical principles into clinical research protocols: a tool for protocol writers and ethics committees. *Journal of Medical Ethics*, 42(4), pp. 229-234. |
| **Study title:** |
| **Short title (optional):** |
| **Introduction:**  Background to the study and relevant literature.  What is the scientific and/or theoretical justification for the study. |
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| **Study aim(s):**  Specify the study question(s) or hypothesis(es).  The question(s) or hypothesis(es) should link to the scientific and theoretical justification provided in the introduction. |
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| **Study design and methods:**  Name the study design being used (e.g. RCT, single-case design, grounded theory). |
| State the location where study will take place (e.g. online, GCU campus, or NHS). Describe any intervention(s) and/or study procedure(s) (e.g. motivational interviewing, exercise bike).  Explain how data will be collected (e.g. online survey, interviews).  Attach copies of any data collection tools being used (e.g. PHQ9, MMSE). Specify the length of time participants will be involved in the study (e.g. two half hour appointments in July 2019). |
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| **Data management:**  Will the study collect data (or personal data)?  What data (or personal data) will be collected (e.g. names, matric number)? Who will collect data (or personal data)?  Who will have access to data (or personal data)? How will data (or personal data) be used?  Where and how will data (or personal data) be stored (e.g. on GCU-approved OneDrive with access restricted to authorised staff)?  When and by whom will anonymisation occur?  When and how will data (or personal data) be destroyed (e.g. confidentially after five years)?  Will the study adhere with GCU data security and data protection/GDPR legislation? |
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| **Safeguarding**  Are there any safeguarding implications for this study?  Is the researcher aware of the University Policy and procedures in relation to safeguarding? |
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| **Choice of control group and standard care (if applicable):**  Will the study use a control group?  What will participants in the control group receive (e.g. usual care)? |
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| **Inclusion and exclusions criteria:**  List inclusion criteria (e.g. adult, student, living with long-term condition).  List exclusions criteria (e.g. child, pregnant, currently on sick leave from work). |
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| **Recruitment of participants:**  Anticipated sample size (e.g. 5 participants). Sampling method (e.g. convenience).  Recruitment methods and copies of any advertisements/emails (e.g. social media, posters).  Who will make first contact with potential participants (e.g. the gatekeeper)? |
| How will the first approach to potential participant be made (e.g. email sent by gatekeeper)?  Will potential participants be asked more than once to participate (e.g., a reminder email will be sent after four week)? |
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| **Consent:**  When and how will potential participants learn about the study?  When and how will potential participants receive the participant information sheet? When and how will potential participants be able to ask questions?  Will written consent be used?  When and how will consent be secured?  Who will be responsible for securing informed consent prior to starting the study? Will participants be told they can withdraw from the study? |
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| **What are the possible harms for participants and the study team:**  What possible harms does the study pose for participants and/or the study team? Could the study have a negative impact on health and/or wellbeing? |
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| **What steps will be taken to mitigate possible harms:**  How are the possible harms being mitigated by the study team? Is debriefing being offered to participants and/or the study team?  Are safety procedures in places to support participants and/or the study team? |
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| **Possible benefits:**  What are the possible benefits associated with participating in the study? |
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| **Community engagement (if applicable):**  Does the study include any patient and/or public engagement (e.g. yes/no)? How will patient and/or the public be involved in the study (e.g. dissemination of findings)? |
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| **Return of results and incidental findings (if applicable):**  Will the study team notify participants of any important health related findings (e.g. high blood pressure)?  Will the study team signpost the participants to their General Practitioner, if they find any concerning health related information?  What steps will the study team take if a participant discloses professional misconduct and/or poor practice during the study?  Will participants be able to access the findings from the study they were involved with?  How will participants be able to access the findings from the study after it is completed? |
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| **Post-trial access (if applicable):**  Will participants be able to continue using any intervention they received during the study after it is completed? |
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| **Payment and/or reimbursement:**  Will participants receive any payment or reimbursement for their participation? How and when will participants receive payment/reimbursement?  How much payment/reimbursement will participants receive? |
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| **Study related injury or difficulties:**  How and when will study related difficulties be reported?  Will study related difficulties be reported to chief investigator/sponsor?  Will study related difficulties be documented in the final report/dissemination? |
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| **Other ethical concerns:**  What other ethical issues need to be considered? |
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