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| Georgian College Research Ethics Board  Review Checklist | | | | | | | |
| **GCREB File #:** | |  | | **Principal Investigator:** | |  | |
| **Study Title:** | |  | | | | | |
| **Reviewer Name:** | |  | | | | | |
| **Date Reviewed:** | |  | | | | | |
| Reviewer Recommendation | | | | | | | |
|  | **Recommend approval** | | | | | | |
|  | **Recommend resubmission with minor changes for GCREB chair review** | | | | | | |
|  | **Recommend resubmission with minor changes for delegated review** | | | | | | |
|  | **Recommend resubmission with major changes for full GCREB review** | | | | | | |
|  | **Recommend approval be DENIED** | | | | | | |
|  | **More than Minimal Risk – Submit for full GCREB review** | | | | | | |
|  | **Recommend exemption – Chapter 2 Category** | | | | Choose Category | | |
| Overview | | | | | | | |
| Core Principles of the TCPS 2 (2018) Chapter 1 B | | | Comments | | | | Project adheres to principal? |
| Respect for Persons | | |  | | | | Choose one. |
| Concern for Welfare | | |  | | | | Choose one. |
| Justice | | |  | | | | Choose one. |

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| Review Notes | | | |
| Part 1: Application Form | | | |
| SECTION A – GENERAL INFORMATION | | | |
| Question | TCPS 2Reference | Comments | Assessment |
| 1. Title of the Research Project |  | |  |  | | --- | --- | | Choose one. | Is it clear? | | Choose one. | Is it consistent? | | Choose one. | Are acronyms spelled out? | | **Comments:** | | |  | | | Select one |
| 1. Investigator Information | 3, 6, 8, 9, 11, Glossary | |  | | --- | | Notes:  Novice investigators are considered high risk.  Must have one person designated one person as PI.  If it is student research, the faculty advisor is the PI. | | **Comments:** | |  | | Select one |
| 1. Manager Approval | 3.6, 5.4, 5.5A, 9 | |  | | --- | | **Comments:** | |  | | Select one |
| 1. Project Start/End Dates |  | |  |  | | --- | --- | | Choose one. | Do the timelines make sense? | | Choose one. | Do you think the time allotted is reasonable? | | **Comments:** | | |  | | | Select one |
| 1. Locations | 5.1, 6.1, 8, 9 | |  | | --- | | **Comments:** | |  | | Select one |
| 1. Other REB Approval | 8, 9.9 | |  | | --- | | **Comments:** | |  | | Select one |
| 1. Project Funding | 7.4 | |  | | --- | | **Comments:** | |  | | Select one |
| 1. Conflict of Interest | 7.4  3.2 (e) | |  |  | | --- | --- | | Choose one. | Conflict of interest issues are clearly described | | Choose one. | Commercialization potential is clearly outlined and complete | | **Comments:** | | |  | |   Relationships with participants is part of this - authority; supervisory; influence; employment  Research involving students has a power dimension  Friends /colleagues /partnerships | Select one |
| SECTION B – SUMMARY OF THE PROPOSED RESEARCH | | | |
| Question | TCPS 2Reference | Comments | Implication |
| 1. Rationale | 3.2 (b) | |  |  | | --- | --- | | Choose one. | The purpose/objectives of the study are clearly described | | Choose one. | Rationale for the study is clearly outlined | | Choose one. | The research question(s) are clear | | **Comments:** | | |  | | | Select one |
| 1. Methodology | 3, 4, 5, 9, 10  11: Clinical Trials  12: Human Biological  13: Human Genetic | |  |  | | --- | --- | | Choose one. | Methodology is clearly described | | Choose one. | Methodology/design adequate to answer research question(s) | | Choose one. | Data analysis plan is adequately described | | Choose one. | Data analysis plan is appropriate | | Choose one. | Use of deception, placebo, or control, this is well explained and justified | | Choose one. | Experimental aspects are identified as such | | **Comments:** | | |  | | | Select one |
| 1. Participants | 4, 9 | |  |  | | --- | --- | | Choose one. | The participant group is fully described | | Choose one. | Exclusions are explained | | Choose one. | If Indigenous, vulnerable or marginalized, protection of interests is addressed | | **Comments:** | | |  | | | Select one |
| 1. Recruitment | 3.1, 3.3, 4.1, 4.7, 6.11, 7.4 | |  |  | | --- | --- | | Choose one. | Description of recruitment procedures is complete | | Choose one. | Recruitment materials are included | | Choose one. | Methods of recruitment are appropriate | | Choose one. | Recruitment procedures are not coercive, unduly influential | | **Comments:** | | |  | | | Select one |
| 1. Informed Consent   See also the detailed checklist for the informed consent documents in Part 2 of this checklist. | 3 | |  |  | | --- | --- | | Choose one. | Information on the consent form corresponds to application | | Choose one. | Description of informed consent process is complete (if no written consent, alternative process is adequate) | | Choose one. | Process for handling consent if participant is not capable is adequate | | Choose one. | Process for handling withdrawal is adequate | | **Comments:** | | |  | | | Select one |
| 1. Collection of Personal Information | 5 | |  |  | | --- | --- | | Choose one. | All identifiers from data collection instruments are addressed | | Choose one. | Includes personal information collected for administrative purposes (e.g. recruitment, incentives, feedback) | | Choose one. | Collection is explained and justified for all identifiers | | Choose one. | Appropriate terms used for collection of demographic information (e.g. gender) | | **Comments:** | | |  | | | Select one |
| 1. Confidentiality |  | |  |  | | --- | --- | | Choose one. | Demonstrates how confidentiality will be maintained | | Choose one. | Explains procedure to obtain participant consent to include identifiable information | | Choose one. | Coding procedure and storage are adequate, e.g. identifiers and data are stored separately | | **Comments:** | | |  | | | Select one |
| 1. Storage and Protection of Information (Data at rest) |  | |  |  | | --- | --- | | Choose one. | Storage methods, locations are addressed for all data at rest | | Choose one. | Sufficient safeguards in place for paper files, e.g. locked file cabinet in locked office | | Choose one. | Sufficient safeguards in place for electronic files (e.g. password-protected computer in locked, secure office, password-protected shared drive) | | Choose one. | Adequate encryption protocol provided for electronic files on mobile devices or devices in unlocked office | | Choose one. | Encryption protocol for all electronic files is provided and adequate (e.g. AES 256 or higher) | | Choose one. | Data retention period is appropriate | | Choose one. | Data destruction method is described and adequate | | Choose one. | Data at rest is backed up | | **Comments:** | | |  | | | Select one |
| 1. Transmission or Movement of Data (Data in transit/motion, upload-download) |  | |  |  | | --- | --- | | Choose one. | All data in motion is addressed | | Choose one. | Safeguards are sufficient for physical media in transit (e.g. paper in envelopes, courier/mail with signature) | | Choose one. | Safeguards are sufficient for all electronic information being transmitted/transported (e.g. portable digital devices are encrypted) | | Choose one. | De-encryption passwords are provided in a different way than the encrypted files are (e.g. if file access is provided via emailed link, password is provided by phone or in person) | | Choose one. | Data in transit is backed up | | **Comments:** | | |  | | | Select one |
| 1. Other’s Access to Data |  | |  |  | | --- | --- | | Choose one. | People handing identifiable data, and their role/affiliation are identified (e.g. transcribers) | | **Comments:** | | |  | | |  |
| 1. Secondary Use of Data |  | |  |  | | --- | --- | | Choose one. | Participants have consented to use of identifiable data for secondary purposes | | Choose one. | Permission obtained from holder of data | | Choose one. | Dataset linkages are adequately explained for pre-existing data | | Choose one. | Details and security of data repository for data collected in this study is sufficient | | **Comments:** | | |  | | | Select one |
| 1. Compensation/   Incentives |  | |  |  | | --- | --- | | Choose one. | Incentives are used in recruitment messaging | | Choose one. | Value of incentive is not coercive | | Choose one. | Protocol ensures participants who withdraw are still eligible for compensation/incentive | | **Comments:** | | |  | | | Select one |
| SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH | | | |
| Question | TCPS 2Reference | Comments | Assessment |
| 1. Possible Risks to Participants | 1.1, 2 B, 3 | |  |  | | --- | --- | | Choose one. | Study does NOT involve a vulnerable group | | Choose one. | If a vulnerable group is identified, are appropriate measures in place? | | Choose one. | Elements of risk are identified if applicable | | Choose one. | Physical risk (including any bodily contact or administration of any substance)? | | Choose one. | Psychological risks (feeling demeaned, embarrassed worried or upset)? | | Choose one. | Social risks (including possible loss of status, privacy and/or reputation)? | | Choose one. | Economic risks (including incurring expenses, loss of incentive)? | | Choose one. | Academic risks (including loss of bonus marks or course standing)? | | Choose one. | Potential access to personal data | | Choose one. | Researcher has identified a complete mitigation plan to safeguard participants from identified risks; additional safeguards required: | | Choose one. | Included plan for management of adverse effects | | Choose one. | I agree with the researcher’s categorization of risk. If not, please explain. (Assess magnitude, duration, likelihood) | | **Comments:** | | |  | | | Select one |
| 1. Possible Benefits |  | |  |  | | --- | --- | | Choose one. | I agree with the researcher’s assessment of the potential direct benefits to participants | | Choose one. | I agree with the researcher’s assessment of the potential benefits to the scientific community/society | | **Comments:** | | |  | | | Select one |
| SECTION D – PARTICIPANT FEEDBACK | | | |
| Question | TCPS 2Reference | Comments | Assessment |
| 1. Participant Feedback |  | |  |  | | --- | --- | | Choose one. | If the research involves deception, sufficient debriefing is provided | | Choose one. | The researcher has provided participants with a way to obtain the final results of the research | | **Comments:** | | |  | | | Select one |
| SECTION E – ADDITIONAL INFORMATION | | | |
| Question | TCPS 2Reference | Comments | Assessment |
| 1. Additional Information |  | |  | | --- | | **Comments:** | |  | | Select one |
| SECTION F – SIGNATURES | | | |
| Question | TCPS 2Reference | Comments | Assessment |
| PI (or Lead PI) initials:   1. Annual Review 2. Adverse Events 3. TCPS2 CORE |  | |  | | --- | | **Comments:** | |  | | Select one |
| All investigators signatures:   1. Investigator Assurance |  | |  | | --- | | **Comments:** | |  | | Select one |
| Part 2: Other Submitted Documents | | | |
| RECRUITMENT MATERIALS | | | |
| Component | TCPS 2Reference | Comments | Assessment |
| Recruitment scripts, emails, advertising materials, etc. |  | |  |  | | --- | --- | | Choose one. | Provides sufficient information for potential participants | | Choose one. | Is consistent with other outward-facing documents | | Choose one. | Includes appropriate branding and/or images | | **Comments:** | | |  | | | Select one |
| INFORMED CONSENT | | | |
| Component/Heading | TCPS 2Reference | Comments | Assessment |
| Title of Research Project |  | |  |  | | --- | --- | | Choose one. | Same throughout documents | | Choose one. | If title is different for valid deception, sufficient debriefing is outlined in the application | | **Comments:** | | |  | | | Select one |
| Investigators | 3.1 | |  |  | | --- | --- | | Choose one. | Name and contact information of investigators included | | Choose one. | Investigators’ roles disclosed if there is potential for perceived coercion or perceived conflict of interest. | | Choose one. | Any possibility of commercialization of findings are disclosed | | Choose one. | Funder information provided (If applicable) | | Choose one. | If the research is being used to satisfy educational requirements or credentials, this is stated, e.g. “I am doing this research as part of my Master of Arts degree.” | | **Comments:** | | |  | | | Select one |
| Invitation | 3.2 | |  |  | | --- | --- | | Choose one. | Includes a statement of invitation | | **Comments:** | | |  | | | Select one |
| Purpose of the Research | 3.2 | |  |  | | --- | --- | | Choose one. | Brief description of the purpose of the study answers the question, “Why do the study?” | | **Comments:** | | |  | | | Select one |
| Description of the Research | 3.2 | |  |  | | --- | --- | | Choose one. | Answers the question, “How will the study be conducted?” (e.g. brief step-by-step description) | | Choose one. | Distinguishes between interventions/activities that are part of standard practice and those that are research, and explains any changes to standard practice/activity/treatment. | | Choose one. | Answers the question, “How will the participants be involved?” The participant’s role is completely and clearly outlined | | Choose one. | Explains any specific testing, questionnaires, interviews, observation or other data collection, including frequency of data collection and duration of study | | Choose one. | Explains randomization or sequential assignment | | Choose one. | Describes what sort of information will be collected from participants and why | | Choose one. | Includes statement that participants have the choice to leave any questions unanswered or to withdraw from the study at any time | | Choose one. | Provides deadlines for withdrawal in order to have their data removed from the research | | Choose one. | Gives estimated time needed to complete surveys, interviews, focus groups, etc. | | Choose one. | For focus groups, includes caution regarding the limit on confidentiality | | Choose one. | Explains any future use of data/samples and when they’ll be destroyed | | **Comments:** | | |  | | | Select one |
| Access to Research Information | 3.2 | |  |  | | --- | --- | | Choose one. | Explains who will have access to data collected | | Choose one. | Gives information regarding retention of data and disposal schedule | | Choose one. | Explains how participants will be informed of the research results | | Choose one. | Explains details regarding withdrawal of data, and any deadlines for doing so | | Choose one. | If future use of data is anticipated, includes a specific question for consenting to future use | | **Comments:** | | |  | | | Select one |
| Potential Harm, Injuries, Discomforts or Inconvenience | 3.2 | |  |  | | --- | --- | | Choose one. | If there is no known harm to the participants, this is stated | | Choose one. | If there is known harm to the participants, states clearly:   1. the potential harm; 2. current knowledge regarding the probability of the occurrence of the harm; 3. clinical importance of the harm; and 4. any relevant knowledge regarding the probability of reversibility | | **Comments:** | | |  | | | Select one |
| Potential Benefits | 3.2 | |  |  | | --- | --- | | Choose one. | If participants will not benefit directly from participation, this is stated | | Choose one. | If participants might benefit directly, the potential benefits are described | | Choose one. | If society in general or individuals in similar circumstances might benefit from the results of this study, this should be explained. | | **Comments:** | | |  | | | Select one |
| Alternative(s) |  | |  |  | | --- | --- | | Choose one. | If there are alternative treatments/activities available to those who choose not to participate, these are identified | | **Comments:** | | |  | | | Select one |
| Confidentiality | 3.2 | |  |  | | --- | --- | | Choose one. | Includes an appropriate statement regarding confidentiality, including any legal obligations related to anticipated possible risks | | Choose one. | Includes information about any potential access by a sponsor or a regulatory authority (e.g. REB, police as required by law if likelihood exists) | | Choose one. | If data will be stored outside of Canada (e.g. on a U.S. server), includes a statement regarding access to data under jurisdictional law | | Choose one. | Explains any limits on confidentiality (e.g. for focus groups) | | Choose one. | Explains the level of detail that will be given in the disseminated results (e.g. whether or not individuals could be identified directly or indirectly) | | Choose one. | Explains how data will be secured to protect confidentiality | | **Comments:** | | |  | | | Select one |
| Reimbursement | 3.1 | |  |  | | --- | --- | | Choose one. | Explains reimbursement (e.g. for transportation, meals), and/or incentive; and does NOT offer payment for harm/discomfort | | Choose one. | States clearly that participant will still receive the reimbursement if they withdraw (can be pro-rated) | | **Comments:** | | |  | | | Select one |
| Participation | 3.1, 3.2 | |  |  | | --- | --- | | Choose one. | Explains any parts of the research that are optional | | Choose one. | Includes: “Participation in research is voluntary. If you choose to participate in this study you may withdraw at any time.” | | Choose one. | Explains how to withdraw and any deadlines | | Choose one. | States there will be no loss of benefit or negative consequences should they choose not to participate | | Choose one. | Parents of participants made aware that assent may be required from their child | | Choose one. | Participants receive a copy of the consent form to keep | | **Comments:** | | |  | | | Select one |
| No Waiver of Rights |  | |  |  | | --- | --- | | Choose one. | Does NOT seek waivers of participant’s legal rights. | | Choose one. | Includes a statement that by consenting participants are not giving up their rights to legal recourse in the event of any research-related harm | | **Comments:** | | |  | | | Select one |
| Contact |  | |  |  | | --- | --- | | Choose one. | Includes: “If you have any questions about this study, please contact [investigator’s name and contact information]” | | Choose one. | Includes: “If you have questions about your rights as a research participant, you may contact the Georgian College Research Ethics Board at reb@georgiancollege.ca or 705.728.1968, ext. 5395.” | | **Comments:** | | |  | | | Select one |
| Consent |  | |  |  | | --- | --- | | Choose one. | Includes **(as appropriate)** these (or similar) statements in the first person, with a function for participants to indicate Yes/No for items of particular concern:   1. The study has been explained to me. 2. All my questions about the research were answered. 3. Possible harm and discomforts and possible benefits (if any) of this study have been explained to me. 4. I understand that I have the right not to participate and the right to stop at any time. 5. I understand that I may refuse to participate without consequence. 6. I have a choice of not answering any specific questions. 7. I am free now, and in the future, to ask any questions about the study. 8. [Statement of understanding of any anticipated risks, if any] 9. I have been told that my personal information will be kept confidential [and/or acknowledge any limits to confidentiality] 10. I understand that no information that would identify me will be released without asking me first. 11. I understand that I will receive a signed copy of this consent form. | | Choose one. | Includes this statement (or similar): “I hereby consent to participate in this study.” and a signature line and date, or other appropriate method for the participant to indicate consent | | Choose one. | If data will be used in future research, includes explanation and a separate statement of consent for future research projects | | Choose one. | Includes a statement that any changes to the research that require participants’ consent will be communicated to the participants | | **Comments:** | | |  | | | Select one |
| Readability | 3.2 | |  |  | | --- | --- | | Choose one. | Uses plain language appropriate to reading level and experience of the potential participants | | Choose one. | Does NOT contain grammar, spelling or punctuation errors | | Choose one. | Format is accessible (e.g. adequate font size, AODA, suitable for target participants) | | Choose one. | Uses consistent tense (second person you/your) to provide information about the research; First person (I/my/me) to collect consent | | **Comments:** | | |  | | | Select one |
| QUESTIONNAIRES, INTERVIEW GUIDES OR OTHER DATA COLLECTION TOOLS | | | |
| Component | TCPS 2Reference | Comments | Assessment |
| Questionnaires, interview guides or other data collection tools |  | |  |  | | --- | --- | | Choose one. | Questions/measures relate to stated purpose/research questions | | Choose one. | Uses plain language appropriate to reading level and experience of the potential participants | | Choose one. | Does NOT contain grammar, spelling or punctuation errors | | Choose one. | Format is accessible (e.g. adequate font size, AODA, suitable for target participants) | | Choose one. | Uses consistent tense (second person you/your) to provide information; First person (I/my/me) for multiple choice answers | | Choose one. | Readability level is appropriate to participant group (if applicable) | | **Comments:** | | |  | | | Select one |
| DEBRIEFING SCRIPT/LETTER (IF APPLICABLE) | | | |
| Component | TCPS 2Reference | Comments | Assessment |
| Debriefing script/letter |  | |  |  | | --- | --- | | Choose one. | Provides sufficient information regarding any use of deception | | Choose one. | If necessary to address potential harms or discomforts, contact information for support services is provided in a format that the participants can keep | | **Comments:** | | |  | | | Select one |
| OTHER | | | |
| Component | TCPS 2Reference | Comments | Assessment |
|  |  | |  |  | | --- | --- | | Choose one. |  | | **Comments:** | | |  | | | Select one |

This checklist has been adapted from the *ONTARIO COMMUNITY COLLEGE MULTI-SITE FORM REVIEWER CHECKLIST* used in partnership with the Ontario Community College’s Heads of Applied Research – Subcommittee of Research Ethics, which in turn was adapted from the University of Waterloo with their permission. It also contains information from the Health Canada and Public Health Agency of Canada Research Ethics Board *Template to obtain informed consent of individuals over 18 years of age*.