GEORGIAN COLLEGE

RESEARCH ETHICS BOARD

APPLICATION FOR

RESEARCH ETHICS APPROVAL

# INSTRUCTIONS

## Who should complete a **different** form?

Instructors seeking permission from the Georgian College Research Ethics Board (GCREB) to review the ethics of their students’ minimal-risk course-based research should use the Request for Authority to Conduct Course-Based Research Ethics Review form.

Researchers who are planning to conduct research involving human participants at multiple Ontario colleges should use the ONTARIO COMMUNITY COLLEGE MULTI-SITE FORM.

## Who should complete **this** form?

Complete this form if you are a Georgian or non-Georgian researcher planning to conduct research involving Georgian College staff, students or community members as participants, or research involving humans under the auspices of Georgian College or using Georgian College resources. The range of research activities requiring review by the GCREB includes research that involves living human participants, human biological materials, or human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. Please refer to the Georgian College policies on RESPONSIBLE PRACTICE AND ETHICS REVIEW IN RESEARCH and RESEARCH INTEGRITY.

Students doing research for a course in which the instructor holds current authority to conduct course-based research ethics review should submit this APPLICATION FOR RESEARCH ETHICS APPROVAL to their instructor. If the study involves more than minimal risk the instructor will refer the application to GCREB for review.

## Exemption from Ethics Review

Some research activities, and research-like activities, are exempt from ethics review. Please refer to [Chapter 2 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)*](http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html) for more information. Additional information is available in the [Guidelines and FAQs](https://www.georgiancollege.ca/about-georgian/research/research-ethics-board/#faqs) on the GCREB website.

## What do I need to do before I complete this form?

1. ***Familiarize yourself with the applicable policies and take the required tutorials***

See [Policies](https://www.georgiancollege.ca/about-georgian/research/research-ethics-board/#policies) and [Required tutorials](https://www.georgiancollege.ca/about-georgian/research/research-ethics-board/#tutorials) on the [GCREB website](http://www.georgiancollege.ca/researchethicsboard).

1. ***Obtain Permission for Access to Resources for Research***

*(Also known as seeking administrative or institutional approval)*

Before you complete this form, you must confirm you will have access to any needed resources for research purposes. For research that will be done under the auspices of Georgian College or using Georgian College resources, you must submit a **Request for Permission for Access to Resources for Research (RPARR)form**, which is available on the [GCREB website](https://www.georgiancollege.ca/about-georgian/research/research-ethics-board/#forms).

Other research sites such as health facilities, schools, community organizations or businesses may require similar institutional approvals, and may also have their own ethics review requirements.

How do I complete this form?

First save a copy to your computer. You may also need to click something to enable editing.

Rename the file as follows: PILastName\_PIFirstName\_ProjectTitleKeyword.docx *(Keep it short!)*

This is a fillable form for Microsoft Word 2013-2019. Click the first response field to begin each section. You may use the Tab key to move forward one field, and Shift+Tab to move back one field within sections. To select (or to deselect) a check box, either click it with your mouse or navigate to it with the Tab key and use the spacebar to click the box.

Type in the text boxes provided. They will grow as you type. To insert a tab stop within your response, use Ctrl+Tab. (Using Tab only will move you forward one field.)

In some questions, you can add sections for additional responses by clicking the blue plus sign (**+**) in the lower right corner of the line.

You may apply Rich Text Formatting such as bold, colours or italics to your written responses. You may insert graphics, such as charts or diagrams, to help GCREB understand your research protocol.

Complete the application checklist found on the website under [Forms](https://www.georgiancollege.ca/about-georgian/research/research-ethics-board/#forms), and submit it with your application.

Please save your application as a Word document and submit it with the **application checklist** and all attachments to [reb@georgiancollege.ca](mailto:reb@georgiancollege.ca). (If your instructor holds a current Authority to Conduct Course-Based Research Ethics Review, please submit directly to them)

## Whom may I contact if I have any questions?

Please contact your instructor or the Georgian College Research Ethics Board at 705.722.5123 or [reb@georgiancollege.ca](mailto:reb@georgiancollege.ca) .

**Important!**

**Do not commence any recruitment or data collection activities until you have received final ethics approval.**

# APPLICATION FOR RESEARCH ETHICS APPROVAL

*The personal information collected on this form will become part of the records held by the Georgian College Research Ethics Board and will be used to assist in the review of your application and provision of services for your study. A copy of this form may be reviewed by external parties in order to meet legislative, audit and/or regulatory requirements. The information is collected under the legal authority of the Ontario Colleges of Applied Arts and Technology Act, 2002 and in accordance with Sections 38(2) and 41(1) of FIPPA. If you have any questions or concerns about the information collected, please contact the* [*GCREB*](mailto:reb@georgiancollege.ca) *at 705.722.5123. For more information about FIPPA, please contact the* [*Access and Privacy Office*](mailto:accessprivacy@georgiancollege.ca) *at 705-722-5189.*

|  |  |
| --- | --- |
| SECTION A – GENERAL INFORMATION | |
| 1. **Title of the Research Project:** | Click or tap here to enter text. | |
| 1. **Investigator Information** *(Click* ***+*** *to add rows)* | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Courtesy**  **Title** | **First Name** | **Last Name** | **Organization**  **/Department** | **Mailing**  **Address** | **Phone** | **Email** |
| **Principal Investigator (PI) or**  **Faculty supervising the conduct of student research at this site** | Choose/type title. | Click or tap here to enter first name. | Click or tap here to enter last name. | Click or tap here to enter org/dept. | Click or tap here to enter address. | Click or tap here to enter phone. | Click or tap here to enter email. |
| **LEAD PI**  **(For multi-site research only)** | Choose/type title. | Click or tap here to enter first name. | Click or tap here to enter last name. | Click or tap here to enter org/dept. | Click or tap here to enter address. | Click or tap here to enter phone. | Click or tap here to enter email. |
| **Co-Investigator** | Choose/type title. | Click or tap here to enter first name. | Click or tap here to enter last name. | Click or tap here to enter org/dept. | Click or tap here to enter address. | Click or tap here to enter phone. | Click or tap here to enter email. |
| **Student Investigator** | Choose/type title. | Click or tap here to enter first name. | Click or tap here to enter last name. | Click or tap here to enter org/dept. | Click or tap here to enter address. | Click or tap here to enter phone. | Click or tap here to enter email. |
| **Other Investigator** | Choose/type title. | Click or tap here to enter first name. | Click or tap here to enter last name. | Click or tap here to enter org/dept. | Click or tap here to enter address. | Click or tap here to enter phone. | Click or tap here to enter email. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **Research Affiliation** | | | | | | |
| * 1. Is this research being conducted solely on behalf of Georgian College? | | | | | | Choose Yes or No. |
| * 1. Is this research being conducted for another institution or purpose, e.g., for your thesis at another institution?   If **“Yes”**, explain below: | | | | | | Choose Yes or No. |
| Click or tap here to enter details of institutional affiliation/purpose. | | | | | | |
| 1. **Has this research study been approved by a Georgian College manager and/or, if the research will not be conducted at or on behalf of Georgian College, has it been approved by the research site’s administrator?** | | | | | | Choose Yes or No. |
| Attach your approved Request for Permission for Access to Resources for Research (RPARR)and/or letters of support from non-Georgian sponsors, site administrators, etc. | | | | | | |
| 1. **Project Start/End Dates** | | | | | | |
| Indicate the anticipated commencement date for this project: | | | | | Click or tap to enter a date. | |
| Indicate the anticipated completion date for this project: | | | | | Click or tap to enter a date. | |
| Note: The commencement date should be the date the principal investigator (PI) expects to begin interacting with human participants (including recruitment). The completion date should be the date that the PI expects that interaction with human participants, including any feedback or follow-up, will be complete. | | | | | | |
| Indicate the anticipated start date for **recruitment**: | | | | | Click or tap to enter a date. | |
| Indicate the anticipated completion date for **recruitment**: | | | | | Click or tap to enter a date. | |
| Indicate the anticipated start date for **data collection**: | | | | | Click or tap to enter a date. | |
| Indicate the anticipated completion date for **data collection:** | | | | | Click or tap to enter a date. | |
| 1. **Indicate the location(s) where the research will be conducted (Include specific campus locations):** | | | | | | |
| Click or tap here to enter text. | | | | | | |
| 1. **Other Research Ethics Board Approval** | | | | | | |
| Has this project been submitted to any other research ethics board(s), or will it be?  If **“Yes"**, please provide the following information *(Click + to add REBs)*: | | | | | | Choose Yes or No. |
| **Title of the project:** | | | Click or tap here to enter text. | | | |
| **Name of the other research ethics board:** | | | Click or tap here to enter text. | | | |
| This project has been: | | | Choose an item. | | | |
| Date of the decision (if applicable): | | | Click or tap here to enter text. | | | |
| Other research ethics board’s contact name: | | | Click or tap here to enter text. | | | |
| Other research ethics board’s phone number: | | | Click or tap here to enter text. | | | |
| Note: If other research ethics board(s) approved the project, provide the following for each:   * + - 1. A copy of the clearance certificate(s)/approval letter(s), AND       2. A complete copy of the approved application as a separate PDF file. | | | | | | |
| 1. **Project Funding** | | | | | | |
| This project: | Choose an item. | | | | | |
| If you have/will submit the project for funding, please attach the study’s budget and indicate: | | | | | | |
| Period of funding: | | Click or tap here to enter text. | | | | |
| Funding agency or sponsor(s): | | Click or tap here to enter text. | | | | |
| Does the funding agency prohibit/restrict publication? | | | | Choose an item. | | |
| If **“Yes”**, explain any restrictions: | | | | | | |
| Click or tap here to enter text. | | | | | | |
| Note: If the funding source changes, or if a previously unfunded project receives funding, you must submit a change/amendment form to the Georgian College Research Ethics Board. | | | | | | |
| 1. **Conflict of Interest** | | | | | | |
| * 1. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (e.g., a credential, qualification or certification, a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or connected to this study? | | | | | | Choose Yes or No. |
| * 1. Are there any real, perceived or potential [conflicts of interest](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf) of which you are aware (for example, researchers who will benefit financially from the research, research which may be in conflict with institutional roles and responsibilities, faculty members who may be responsible for awarding participant grades)? | | | | | | Choose Yes or No. |
| * 1. Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor or institution has placed on the investigator(s)? | | | | | | Choose Yes or No. |
| * 1. Is there the possibility of commercialization of the research findings? | | | | | | Choose Yes or No. |
| If you answered **“Yes”** to **any** of questions 8a) to 8d) above, please explain: | | | | | | |
| Click or tap here to enter text. | | | | | | |

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Rationale** | | | | | | | | | | | | | | | | | |
| * 1. State the hypothesis(es)/research question(s): | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Provide the rationale (reasons or logical basis) for the proposed research study and relevant supporting literature (including references).   While some background information can provide context, refrain from providing too much background. This section is about the rationale for your research methodology, not the rationale for a certain course, service or program.  Justify each aspect of your chosen methodology, including the tools and data analysis plan. Demonstrate how each addresses your hypothesis(es)/research questions. If a different methodology could be used to achieve the same results, describe it and explain why you have chosen your specific methodology. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Methodology** | | | | | | | | | | | | | | | | | |
| * 1. Explain the methodology. Describe in detail what will happen with the **data** from collection through reporting and discovery, preservation, any reuse and destruction.   Describe how you will process and analyze the data. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Describe sequentially, and in detail, what the **participants** will be asked to do (e.g., provide consent, complete paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests). Clearly separate activities and describe the time requirements for each task, any overlap between activities, and the total time requirement for participation. Include any important details about the research location. For each activity, describe in detail each investigator’s role. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Note: Attach a copy of all questionnaires(s), interview guides or other test instruments. Include supporting literature. | | | | | | | | | | | | | | | | | |
| 1. **Participants** | | | | | | | | | | | | | | | | | |
| * 1. Describe any relevant characteristics of the participants (number, age, gender, institutional affiliation): | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Describe groups that are excluded, if any, and why: | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Is this a captive population (e.g., professor-student; manager-employee-co-worker)?   If **“Yes”**, describe how you will deal with potential coercion issues for recruitment: | | | | | | | | | | | | | | | | | Choose Yes or No. |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Is this an Indigenous population (e.g., people, community, etc.)?   If **“Yes”**, describe how you will protect their interests: | | | | | | | | | | | | | | | | | Choose Yes or No. |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Is this a vulnerable or marginalized population (e.g., children, people residing in institutions such as correctional facilities or long-term care residences, medical research involving people receiving medical attention, or people who lack the capacity to consent for themselves)?   If **“Yes”**, describe how you will protect their interests: | | | | | | | | | | | | | | | | | Choose Yes or No. |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Recruitment** | | | | | | | | | | | | | | | | | |
| * 1. Are you submitting an approved Georgian College RPARR with this application that includes all your recruitment details? | | | | | | | | | | | | | | | | | |
|  | | | | | | | Yes, all my recruitment information is on my RPARR. ***(Proceed to question 14.)*** | | | | | | | | | | |
|  | | | | | | | No, I am including all my recruitment information below. | | | | | | | | | | |
| *Note: If you are doing your research on behalf of Georgian College, you must follow the Georgian College Brand Identity Guidelines and style guides. If your study is* ***not*** *Georgian College research, do* ***not*** *include any Georgian branding but still follow the style guides.* *If submitting material to both the Georgian College Students’ Association (GCSA) and Marketing, Communications and Recruitment (MCR), submit first to MCR. If any edits are made to recruitment material after it has been approved by GCREB, submit the new version for ethics approval.* | | | | | | | | | | | | | | | | | |
| * 1. How do you plan to recruit participants for your study? *(Select all that apply)*: | | | | | | | | | | | | | | | | | |
|  | | Portal Post(s)  *Note:* ***Write your portal post in the third person as a short news story about the project.*** *It must include a* ***headline*** *and a* ***linked URL or contact information*** *for people who want more information. Limit 500 words. You must also include a jpeg image with alt text. Samples are available from the* [*REB Assistant*](mailto:reb@georgiancollege.ca)*.*  **Specify portal(s):** | | | | | | | | | | | | | | | |
|  | | | | Staff News on the Employee Portal  *(Managed by Marketing, Communications and Recruitment (MCR))* | | | | | | | | | | | | | |
|  | | | | Student Portal  *(Managed by the Georgian College Students’ Association (GCSA))* | | | | | | | | | | | | | |
|  | | | | Other Georgian College SharePoint Site  Please specify: | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | | Posting (without email notification) on the student learning system (Blackboard). | | | | | | | | | | | | | | | |
| Specify Program/Community: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
| Specify Course(s): | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Posters displayed on Georgian College Students’ Association (GCSA) bulletin boards  *(Managed by GCSA)* | | | | | | | | | | | | | | | |
|  | | Posters displayed on other Georgian College bulletin boards  *(Managed by MCR)* | | | | | | | | | | | | | | | |
| Provide board locations/descriptions: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Flyers distributed in public area(s) on or off campus: | | | | | | | | | | | | | | | |
| Specify location: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Advertisement in a publication: | | | | | | | | | | | | | | | |
| Name of publication: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Investigators will approach their own students/patients/contacts | | | | | | | | | | | | | | | |
|  | | Investigators will receive referrals from other faculty/contacts | | | | | | | | | | | | | | | |
| Indicate from whom: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Email. Describe details below: | | | | | | | | | | | | | | | |
|  | | | PI/Co-investigators to send email to publicly available email addresses or their own contacts | | | | | | | | | | | | | | |
|  | | | Other person to send email to a distribution list. Provide details: | | | | | | | | | | | | | | |
| Person/department providing the distribution list: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
| Person/department sending the recruitment email: | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | In-person classroom recruitment | | | | | | | | | | | | | | | |
|  | | Existing research participation pool (specify):  Click or tap here to enter text. | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | | Other (specify):  Click or tap here to enter text. | | | | | | | | | | Click or tap here to enter text. | | | | | |
|  | No direct recruitment – Research involves request for information (e.g., from Georgian College academic performance records, Student Information System) | | | | | | | | | | | | | | | | |
| Note: If you add or change a method of recruitment, you must first request an amendment from the GCREB.  Note: Attach a copy of all recruitment scripts and advertising materials (e.g., in-person classroom recruitment script, online Research Participant Pool description, posters and emails). Label each file according to the instructions on the Application Checklist. | | | | | | | | | | | | | | | | | |
| 1. **Informed Consent** | | | | | | | | | | | | | | | | | |
| Note: Participants should actively choose whether or not to participate. A lack of response (i.e., a statement such as “you will be assumed to want to participate unless you indicate otherwise to the researchers”) should not be construed to imply consent.  Written consent is not required in all circumstances. For example, you could require participants to click a box in an online survey or provide verbal consent.  The TCPS2 (2018) sets out specific requirements for consent forms. Please see also the GCREB Review Checklist. | | | | | | | | | | | | | | | | | |
| * 1. Will you be seeking **written** consent from participants? | | | | | | | | | | | | | | | | | |
|  | | | | | Yes, my form is attached. | | | | | | | | | | | | |
|  | | | | | No, I will be collecting consent online. My online consent document is attached. (Participants must actively indicate their consent, e.g., by clicking a box.) | | | | | | | | | | | | |
|  | | | | | No, I will be collecting consent in another way. (Provide details of how you will obtain consent, including any plans for obtaining third party consent. Attach any related scripts, letters or forms.): | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | | | | | No, I will NOT be collecting consent. Please provide rationale: | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Will any participants be under the age of 16? | | | | | | | | | | | | | | | Choose Yes or No. | | |
| * 1. Are there any participants who may **not** be competent to consent? | | | | | | | | | | | | | | | Choose Yes or No. | | |
| If you answered **“Yes”** to b) or c) (i.e., if participants are under age 16 or are not competent to consent) describe the proposed alternate source of consent, including when, where and how consent will be obtained and from whom.  Attach any permission/information letters to be used. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Will participants have the option to withdraw from this study? | | | | | | | | | | | | | | | Choose Yes or No. | | |
| If you answered **“Yes”** to d), answer i) and ii) below: | | | | | | | | | | | | | | | | | |
| * + 1. What do they have to do to withdraw (include any deadlines)? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. Indicate what will be done with the participant’s data and any consequences for the participant withdrawing from the study. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| If you answered **“No”** to d), please explain the rationale: | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Is deception involved in your research? | | | | | | | | | | | | | | | Choose Yes or No. | | |
| If **“Yes”**, please elaborate (including issues around debriefing and an explanation of why the deception is necessary): | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Collection of Personal Information**   The collection, use and disclosure of Personal Health Information (PHI) are regulated by the Personal Health Information Protection Act (PHIPA). Researchers must comply with this legislation.  Personal data should be collected at the lowest level of identifiability possible (e.g., initials instead of a name, age instead of DOB).  See recommended wording for demographic questions on the GCREB website. | | | | | | | | | | | | | | | | | |
| * 1. **Please check all types of data you intend to collect about your participants:** | | | | | | | | | | | | | | | | | |
|  | | | | | Identifying information which identifies a participant through direct identifiers (e.g., full name, medical record number) | | | | | | | | | | | | |
|  | | | | | Identifiable information which could identify a participant through a combination of indirect identifiers (e.g., DOB plus address) | | | | | | | | | | | | |
|  | | | | | De-identified/coded information in which identifiers are removed and replaced with a code; the code can be used to re-identify participants | | | | | | | | | | | | |
|  | | | | | Anonymized information in which all identifiers are removed and no code is kept.  Describe when study data will be anonymized: | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | | | | | Anonymous information in which no identifiers are collected | | | | | | | | | | | | |
|  | | | | | Permission will be obtained to waive anonymity (please elaborate): | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. **In the table below, please detail the specific participant identifiers required for this study and describe why collection of this information is necessary:** | | | | | | | | | | | | | | | | | |
| **Participant Identifiers**  **(Check all that apply)** | | | | | | | | | | **Reason this is necessary**  **(E.g., To recruit participants, compare data from different groups, facilitate scheduling, etc.)** | | | | | | | |
|  | First and/or last name | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Initials | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Student/Employee number | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Social Insurance Number | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Health card number | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Medical record number | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Address | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Full postal code | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Partial postal code | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Telephone number | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Email | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Physician | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Date of birth | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Age | | | | | | | | | Click or tap here to enter text. | | | | | | | |
|  | Other (specify):  Click or tap here to enter text. | | | | | | | | | Click or tap here to enter text. | | | | | | | |
| 1. **Confidentiality** | | | | | | | | | | | | | | | | | |
| It is expected that the data be kept confidential unless the participants explicitly have given their permission otherwise. | | | | | | | | | | | | | | | | | |
| * 1. Please describe in detail how you will maintain confidentiality and ensure all records are secure. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. If confidentiality will **not** be maintained, or if there are any potential limits to maintaining confidentiality, please explain. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. If data will be coded or will have identifying (or potentially identifiable) information removed, describe when this will be done and by whom. Describe how the data will be coded or deidentified, e.g., any computer applications or strategies you will employ to identify the information to be removed or coded. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. If data will be coded, the identifiers and participant data must be stored separately.   Note: The code and consent forms must be isolated from study data and stored in a secure manner.  Describe the separate storage locations and who will have access to the code: | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Storage and Protection of Information**   To protect confidentiality and to demonstrate respect for persons, it is important that the research data be safe from malicious attacks and accidental loss. GCREB recommends the 3-2-1 data management rule: Have three copies on two different platforms/mediums with at least one available should the others be compromised, e.g., kept at a different secure site. | | | | | | | | | | | | | | | | | |
| * 1. In which of the following ways will data be stored? (Provide details to explain how the information will be protected.) | | | | | | | | | | | | | | | | | |
| **Storage Method**  **(Check all that apply)** | | | | | | | | | | | **Provide details:**  **(E.g., Who will have access, location, etc.)** | | | | | | |
| **Note: Paper files with identifiable information must be kept in a locked cabinet within a locked office.** | | | | | | | | | | | | | | | | | |
|  | Locked filing cabinet in a locked office | | | | | | | | | | Click or tap here to enter text. | | | | | | |
| Note: Electronic files with identifiable information may be **stored on a password-protected computer in a locked office, or on a secure access-controlled network** (i.e., one with virus protection, file backup, firewall, and limited access), otherwise they must be **encrypted** and **password-protected**. | | | | | | | | | | | | | | | | | |
|  | Password-protected computer in a secure, permanent location  (Provide details, including details of encryption protocol, type and level.) | | | | | | | | | | Click or tap here to enter text. | | | | | | |
|  | On cloud-based storage or a server with appropriate security  (Provide details, including details of encryption protocol, type and level, and server location.) | | | | | | | | | | Click or tap here to enter text. | | | | | | |
| Note: Electronic files with identifiable information may be stored on mobile devices (e.g., laptop, portable hard drive/disk, USB, tablet, digital recorder); **these files must be encrypted** and **password protected**. | | | | | | | | | | | | | | | | | |
|  | On mobile devices with encryption.  (Provide details, including details of encryption protocol, type and level.) | | | | | | | | | | Click or tap here to enter text. | | | | | | |
| * 1. How long will you keep the study data?   Note: If this study requires Health Canada approval, records must be retained for twenty-five years. For all other studies, the GCREB recommends seven years, with a minimum of one year. Sponsors and institutions may set out other requirements.  You are required to destroy identifiers or links at the earliest possible time. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. How and when will the data be destroyed? (Include details, e.g., shredding protocol, name of overwrite software.)   Note: Destroy data stored on paper or other physical formats by cross-cut shredding, pulping or burning. Destroy data stored in electronic format with overwrite software or through physical destruction of drives. | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Transmission or Movement of Data** | | | | | | | | | | | | | | | | | |
| If you need to transmit or move data (e.g., to send participant data for transcription; to upload data to a central data repository; or to move data from a server or mobile device to a local device, or from one location to another) you must ensure that mechanisms are in place to ensure data security, confidentiality and anonymity.  Identifying and/or identifiable personal information, especially Personal Health Information (PHI), must not be transmitted by email or transported on a portable device unless it is encrypted.  If research data will be uploaded, downloaded or stored on servers (e.g., data collected through online surveys or stored using cloud computing), it may be subject to data surveillance laws in the country where the server’s data centre is located. For example, data uploaded to American servers may be open to access by American regulatory bodies under the U.S. Patriot Act. When using servers located outside of Canada, researchers must inform study participants of this possibility. | | | | | | | | | | | | | | | | | |
| * 1. Will you be transmitting (e.g., uploading/downloading or emailing) or moving data? (If **“Yes”**, indicate how you are doing so and provide details regarding data security below.) | | | | | | | | | | | | | | | | | Choose Yes or No. |
| **Transmission/Transportation Method** | | | | | | | | | | | | | **Provide details:** | | | | |
|  | Email. Provide details, including details of encryption and password protection protocol: | | | | | | | | | | | | Click or tap here to enter text. | | | | |
|  | Upload/download to/from a computer, server or cloud-based storage. Provide details, including details of encryption protocol and server location: | | | | | | | | | | | | Click or tap here to enter text. | | | | |
|  | Transport via encrypted and password-protected portable device (e.g., laptop, portable hard drive/disk, USB, tablet, digital recorder). Provide details, including details of encryption protocol: | | | | | | | | | | | | Click or tap here to enter text. | | | | |
|  | Private Courier (Note: Delivery must be traceable.) | | | | | | | | | | | | Click or tap here to enter text. | | | | |
|  | Canada Post (Note: Regular mail may not be used. Delivery must be traceable.) | | | | | | | | | | | | Click or tap here to enter text. | | | | |
|  | Other (specify):  Click or tap here to enter text. | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| 1. **Others’ Access to Data**   Please list the names and affiliations of persons outside of your research team who will have access to the data. *(Click* ***+*** *to add rows)* | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | **Roles/Affiliations** | | | | | | **Types of Information**  *(See TCPS2 Chapter 5.)* | | **Due to their roles, could this person potentially identify participants?** | |
| Click or tap here to enter name. | | | | | | | | Click or tap here to enter role/affiliation. | | | | | | Choose a type. | | Choose Yes or No. | |
| 1. **Secondary Use of Data**   Use of data for [purposes other than those for which the data was originally collected](file:///C:/Documents%20and%20Settings/jmcdonald/User/mnummelin/Local%20Settings/Temporary%20Internet%20Files/Content.Outlook/TCPS/TCPS_2_FINAL_Web.pdf) is considered to be secondary use of data may require participants’ permission. | | | | | | | | | | | | | | | | | |
| * 1. Does this study use secondary data? | | | | | | | | | | | | | | | | | Choose Yes or No. |
| * + 1. If **“Yes”**, will the data be de-identified before you receive it?   If the data will **not** be de-identified before you receive it, please answer the following: | | | | | | | | | | | | | | | | | Choose Yes or No. |
| * + - 1. Did the participants consent to use of their data for secondary purposes? | | | | | | | | | | | | | | | | | Choose Yes or No. |
| * + - * 1. If you answered **“No”**, is there even a remote possibility participants can be identified indirectly?   Explain: | | | | | | | | | | | | | | | | | Choose Yes or No. |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + - 1. Have you obtained administrative permission/consent from the holder to access the data (e.g., from a hospital, Registrar’s office)?   N.B. If you answered **“Yes”** attach evidence of their administrative consent, e.g., a signed RPARR. | | | | | | | | | | | | | | | | | Choose Yes or No. |
| * 1. Will you combine your research data with any other data sets? | | | | | | | | | | | | | | | | | Choose Yes or No. |
| If you answered **“Yes”** to question b), please: | | | | | | | | | | | | | | | | | |
| * + 1. Identify the dataset(s): | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. Explain how the linkage will occur: | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. Provide a list of data items contained in the dataset(s): | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * 1. Will your data be entered into another database or repository for future use? | | | | | | | | | | | | | | | | | Choose Yes or No. |
| If you answered **“Yes”** to c), please answer the following: | | | | | | | | | | | | | | | | | |
| * + 1. Where it will be stored? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. Who will be the custodian? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. Who will have access to the database? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| * + 1. What security measures will be in place? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| 1. **Compensation/Incentives** | | | | | | | | | | | | | | | | | |
| * 1. Will participants receive compensation for participation? | | | | | | | | | | | | | | | | | Choose Yes or No. |
| If you answered **“Yes”** to a), please answer i) and ii): | | | | | | | | | | | | | | | | | |
| * + 1. Please select boxes for **all** that apply: | | | | | | | | | | | | | | | | | |
|  | | | | | | **Type** | | | **Details** | | | | | | | | |
|  | | | | | | Financial (e.g., cash, cheque, money transfer, prepaid credit card) | | | Click or tap here to enter text. | | | | | | | | |
|  | | | | | | Gift card/certificate | | | Click or tap here to enter text. | | | | | | | | |
|  | | | | | | Non-financial | | | Click or tap here to enter text. | | | | | | | | |
| * + 1. If participants choose to withdraw, how will you deal with compensation? | | | | | | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | | | | | | |

SECTION C – DESCRIPTION OF THE [RISKS](file:///C:/Documents%20and%20Settings/jmcdonald/User/Local%20Settings/Final%20Guidelines%20Approved/G_18%20Level%20of%20Risk%20to%20Participants%27%20Assessment%20Tool.doc) AND [BENEFITS](file:///C:/Documents%20and%20Settings/jmcdonald/User/Local%20Settings/Final%20Guidelines%20Approved/G_18%20Level%20of%20Risk%20to%20Participants%27%20Assessment%20Tool.doc) OF THE PROPOSED RESEARCH

|  |  |  |
| --- | --- | --- |
| 1. **Possible Risks to Participants**   *(If risks vary, click* ***+*** *to add sections for each participant group.)* | | |
| **Participant Group** | **Click or tap here to enter text.** | |
| * 1. Indicate if the participants might experience any of the following risks: | | |
| * + 1. Physical risk (including any bodily contact or administration of any substance)? Do not include “fatigue” as a risk unless it is significant for the population you are studying. | | Choose Yes or No. |
| * + 1. Psychological risks (including feeling embarrassed, worried or upset)? | | Choose Yes or No. |
| * + 1. Social risks (including possible loss of status, privacy and/or reputation)? | | Choose Yes or No. |
| * + 1. Economic risks (including expenses incurred for participation, long travel to research site) | | Choose Yes or No. |
| * + 1. Academic risks (including loss of bonus marks or course standing) | | Choose Yes or No. |
| * 1. If you answered **“Yes”** to any of the points in question a), please answer i) to iv) below. (If risks vary for different participant groups, use the + to address each participant group separately in your explanations.): | | |
| * + 1. Are any possible risks to any of the participants greater than those the participants might encounter in their everyday life? | | Choose Yes or No. |
| * + 1. What magnitude and duration of harm might the participants encounter (e.g. minimal or substantial; transient or longer lasting)? Explain: | | |
| Click or tap here to enter text. | | |
| * + 1. What is the likelihood that participants will encounter harm? Explain: | | |
| Click or tap here to enter text. | | |
| * + 1. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used). For example, indicate if a list of resources will be given to participants so they know where to go if needed (e.g., counseling). | | |
| Click or tap here to enter text. | | |
| * 1. Describe time commitment and any travel demands expected of participants: | | |
| Click or tap here to enter text. | | |
| **Participant Group** | **Click or tap here to enter text.** | |
| * 1. Indicate if the participants might experience any of the following risks: | | |
| * + 1. Physical risk (including any bodily contact or administration of any substance)? Do not include “fatigue” as a risk unless it is significant for the population you are studying. | | Choose Yes or No. |
| * + 1. Psychological risks (including feeling embarrassed, worried or upset)? | | Choose Yes or No. |
| * + 1. Social risks (including possible loss of status, privacy and/or reputation)? | | Choose Yes or No. |
| * + 1. Economic risks (including expenses incurred for participation, long travel to research site) | | Choose Yes or No. |
| * + 1. Academic risks (including loss of bonus marks or course standing) | | Choose Yes or No. |
| * 1. If you answered **“Yes”** to any of the points in question a), please answer i) to iv) below. (If risks vary for different participant groups, use the + to address each participant group separately in your explanations.): | | |
| * + 1. Are any possible risks to any of the participants greater than those the participants might encounter in their everyday life? | | Choose Yes or No. |
| * + 1. What magnitude and duration of harm might the participants encounter (e.g. minimal or substantial; transient or longer lasting)? Explain: | | |
| Click or tap here to enter text. | | |
| * + 1. What is the likelihood that participants will encounter harm? Explain: | | |
| Click or tap here to enter text. | | |
| * + 1. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used). For example, indicate if a list of resources will be given to participants so they know where to go if needed (e.g., counseling). | | |
| Click or tap here to enter text. | | |
| * 1. Describe time commitment and any travel demands expected of participants: | | |
| Click or tap here to enter text. | | |
| 1. **Possible Benefits**   *(If benefits vary, click* ***+*** *to add sections for each participant group.)* | | |
| **Participant Group** | **Click or tap here to enter text.** | |
| * 1. Discuss any potential **direct benefits to the participants** from their involvement in the project (not including compensation). If there are none, please state this. | | |
| Click or tap here to enter text. | | |
| * 1. Comment on the (potential) benefits **to the scientific community/society** that would justify involvement of participants in this study. | | |
| Click or tap here to enter text. | | |

SECTION D – PARTICIPANT FEEDBACK

|  |
| --- |
| 1. **Details of Participant Feedback** |
| Explain what feedback/information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research.) Indicate when results will be available and, if they will be made available on the internet, the URL to be used to access the results: |
| Click or tap here to enter text. |
| Note: Feedback should be provided in a way which is accessible to participants. For example, some participants may not have access to a computer so uploading results to a website may not be sufficient. |

SECTION E – ADDITIONAL INFORMATION

|  |
| --- |
| 1. **Is there any additional information that you would like to add that may assist us in reviewing your protocol?** |
| Click or tap here to enter text. |

SECTION F – SIGNATURES

|  |  |  |  |
| --- | --- | --- | --- |
| *If needed, create additional copies of pages in this section to collect signatures from all investigators who will interact with research participants or their data. The following will be accepted as valid signatures:*   * *Scans of hard copies, preferably in PDF format* * *Electronic signatures\** * *A typed statement on the signature line, “By typing my name below I am signing this form” plus their printed name on a new line\**   *\*Provided the investigators submit their signature page(s) directly to GCREB from the contact email listed for them in the application.* | | | |
| **Title of the Research Project:** Click or tap here to enter text. | | | |
| sdsdss | | | |
| 1. **Annual Review**   It is the principal investigator’s responsibility to notify the GCREB when the project is completed, or if it is cancelled, using the appropriate form.  I understand that the completion of a RENEWAL REQUEST or FINAL REPORT is required at least annually. | | | |
| **Principal Investigator Initial:** Click or tap here to enter text. |  | | |
| 1. **Adverse events**   I understand that adverse events (i.e. unanticipated negative consequences or results affecting participants) must be reported to the Georgian College Research Ethics Board (GCREB) as soon as possible. | | | |
| **Principal Investigator Initial:** Click or tap here to enter text. |  | | |
| 1. **Required Tutorial on Ethical conduct for Research Involving Humans (TCPS2 CORE-2022)**   I have attached certificates of Tri-Council Policy Statement 2 Course on Research Ethics (TCPS2 CORE-2022) completion for **all investigators**, and I confirm all investigators have read **The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018).** | | | |
| **Principal Investigator Initial:** Click or tap here to enter text. |  | | |
| 1. **Principal Investigator Assurance/Lead Principal Investigator Assurance**   I agree to conduct the research in accordance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Georgian College’s policies and procedures for ethical conduct of research, and any conditions communicated by the Georgian College Research Ethics Board (GCREB).  I further acknowledge the Principal Investigator (PI) is responsible for the ethical conduct of research, and for the actions of any member of the research team at this research site; and if this is a multi-jurisdictional study the LEAD Principal Investigator (Lead PI) is responsible for the ethical conduct of the study at all research sites.  I also understand that if I make any changes whatsoever to the documents provided with this application (including, but not limited to, the application form, recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I must complete a CHANGE REQUEST form and submit it to GCREB for review. I further understand that these changes, if determined to be substantive by GCREB, may require a new application for research ethics approval if they constitute new research.  If any changes are made to the protocol submitted, or if unanticipated risks or events are observed, I will bring these to the attention of the GCREB immediately. I understand that if I fail to advise GCREB of any changes or adverse events, or fail to comply with research protocols outlined in this application, or make any unauthorized changes to any document submitted with this application, ethics approval may be rescinded.  I further understand that I may not start any recruitment or research without receiving ethics approval. I further understand that ethical approval does not constitute institutional approval of this research.  I consent to the collection of my name and contact information on this form. I understand this form may be reviewed by external parties in order to meet legislative, audit and/or regulatory requirements. I will notify GCREB immediately of any changes to my contact information or status as an investigator for this study. | | | |
| **Title of the Research Project:** | | |
| Click or tap here to enter text. | | |
| Click or tap here to enter text. | | Click or tap here to enter text. | |
| Signature of Principal Investigator (PI) or Faculty/Thesis Supervisor for student research | | Date | |
| Click or tap here to enter text. | | Click or tap here to enter text. | |
| Signature of LEAD Principal Investigator (Lead PI) for multi-jurisdictional research | | Date | |

1. **Co-investigator/Student Investigator/Other Investigator Assurance**

***(Print additional copies of this page if needed.)***

|  |
| --- |
| I have read the application for research ethics approval being submitted to the Georgian College Research Ethics Board (GCREB) for this research project. I agree to conduct the research in accordance with the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Georgian College’s policies and procedures for ethical conduct of research, and any conditions communicated by the GCREB.  I also understand that before I make any changes whatsoever to the documents provided with this application (including, but not limited to, the application form, recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I must first consult the Principal Investigator (and/or Lead Principal Investigator, if applicable), who may then submit a CHANGE REQUEST to GCREB for approval.  If any unanticipated risks or adverse events are observed, I will bring these to the attention of the Principal Investigator (and/or Lead Principal Investigator, if applicable) and notify GCREB immediately. I understand that if the research team fails to advise GCREB of any changes or adverse events, or fails to comply with research protocols outlined in this application, or makes any unauthorized changes to any document submitted with this application, then ethics approval may be rescinded.  I further understand that I may not start any recruitment or research without receiving the required ethics approval. I further understand that ethical approval does not constitute institutional approval of this research.  I consent to the collection of my name and contact information on this form. I understand this form may be reviewed by external parties in order to meet legislative, audit and/or regulatory requirements. I will notify GCREB immediately of any changes to my contact information or status as an investigator for this study. |

|  |
| --- |
| **Title of the Research Project:** |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Signature of Co-Investigator/Student Investigator/Other Investigator | Date |
| Click or tap here to enter text. | |
| Print Name  Click or tap here to enter text. | |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Signature of Co-Investigator/Student Investigator/Other Investigator | Date |
|  | |
| Print Name  Click or tap here to enter text. | |