

This application is a generic form that is designed to capture a diverse assortment of research activities. If a question is not relevant to the context of your research activities, indicate 'N/A' or explain as appropriate why it is not applicable for your research.

Section 1: Overview

1.1) * Are you eligible to use one of GREB's other TRAQ application forms? If you are conducting a Clinical Trial you must submit the HSREB Standard Application Form in TRAQ. If you are not eligible to submit another form indicate 'No' below:

Refer to the [Office of Research Ethics Compliance Application Forms Descriptions \(PDF, 85 KB\)](#) to determine if you are eligible to use another application form in TRAQ. A Clinical Trial (See [NIH's definition](#) as a reference) is an investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes ([Chapter 11, TCPS 2](#)). A clinical trial may involve the assignment of participants to one or more health-related interventions (e.g., drugs, surgical procedures, devices, behavioural treatments, exercise interventions, dietary interventions, and process-of-care changes) to evaluate an outcome (e.g., effectiveness of a drug/device/diagnostic tool and/or improvement in the quality of life). Contact the [Ethics Office](#) if you are unsure about the type of study you are conducting.

- No, continue completing the GREB Standard Application Form (i.e. I am not eligible to use any other application form)
- If yes, close this form, delete this draft, and complete the appropriate application form

1.2) * Indicate if any of the below are applicable to your research (Select all that apply):

'Federally supported' is defined as the U.S. Government providing any funding or other support including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes and/or the conduct of the research involving U.S. Government employees. Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46) protects human subjects in research carried out or supported by most federal departments and agencies. The GDPR implementation date is 2018MAY25. This may affect researchers working in and/or with participants from the EU. Refer to the [GDPR Regulations](#) for additional guidance. You may need to consult with your EU partner to ensure you are following all local regulations. If you will be transferring data, follow up with the [Research Contracts Unit](#) (RCU) if a data transfer agreement may be required researchcontracts@queensu.ca. The RCU may also be able to clarify questions in relation to the GDPR.

- Funded and/or is receiving support from the United States Federal Government (i.e. subject to Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects)
- Subject to the General Data Protection Regulation (GDPR) mandated by the European Union (EU)
- N/A

1.3) * Is this a multi-site research study (i.e. multiple research sites participating in the same study, following the same protocol and combining data) or does it require you to obtain a foreign research permit/license (select all that apply)?

Multi-site research is when all sites follow the same protocol and the data is being collected/participants are being recruited at more than one site, and all data is being combined for analysis. Contact the [Ethics Office](#) if you are unsure about the type of study you are conducting.

For internet based research it would likely not reference a 'site' and there is generally no distinction between local/global participants/data.

- No, not multi-site research
- Yes, more than one site in Ontario
- Yes, National

- Yes, International
- Yes, foreign research permit/license

1.4) * What is the current status of the Principal Investigator (PI) (Select all that apply)?

Select the level of research that applies to the Principal Investigator (PI). NOTE: if you are applying as a Queen's employee or as an external applicant, you may be asked to include the name of a local investigator or faculty member as a supervisor on your ethics application.

- Undergraduate*
- Master's*
- Doctoral*
- Postdoctoral*
- Queen's Faculty
- Queen's Employee
- Hospital Employee (KHSC or PCC)/Physician/Health Professional
- External Applicant

1.5) If the PI status is indicated by an asterisk (*) above list your Research Supervisor(s) and attest below that they have review and approved this ethics application:

Make sure to add your supervisor(s) to the ethics file in TRAQ by using the PROJECT INFO TAB under 'Other Project Member Info'. ANYONE who is performing significant study-related duties or who has access to study data should also be added to the ethics file in TRAQ. A confidentiality agreement may suffice for some roles but is not required for those performing their normal job-related duties that would be covered under an employee confidentiality agreement. ALL TEAM Members must first self-register in TRAQ before they can be added to the ethics application. Follow the instructions under FAQs titled '[How Do I Self-Register in TRAQ as a Student/External User?](#)'.

1.6) * Attach a copy of the CORE completion certificate and/or proof of equivalent ethics training/exemption for all research team members performing significant study-related duties, including external applicants. Proof of ethics training is required for those who have access to study data and/or participants and all team members listed on the ethics file (Select all that apply):

All project team members performing significant study-related duties, including those who have access to study data, are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics ([CORE](#)). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external applicants. Contact the Office of Research Ethics if you require an exemption from CORE. Exemptions may be provided if your duties are only administrative in nature (i.e. Research Coordinator only involved with ethics submissions/administrative duties). Evidence of equivalent ethics training may be acceptable depending on the nature of the research study. The Office of Research Ethics will accept GCP, CORE, or the Biomedical Research Ethics Tutorial (CITI) as evidence of ethics training.

- Yes, CORE certificate(s) attached for all Team Members
- Yes, CORE certificate(s) attached for my Research Supervisor(s)

- Yes, equivalent ethics training attached
- Yes, ethics training exemption(s) from Ethics Office attached

1.7) * Do you need to obtain additional permissions for your research as indicated below (Select all that apply)?

Restrictions are now in place for in-person research. The process to start or resume in-person research can be found on the VPR website and includes 3 key steps: <https://www.queensu.ca/vpr/human-participant-research-guidelines-and-sop>. Additional clarification on COVID-19 spread and risk of infection is provided by Queen's University and our Public Health partners and are continuously being re-assessed. Visit <https://www.queensu.ca/vpr/covid-19> for the most up to date information. All members of the Queen's community involved in off-campus activities must register their trip/activity in the Off-Campus Activity Safety Policy On-line Planning Tool. The Policy applies to not only all Students, but also all Faculty and Staff, who are undertaking studies, doing research, or carrying out any other work that takes place off-campus and is under the purview of the University. Refer to the [OCASP website](#) if you will be conducting your research off campus.

If you will be conducting human participant research at any research facility on Queen's University campus outside of the regular business hours of Monday – Friday 8:30am – 6:00pm, excluding observed holidays, ensure that you refer to the Office of Research Ethics Security Protocol and attach a copy of the Security Protocol Form, as applicable to your application. These documents are available on the [GREB website](#) under 'Resources' and 'Guidelines'. This policy does not apply to course-based research conducted during class time outside of the regular business hours (e.g., evening labs/classes).

- No additional approvals needed
- Yes, VPR approval for in-person research due to COVID-19
- Yes, OCASP approval using the on-line planning tool for off-campus research
- Yes, Ethics Office Security Protocol Form attached for conducting research on Queen's campus outside of regular business hours (i.e. Monday - Friday 8:30 AM - 6:00 PM)
- Yes, other, describe below

1.8) * Describe if any other approvals are required (e.g., external REB review, school and school board approval, research licence, correctional/police services approval):

If not applicable, enter 'N/A'. It is the applicant's responsibility to ensure that all necessary external approvals are obtained. Queen's research ethics clearance may not be adequate if additional approvals are required. Some jurisdictions require additional authorizations, approvals, and/or licenses for conducting research.

Section 2: Purpose and Methods

2.1) * Explain in plain language why there is a need to conduct this study in relation to the anticipated public and/or scientific and/or educational benefits:

Outline what new knowledge will come from the research, how it will benefit society, and/or how it will have the potential to inform future work. Include information about the main objectives and secondary objectives as applicable.

2.2) * This study will involve the following (select all that apply):

- Web-based Surveys/Questionnaires
- In-person/Verbal Surveys/Questionnaires
- Interviews

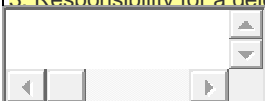
- Focus Groups/workshops
- Audio/Video Recording
- Virtual teleconferencing (e.g., Zoom, Teams, FaceTime, phone)
- Sharing Circles/talking circles
- Story-based research/learning from Elders
- Art-based data collection
- Interventions/Exercise
- Experiments (lab-based, field, on-line)
- Secondary Use of Data
- Observation
- *Conducting, administering or supervising tests or therapies that require professional credentials, describe below
- *Delegation of a “controlled act” as specified in the Regulated Health Professions Act, 1991 (RHPA), describe below
- *Other, describe below

2.3) * Describe how each method listed above will be implemented, making sure to include all details related to data collection in plain language. If your project involves multiple stages/phases or multiple studies, describe each specific method separately. If using emergent design or some details are still pending, indicate that an Amendment Event Form in TRAQ will be submitted to outline emerging methods. If you have selected a method with an asterisk (*) above, describe the specific details as highlighted in the information tab, as well as those who have the necessary credentials to use such methods. If ‘other’ selected, describe:

Give specific details of your data collection as it relates to human ethics. Avoid cutting and pasting extensive sections from the protocol. Ensure that all elements noted in this section are consistent with the other sections of this application and with supplemental documentation. Emergent Design research means that all project details are not known at the start of the project (i.e. driven from the study design/data rather than from theory). An amendment is required for any updates/changes made to the methods, data collection/sharing strategies, recruitment and to study materials unless the changes are solely administrative in nature.

There are many psychological tests such as personality, intelligence, or emotional functioning assessments that may be restricted for use based on credentials (e.g., only to be used by Registered Psychologists). Controlled acts are defined in the [Regulated Health Professions Act, 1991 \(RHPA\)](#). For more information refer to the [Delegation of Controlled Acts policy on the College of Physicians and Surgeons of Ontario's website](#). If you plan to delegate a controlled act the following considerations must be made:

1. In every instance of delegation, the primary consideration must be the best interests of the participant.
2. An act undertaken through delegation must be as safe and effective as if it had been performed by the delegating physician.
3. Responsibility for a delegated controlled act always remains with the delegating physician.



2.4) * When is local recruitment expected to start and end? Include information about multi-site recruitment as applicable:

Multi-site research is when all sites follow the same protocol and the data is being collected/participants are being recruited at more than one site, and all data is being combined for analysis. Contact the [Ethics Office](#) if you are unsure about the type of study you are conducting.

For internet based research it would likely not reference a 'site' and there is generally no distinction between local/global participants/data.

2.5) If using secondary data (i.e. data originally collected for a purpose other than the current research study), describe the source of the data. Indicate if the data set contains identifiable information or if it will be de-identified and/or anonymous data:

For more information on the use of secondary data, refer to [TCPS 2 Chapter 5](#).

2.6) * Attach all data collection tools that will be used for this study (e.g., surveys, questionnaires, screenshots, interviews/focus group scripts/guides, copies of all assessments/tests/debriefing materials, data collection/extraction forms):

- Yes, attached
- N/A

2.7) If your research involves materials that will not be in English (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.) attach a copy of these translated documents and an English version, as GREB only reviews in English. If external services were used for translation, attach a copy of the translation certificate. If translation was done by the study team, attest below that the materials were translated accurately (Select all that apply):

- Yes, material(s) attached (English and translated versions) and I attest to the accuracy of the translation
- Yes, material(s) attached and translation certificate(s) attached
- N/A

Section 3: Benefits and Risk

3.1) * Describe any direct benefits that participants and/or communities may receive from participating in this study. If there are no direct benefits to participants and/or communities, state this in the application form and the Letter of Information/Consent Form (LOI/CF):

Human participant research may result in benefits that positively affects society through the advancement of knowledge for future generations, for participants themselves, or other individuals; however, most research offers no direct benefit to participants. Incentives should not be listed as a benefit to research participation.

3.2) * Select all risks (real or potential) associated with participation in this study (select all that apply):

Research would be classified as 'Minimal risk' if the probability and magnitude of possible harms, related to participating in the research, is no greater than that which would be encountered in aspects of everyday life. Anything greater than minimal risk needs to be communicated. For additional guidance, see: [TCPS 2, Chapter 2: Section B, Concepts of Risks and Potential Benefits](#).

If you will be recruiting 5 participants or less there may be an increased risk of identification/re-identification due to the small number of participants. Risk mitigation strategies can include communicating this risk information in the LOI/CF, suppressing small cells and/or giving participants the option to be identified.

- Physical risk (e.g., injury)
- Privacy Risk (e.g., sending information, collection of sensitive and personal information)
- Less than 6 participants (increased risk of identification/re-identification)
- Psychological or emotional risk
- Questions about sensitive or personal issues
- Economic risk
- Social risk
- Dangerous location, such as war-torn country
- Risks to participants due to power imbalance (e.g., Instructor/Student)
- Cultural sensitivities
- Third party risks (e.g., risks to family)
- Reproductive Risks
- Risk to greater community
- Other, describe below
- No known risks

3.3) * Describe all potential short-term/long-term risks, foreseeable harms, contextual sensitivities, discomforts, and inconveniences, any risks, any potential harms, etc., for study participants in general and/or the general population/community. If 'other' selected above, describe:

If not applicable, enter 'N/A'. Ensure that you describe risks to all participant populations/communities as applicable. If there are different risks, or different degrees of risk for different populations, ensure that this is clearly outlined in your response.

If you are including images/videos or content that may be upsetting it is recommended that language be added in advance of this type of content to provide an immediate notification in advance (e.g., trigger warnings for on-line survey).

3.4) * Describe your plan if an identified risk were to occur. Describe how you will provide support to participants/communities in the context of these risks:

If not applicable, enter 'N/A'. Ensure that you have included a plan to mitigate risks for all participant populations/communities as applicable. If there are different degrees of risk for different populations, ensure that all risk mitigation plans are clearly outlined in your response.

3.5) * If abnormal and/or incidental findings (i.e. unanticipated discoveries made in the course of research) could occur from study participation, outline your plan for telling participants. If you will not be disclosing incidental findings explain why not:

If not applicable, enter 'N/A'. Incidental findings are unanticipated discoveries made in the course of research, which are outside the scope of the research. (e.g., participant will be referred to their local doctor for additional follow up if abnormal findings noted on a cognitive functioning assessment). See [TCPS 2 How to Address Material Incidental Findings Guidance in Applying TCPS 2 Article 3.4](#)

3.6) * Describe what will happen if a participant suffers an injury from participating in the study. List any criteria for stopping the study early due to safety concerns or for any other reason:

If not applicable, enter 'N/A'. This information must be communicated on the LOI/CF.

3.7) Describe if this study involves deception or partial disclosure (i.e. participants do not know the true purpose of the research in advance). Outline your plan for debriefing participants. If you do not plan to debrief participants, explain why not. Attach a copy of all debriefing material:

Some types of research may only be carried out if the participants do not know the true purpose of the research in advance. This research may involve giving participants false information about themselves, events, social conditions, and/or the purpose of the research. For additional guidance on deception, see [TCPS 2 Chapter 3 Article 3.7B](#).

If you do not plan on debriefing your participants, you must justify why not based on the [TCPS 2 Article 3.7B](#): "Debriefing must be a part of all research involving an alteration to consent requirements whenever it is possible, practicable, and appropriate. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable, and appropriate (Article 3.1)".

Section 4: Participants & Recruitment

4.1) * Describe the participant populations(s) that will be recruited for this study and explain how they will be identified for recruitment. Provide information about who will be recruiting participants:

If not applicable, enter 'N/A'.

GREB prefers that participants are not recruited or consented to participate in a research study by someone in a 'power-over' position. Undue influence and manipulation may arise when prospective participants are recruited by individuals in a position of authority. This may include study doctors recruiting their patients, or instructors recruiting their own students. How, when, and where participants are approached, and who recruits them, are important elements in assuring (or undermining) voluntariness ([TCPS 2 Chapter 3](#)). If you plan to use recruitment techniques that may involve power imbalances, you must justify this approach and describe how you will minimize undue influence. For additional guidance, refer to the guidance document titled, 'Ethical Considerations for Instructors Conducting Research on their Students' which is posted on the [GREB website](#) under 'Guidelines' or refer to [TCPS 2 Chapter 3](#).

4.2) * Indicate how many participants will be recruited and describe how you have reached this number. Differentiate how many from each population and/or from each stage/phase of the research:

If not applicable, enter N/A.

If you are seeking a specific number of participants, give that number. If a range better describes your number of participants,

give that range. If you are seeking participants throughout multiple phases/stages of your study, indicate the number of participants required for each phase/stage.

4.3) If this study is excluding populations based on culture, language, religion, race, disability, sexual orientation, gender, ethnicity, linguistic proficiency, competency/capacity, or age, describe the exclusion and explain why these populations have been excluded:

Historically, researchers have not sufficiently considered the ethical rights of certain populations. For additional guidance, see [TCPS 2 Chapter 4](#).

4.4) * Describe all recruitment procedures and materials that will be used for recruitment. Explain how each recruitment tool will be used, including the location of use (e.g., posted on website, social media, email script, radio add, etc.). Describe any approvals that need to be obtained (e.g., access to private institution/ mailing lists) and outline plans for third parties to help with recruitment (e.g., listserve, snowball recruitment, website/app):

If not applicable, enter N/A. If you will be asking third parties (e.g., mailing lists, circulate through an organization, etc.) to aid in recruitment by circulating study recruitment materials, you must include the circulation script for the dissemination process. Snowball sampling is a recruitment technique where current participants are asked to identify potential participants. For additional information, refer to the 'Snowball Sampling Recruitment Guidelines' posted on the [GREB website](#) under 'Guidelines'.

4.5) * Attach a copy of all recruitment notices, emails, scripts, advertisements, information sheets, and/or media releases:

- Yes, attached
- N/A

Section 5: Informed Consent

5.1) * How will you obtain informed consent (select all that apply)?

For consent to be informed it must involve providing information about the study to the participant; ensuring the participant understands by answering any questions they may have; and by obtaining the voluntary agreement of the participant to join the study. Implied consent is consent that is not expressed by a person, but rather implicitly granted through a person's actions. Assent is the expression of approval or agreement. For additional guidance on alterations to consent, refer to [TCPS 2 Chapter 3](#).

- Written Informed Consent Form (active consent)
- Written Letter of Information with separate written Consent Form (active consent)
- Written Letter of Information with completion of a survey as representing consent (active consent)
- Written Letter of Information with the recording of verbal consent (e.g., via Teams, Zoom, recorder) (active consent)
- Verbal consent (*no active consent)
- Implied consent (*no active consent)

- Assent (*no active consent)
- Opt-out consent process (*no active consent)
- Parent/Guardian/Substitute decision-maker consent (*no active consent)
- Waiver/Alteration to the consent process (*no active consent)
- Participant unable to provide consent (*no active consent)
- Other (*no active consent)

5.2) If you have chosen a ‘no active consent’ option above (i.e. denoted with an asterisk*) describe how you will be documenting the consent/assent process. If you are requesting a waiver or alteration to the consent process, explain why as described in the information tab:

Refer to [GREB’s website](#) section ‘Letter of Information/Consent Form Resources’ for tools to assist with documentation of the informed consent documentation process (e.g., [Verbal Letter of Information and Script Template](#), [Verbal Consent Script Template](#), [Verbal Consent Log Template](#), [Visual Assent Form Template](#)).

Refer to GREB’s [Virtual Research Guidelines](#) for additional information and strategies related to obtaining consent virtually.

Justification should be based on TCPS 2 Article 3.7A and all points a-e must be addressed in your response: The REB may approve research that involves an alteration to the requirements for consent set out in [Articles 3.1](#) to [3.5](#) if the REB is satisfied, and documents, that all of the following apply:

- a. the research involves no more than minimal risk to the participants;
- b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
- c. it is impossible or impracticable (see [Glossary](#)) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
- d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
- e. the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with [Article 3.7B](#).

Justification is also required for not obtaining consent for use of identifiable secondary information as per TCPS [Article 5.5A](#).

‘Assent’ is the expression of approval or agreement. Assent is obtained from a participant who lacks the decision-making capacity to provide fully informed Consent. An authorized third party will provide Consent on their behalf but the Assent of the participant is still sought. For example, you would seek Consent from a parent and Assent from a child whose capacity for judgment and self-direction is still maturing. For additional guidance on Decision-Making Capacity and Consent, refer to TCPS 2 Chapter 3 [Section C](#).

5.3) * Explain how and when participants will be approached and who will obtain consent/assent. If there is a relationship between the potential participants and the person obtaining the consent/assent, explain the nature of the relationship (e.g., circle of care, employer, supervisor, instructor, etc.) and describe how you will minimize any undue influence/power imbalance.

If not applicable, enter ‘N/A’. How, when, and where participants are approached, and who recruits them, are important elements in assuring (or undermining) voluntariness ([TCPS 2 Chapter 3](#)).

5.4) * Explain the procedures in place for participants who may have communication difficulties (e.g., who may need translation, who are illiterate, who have trouble understanding or producing speech and require special support including the use of

assistive devices), or do not have the capacity to provide consent. If participants have trouble communicating but there are no procedures in place, explain why:

If not applicable, enter 'N/A'.

5.5) * Describe how you will provide participants with new information, if it becomes available, which may affect their willingness to participate:

If not applicable, enter 'N/A'.

5.6) * Describe the process by which participants can withdraw their consent and, if they desire, withdraw consent to use their data. Describe any limitations to the withdrawal of data (e.g., submission of an anonymous survey; limitations to removing data from focus group/sharing circle):

If not applicable, enter 'N/A'.

5.7) * Attach all Letters of Information/Consent Forms/Assent Forms to the ethics application and any other materials that will be distributed to study participants:

Refer to [GREB's website](#) under 'LOI/CF Resources' for GREB's LOI/CF Checklist and template (LOI/CF) that includes all of the Informed Consent Form required elements as per the TCPS 2.

- Yes, attached
- N/A

5.8) * Attach a completed copy of GREB's current Letter of Information/Consent Form (LOI/CF) Checklist to this application:

You must attach a completed copy of this checklist with your ethics application unless you can justify why it is not required below. Refer to [GREB's website](#) under 'LOI/CF Resources' for GREB's LOI/CF Checklist and template (LOI/CF) that includes all of the Informed Consent Form required elements as per the TCPS

- Yes, GREB's completed LOI/CF checklist is attached
- No, explain below

5.9) If a copy of the completed LOI/CF Checklist was not attached, explain why not:

Refer to [GREB's website](#) under 'LOI/CF Resources' for GREB's LOI/CF Checklist and template (LOI/CF).

Section 6: Incentives/Compensation/Expenses

6.1) * Describe any incentives or compensation being provided and explain why it is being offered:

If not applicable, enter 'N/A'. Incentive information must be communicated on the LOI/CF. Incentives: Anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury). Compensation:

Payment for one's time (e.g., minimum hourly wage). For more information about incentives, refer to the document titled 'Incentive Guidelines for Human Participant Research,' which is posted on [GREB's website](#) under 'Guidelines'.

6.2) * Describe any anticipated expenses directly associated with participation in the study (e.g., parking, food, travel). Explain if remuneration be provided for these expenses. If not, explain why not:

If not applicable, enter 'N/A'. Reimbursement information must be communicated on the LOI/CF. Reimbursement: Payment to participants to ensure that they are not put at a direct, or indirect, financial disadvantage for the time and inconvenience associated with participation in research (e.g., payment for out-of-pocket expenses such as parking, travel, daycare, and meals). Only include those expenses that are directly related to study participation.

6.3) * If participants withdraw from the study, describe how compensation will be handled/distributed:

If not applicable, enter 'N/A'. This information must be communicated on the LOI/CF. Remuneration: Payment for out-of-pocket expenses such as parking, travel, daycare, and meals. Only include those expenses that are directly related to study participation.

Section 7: Privacy & Confidentiality

7.1) * List all Demographic Information, Personal Information (PI)/Sensitive Information, and/or Personal Health Information (PHI) that you will be collecting. Explain why you need to collect this information and how it will be used for the study, including all research and logistical purposes (e.g., as research data, for scheduling appointments/interviews, providing compensation, etc.):

If not applicable, enter 'N/A'.

Personal Information (PI) is information relating to an individual that may identify an individual; that could be used or manipulated to identify an individual; or information that could be linked to other information to identify an individual.

Demographic information can relate to population factors such as age, race /ethnicity, and sex.

PHI is information about an individual that is related to health and/or mental well-being, healthcare, long-term care, payments or eligibility for healthcare, donation of human biologics, health card numbers, hospital registration numbers, or information related to another person who is authorized to provide consent relating to an individual's healthcare.

The collection of full Postal Code/Date of Birth/Date of Death has the potential to increase the risk of re-identification. Consider if the same objectives could be achieved by using month and year and a default number (e.g., 15) for the day. If you require this information a strong justification must be provided. If you are storing a code linking participants, this re-identification code must be kept separately and securely from any identifiable information. If you are collecting contact information (e.g., emails, phone numbers, addresses) include this information and outline why you need to collect it (e.g., to provide compensation, send reminders, etc.).

7.2) * Describe if any of the information listed above will directly identify participants (e.g., name, email address) or could be used in combination to identify participants (e.g., age, gender, income, postal code) and describe the measures in place to protect confidentiality:

If not applicable, enter 'N/A'.

Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic). For more information on the types of information collected for research refer to [TCPS 2 Chapter 5](#).



7.3) * If you will be using audio/video recording or taking photographs/images of participants explain this process and why this information is required for research purposes. Comment on if the collection of this information could be used to identify participant's responses or if participants will be named:

If not applicable, enter 'N/A'.



7.4) * If you are collecting information anonymously, describe the measures in place to ensure the data is truly anonymous (i.e. never has identifiers associated with it) and outline what will be communicated to participants about the collection of their anonymous information (e.g., limitations of withdrawal of data):

If not applicable, enter 'N/A'. Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and the risk of identification of individuals is low or very low. Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and the risk of re-identification of individuals from remaining indirect identifiers is low or very low. For more information on the types of information collected for research refer to TCPS 2 Chapter 5.

If using Qualtrics, refer to the document titled, "How do I create an anonymous survey using Qualtrics? and How do I distribute an anonymous survey using Qualtrics? posted in FAQs on GREB's website.

If you are conducting an anonymous survey you must communicate that after the submission of the survey withdrawal will not be possible as you will not be able to link the survey responses back to the participants.



7.5) * If other sources of records and/or information (e.g., secondary data) need to be accessed for this study, describe the source and include details how permission to access the information was obtained:

If not applicable, enter 'N/A'.



7.6) * If there will be a code linking identifiers to the study participants, describe who will have access to the code:

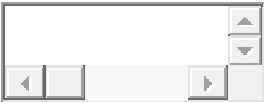
If not applicable, enter 'N/A'.



7.7) * Describe storage measures that will be used for all hard copy and electronic research records during the ongoing research study. If you are storing Personal Health Information (PHI) describe:

If not applicable, enter 'N/A'.

Queen's staff and faculty are eligible for free encryption of their devices as long as minimum system requirements are met. Students can be provided with free assistance to encrypt their devices. Refer to the [Queen's University ITS](#) for additional guidance on data security. We prefer that students do not store confidential data on their laptops for several reasons. Most student laptops are used for multiple purposes, including personal, which can increase the risk of storing data on a personal device. It is difficult to permanently erase data from hard drives and Queen's ITS recommends physical destruction as the only method to truly ensure the data is destroyed. This is not an optimal choice for most students. In addition, research data needs to be retained for at least 5 years as per Queen's policies and often students leave prior to that time frame.



7.8) * Describe who will conduct data collection and analysis/have access to the study data, why their access is necessary, and their roles in the research. Describe if confidentiality agreements will be required and attach a copy of the template as applicable:

If not applicable, enter 'N/A'.

A confidentiality agreement may suffice for some roles but is not required for those performing their normal job-related duties that would be covered under an employee confidentiality agreement.

GREB requires access to study data to ensure researchers are maintaining their confidential obligations and for research integrity purposes as outlined in GREB SOP Quality Assurance Inspections. Participants/Communities need to be fully informed should a question arise around the ethical treatment of participants or information. If a data ownership agreement is in place for a research study, GREB may request that study data be made available for verification purposes. GREB is bound by confidentiality.



7.9) * If there any plans to share study data outside of the research team, provide all of the details related to data transfer, including privacy and security considerations. Indicate if a data transfer agreement (DTA) will be used:

If not applicable, enter 'N/A'. The information to be transferred outside your research group must be communicated on the LOI/CF. All agreements must be reviewed by the [Research Contract Unit](#) Queen's supports the use of [OneDrive for Business](#) as a secure method for file sharing with external users. Queen's supports [Windows File Service](#) for internal users. Email transfer is generally not an acceptable method of secure file transfer, even when sending de-identified information (which can still carry the risk of re-identification). However, if email is the only transfer option available, there are steps to follow to reduce the risk:

1. Encrypt the file, which is different from password protected. The encryption key typically remains with the sender.

2. The sender would provide the password to open the encrypted file to the receiver by phone or in a separate email (that should not have an identifying subject heading such as "Here is your password". Refer to [GREB's Virtual Research Guidelines](#) for help with data transfer strategies.



7.10) * If there are any plans to link the database with any other databases (e.g., student/staff data, external secondary data set, etc.), describe the types of data that will be linked and the likelihood that identifiable data will be created through the linkage:

Indicate 'N/A' if not applicable. This would not include linking current study data with the master Participant ID log.

7.11) * Describe the security and storage measures that will be in place during the mandatory 5-year storage period for all study data as dictated by Queen's policies. Indicate who will be the data custodian during the storage period. Describe what will happen to the study data after 5 years and indicate who will be responsible for this (e.g., archived indefinitely in a suitable repository, permanently erased/securely shredded per institutional policy, etc.):

If not applicable, enter 'N/A'. Queen's University requires that research data be saved for a minimum of 5 years. For assistance with developing a secure data management plan, visit Research Data Management at Queen's University on the [Library website](#).

Students should ensure that research supervisors have access to study data and we recommend that personal devices are not used to store study data. We generally recommend using a secure cloud method such as Queen's OneDrive (supported by Queen's ITS), a secure departmental drive or a portable device that can be encrypted and destroyed (such as a USB) for the storage of data. If a large amount of storage space is required, the Centre for Advanced Computing has additional options for Queen's researchers.

7.12) * Attach a copy of all forms that you will be using to collect study data (e.g., data collection/extraction forms). Ensure the variables you have outlined in this section are consistent with the attached forms:

If not applicable, enter 'N/A'. Ensure the data collection/extraction forms are limited to only collecting the information that you have described above. Commonly standardized questionnaires generally need to be edited to replace the name with Participant ID and Date of Birth with Age information.

- Yes attached
 N/A

Section 8: Funding/Dissemination/Contact & Agreements/PI Attestation

8.1) * Indicate the funding status for the study (select all that apply):

- No funding required
 Departmental
 Tri-agency
 National Institutes of Health (NIH)
 Not-for-Profit
 Industry
 Other

8.2) If 'other' indicated above, specify:

8.3) * Describe any agreements in place regarding use, publication, transfer, or disposal of the data. If there is a contract involved with this study, has the contract/research agreement/Data transfer agreement been submitted for review and signing through the submission of a TRAQ DSS Form? If the data is subject to an open access policy, describe:

Indicate 'N/A' if not applicable. All Tri-Agency funded research is subject to the Tri-Agency [Open Access Policy](#) on Publications. For additional information, refer to the Open Access Policy. All National Institutes of Health (NIH) funded studies must abide by the [NIH Public Access Policy](#). This policy dictates that you will be required to deposit the final manuscript of your journal articles in PubMed Central (PMC) and ensure their free availability (open access) within 12 months of publication. For assistance in contract related issues, contact the Queen's University Research Contracts Unit at researchcontracts@queensu.ca.

8.4) * Describe how you plan to disseminate your research findings. Including plans to communicate results to participants and other stakeholders as applicable (e.g., community partners, advocacy groups, departments, conferences, peer reviewed journal, host country):

8.5) * Describe how you plan to disseminate your research findings. Including plans to communicate results to participants and other stakeholders as applicable (e.g., community partners, advocacy groups, departments, conferences, peer reviewed journal, host country):

If not applicable, enter 'N/A'. Sources of personal financial benefit may include but are not limited to: patent or intellectual property rights; royalty income; employment; shared ownership; stock options; spin-off companies in which researchers have stakes or private contract research outside of the academic realm; proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study; having any association (e.g., as a consultant, advisor, board member, employee, director, etc.) or connection with an entity that is sponsoring or otherwise interested in the outcome of the study; receiving any other incentives (e.g., honorarium, trips to conferences unrelated to this study); or any other incentives that may compromise integrity, independence, or ethical duties in the conduct of the research. For additional guidance, see [GREB's website](#) or [TCPS 2 Chapter 7](#).

8.6) * The Principal Investigator (or their Research Supervisor, if the PI is a student), is/are aware of and shall make all reasonable efforts to comply with the applicable laws, guidelines, policies, and professional obligations:

- Yes
- No, explain below

8.7) If 'no' above, explain:

Section 9: Indigenous & Community Based Research

This section of the application is designed to capture additional aspects of Indigenous and/or community-based related research activities that may not be reflected in the other sections of the application form. While this section was designed through consultation with knowledgeable Indigenous and non-Indigenous stakeholders, Queen's University is

currently in the process of evaluating the full ethics review process for Indigenous/community-based research. Further modifications may be made to this ethics review process following extensive consultation process with diverse indigenous stakeholder groups.

9.1) * Is this research designed to specifically recruit or analyze data from Indigenous participants and/or will it involve community based research (i.e. involves peoples with a shared identity or interest that has the capacity to act or express itself as a collective)?

Per [TCPS 2 Chapter 9](#) 'Community – describes a group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may include members from multiple cultural groups. A community may be territorial, organizational, or a community of interest. "Territorial communities" have governing bodies exercising local or regional jurisdiction (e.g., members of First Nations who reside on reserve lands). "Organizational communities" have explicit mandates and formal leadership (e.g., a regional Inuit association or a friendship centre serving an urban Indigenous community). In both territorial and organizational communities, membership is defined and the community has designated leaders. "Communities of interest" may be formed by individuals or organizations who come together for a common purpose or undertaking, such as a commitment to conserving a language. Communities of interest are informal communities whose boundaries and leadership may be fluid and less well- defined. They may exist temporarily or over the long term, within or outside of territorial or organizational communities. An individual may belong to multiple communities, both Indigenous and non-Indigenous (e.g., as a member of a local Métis community, a graduate students' society and a coalition in support of Indigenous rights). An individual may acknowledge being of Indigenous descent but not identify with any particular community. There may also be differentiation between ancestry and heritage and with respect to individuals and communities. How individuals define which of their community relationships are most relevant will likely depend on the nature of the research project being proposed.

- Yes
- No

9.2) * Is this research likely to affect the welfare of Indigenous peoples and/or communities (i.e. involves peoples with a shared identity or interest that has the capacity to act or express itself as a collective)?

Where welfare refers to the physical, social, economic, and cultural environments, as well as concern for the community. Research should enhance Indigenous peoples' capacity to maintain their cultures, languages, and identities. See [TCPS 2 Chapter 9](#)

- Yes
- No

9.3) * If you answered 'yes' to questions 1 and/or 2 proceed to the remaining questions in section 9. If 'No' above, select response option '2':

- Yes, proceed to the remainder of this section
- No, not applicable for my research – skip the rest of this section

9.4) If you are seeking an exception for the requirement for community engagement explain why. In your response discuss why the welfare of participants/communities will not be impacted by the proposed research:

The TCPS 2 does define 'Community engagement' as a process that establishes an interaction between a researcher (or a research team) and a community with regard to a research project. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. Researchers will be asked to demonstrate community engagement in their ethics application

based on the following:

[Requirement of Community Engagement in Indigenous Research - Article 9.1](#) Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

- a) research conducted on Indigenous territory:*
- b) recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;
- c) research that seeks input from participants regarding a community's cultural heritage, Ancestor artefacts (i.e. objects of an earlier period, valued for their age and associations), traditional knowledge, or unique characteristics;
- d) research in which Indigenous identity or membership in an Indigenous community is used as a variable in the analysis of the research data; and
- e) interpretation of research results that will refer to Indigenous communities, peoples, language, history, or culture.

While we acknowledge that all land can be considered ancestral Indigenous lands, As per Article 9.1 of the TCPS2, and for the purposes of the ethics review process, the following definition will be applied: [Indigenous territory](#) (also referred to as traditional territory) — describes the ancestral and contemporary connections of Indigenous peoples to a geographical area. Territories may be defined by kinship ties, occupation, seasonal travel routes, trade networks, management of resources, and cultural and linguistic connections to place.

Community engagement may take many forms including review and approval from formal leadership to conducting research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The engagement may range from information sharing to active participation and collaboration, to empowerment and shared leadership of the research project. Communities may also choose not to engage actively in a research project, but simply to acknowledge it and register no objection to it.

If you require additional guidance with your research, reach out to the [Office of Indigenous Initiatives](#) indigenous.initiatives@queensu.ca at Queen's or Aleksandra Bergier, Research Advisor, Indigenous Initiatives, email: a.bergier@queensu.ca. There is also a NEW on-line, open access training resource titled, "[Indigenous Community Research Partnerships training resource](#)" now available on the [Office of Indigenous Initiatives website](#).



9.5) Have potential participants/communities been involved with the development of this research project (individuals, organizations, advisory groups, etc.) to date? If no consultation process is planned explain why not:

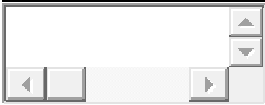
If details are still emerging through consultations, once this application has been cleared, you will be required to submit this information in future using an Amendment Event form in TRAQ.

Per [TCPS 2 Chapter 9](#) community engagement is a process that establishes an interaction between a researcher (or a research team) and the Indigenous community relevant to the research project. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. The engagement may take many forms including review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The engagement may range from information sharing to active participation and collaboration, to empowerment and shared leadership of the research project. Communities may also choose not to engage actively in a research project, but simply to acknowledge it and register no objection to it.



9.6) Describe if Elders and/or knowledge holders will be involved in the project. Explain the protocols used for engagement with Indigenous knowledge and describe how it will be protected:

Per [TCPS 2 Chapter 9](#) traditional knowledge is the knowledge held by the Indigenous peoples of Canada. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is determined by an Indigenous community's land, environment, region, culture and language. Traditional knowledge is usually described by Indigenous peoples as holistic, involving body, mind, feelings and spirit. Knowledge may be expressed in symbols, arts, ceremonial and everyday practices, narratives and, especially, in relationships. The word "tradition" is not necessarily synonymous with old. Traditional knowledge is held collectively by all members of a community, although some members may have particular responsibility for its transmission. It includes preserved knowledge created by, and received from, past generations and innovations and new knowledge transmitted to subsequent generations. In international or scholarly discourse, the terms "traditional knowledge" and "Indigenous knowledge" are sometimes used interchangeably.



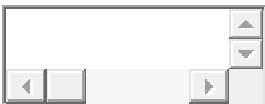
9.7) Describe any relevant customs/protocols/codes of practice that will need to be considered for this research:

Per the [TCPS 2 Chapter 9](#) Indigenous community customs and codes of research practice may embody kinship networks and responsibilities that include multi-generational obligations to ancestors and future generations. Ethical obligations often extend to respectful relations with plant, animal and marine life.



9.8) Describe all incentives or honoraria that will be provided to research participants, Elders, knowledge holders, or communities. Only include information necessary for the consideration of voluntarism (i.e. exclude customary practices outside of the scope of the research project):

Each community or nation has particular ways of approaching Elders or knowledge holders respectfully. Researchers should seek advice from the community and the Elders regarding the appropriate recognition of the contribution of Elders and knowledge holders, which may include providing honoraria, acknowledging contributions by name or, as directed, withholding the Elder's identity in reports and publications. See [TCPS 2 Article 9.15](#). Incentives are anything offered to participants, monetary or otherwise, for participation in research. See [TCPS 2 Chapter 3, Article 3.1](#).



9.9) Explain any necessary considerations for the informed consent process (e.g., protocols in relation to language and culture for obtaining consent):

Researchers should be aware of the first language of Indigenous participants, and if it is an Indigenous language, researchers should make a translation available by a knowledgeable person during the consent process, and during the conduct of research in accordance with the wishes of the participant ([TCPS 2 Article 4.1](#))



9.10) Describe how your project will help address participants' and/or communities local priorities and/or describe the relevance of this research project for the participants/communities. Describe if your project will help to build capacity that supports local needs:

Where the form of community engagement and the nature of the research makes it possible, research should be relevant to community needs and priorities. The research should benefit the participating community (e.g., training, local hiring, recognition of contributors, return of results), as well as extend the boundaries of knowledge. See [TCPS 2 Article 9.13](#).



9.11) Describe who will make decisions about data governance and discuss if a data governance agreement will be maintained with the participants/communities throughout the life of the project. Attach a copy of agreements as applicable:

GREB requires access to study data to ensure researchers are maintaining their confidential obligations and for research integrity purposes as outlined in [GREB SOP Quality Assurance Inspections](#). Communities and study participants need to be fully informed should a question arise around the ethical treatment of participants or information. If a data ownership agreement is in place for a research study, GREB may request that study data be made available for verification purposes. GREB is bound by confidentiality. This information should be provided to participants/communities in early discussions and reiterated in the informed consent process. Chapter 9 of the [TCPS 2 Article 9.16](#) suggests that "Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process."

[What is OCAP®?](#) The First Nations principles of OCAP® are a set of standards that establish how First Nations data should be collected, protected, used, or shared. They are the de facto standard for how to conduct research with First Nations.

If you will be using the OCAP® principles, describe who will own the data and research results; who will have access to data; and describe how and where the data be stored. There are four components of OCAP®: Ownership, Control, Access, and Possession.

Ownership refers to the relationship of First Nations to their cultural knowledge, data, and information. This principle states that a community or group owns information collectively in the same way that an individual owns his or her personal information.

Control affirms that First Nations, their communities, and representative bodies are within their rights in seeking control over all aspects of research and information management processes that impact them. First Nations control of research can include all stages of a particular research project-from start to finish. The principle extends to the control of resources and review processes, the planning process, management of the information, and so on.

Access refers to the fact that First Nations must have access to information and data about themselves and their communities regardless of where it is held. The principle of access also refers to the right of First Nations communities and organizations to manage and make decisions regarding access to their collective information. This may be achieved, in practice, through standardized, formal protocols.

Possession While ownership identifies the relationship between a people and their information in principle, possession or stewardship is more concrete: it refers to the physical control of data. Possession is the mechanism by which ownership can be asserted and protected.



9.12) Describe any plans to continue the research relationship after the completion of the project. If there are no plans, explain why not:

As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community. See [TCPS 2 Article 9.12](#)

9.13) What research knowledge will be shared, revisited, and/or be made known to the researchers? Describe how the participants and/or communities will be involved in the interpretation, analysis, and dissemination of knowledge sharing (e.g., conferences, workshops, creation of audiovisual materials, co-creation of knowledge mobilization plan). If no external involvement is planned, explain why not:

Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before the completion of the final report, and before finalizing all relevant publications resulting from the research. See [TCPS 2 Article 9.17](#).

9.14) Describe the study team's experience conducting collaborative community/population based research:

9.15) Attach letters of support, research licenses from territorial licensing bodies, data governance agreements as applicable:

- Yes, attached
- N/A