

Use for research studies that involve interviews, surveys, questionnaires, focus groups/sharing circles, and evaluation/assessment. Form activated May 5, 2019.

1. Surveys
2. Questionnaires
3. Interviews
4. Focus Groups
5. Sharing Circles
6. Evaluation/Assessment

1.1) \* Are you actively recruiting participants?

The HSREB Non-Recruitment Application Form should be used for research studies that are NOT ACTIVELY RECRUITING participants with the exception of case reports.

- Yes
- No, close this form, delete this draft and complete the HSREB Non-Recruitment Application Form

1.2) \* Are you conducting a clinical trial?

Use the following four questions to determine if the study meets the [NIH definition of a clinical trial](#):

1. Does the study involve human participants?

2. Are the participants prospectively assigned to an intervention?

3. Is the study designed to evaluate the effect of the intervention on the participants?

4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

NOTE: An "intervention" is defined as a manipulation of the participant's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies. Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if...

a) You are studying healthy participants

b) Your study does not have a comparison group (e.g., placebo or control)

c) Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug

d) Your study is utilizing a behavioral intervention.

- Yes, close this form, delete this draft and complete the HSREB Standard Application Form
- No

1.3) \* Does your research involve an intervention, invasive contact or the performance of a physical task (e.g., exercise, KINARM, motion capture)?

An "[intervention](#)" is defined by the NIH as a manipulation of the participant or participant's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery

systems (e.g., telemedicine) strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

- Yes, close this form, delete this draft and complete the HSREB Standard Application Form
- No

1.4) \* Is this study funded or supported by the United States Federal Government or is your study subject to the Code of Federal Regulations Title 21 Food Drug Administration and/or Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects?

'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. Title 21 is the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP). Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46) provides protection for human subjects in research carried out or supported by most federal departments and agencies.

- Yes
- No

1.5) \* Is this study subject to the General Data Protection Regulation (GDPR) mandated by the European Union (EU)?

The GDPR implementation date is 2018MAY25. This may impact researchers working in and/or with participants from the EU. Refer to the [GDPR website](#) for additional guidance.

- Yes
- No

1.6) \* Is this a multi-site research study?

- Yes
- No

1.7) \* Has this study started elsewhere (provincially, nationally, or internationally)?

- Yes
- No

1.8) \* When is local enrollment expected to start?

[Open the calendar popup.](#)

1.9) \* When is overall (global) enrollment expected to end?

This date may be the same as the local enrollment end date if there is only one research site.

[Open the calendar popup.](#)

1.10) \* When is local enrollment expected to end?

This date may be the same as the global enrollment end date if there is only one research site.

[Open the calendar popup.](#)

1.11) \* If this study has been submitted to another REB and subsequently withdrawn and/or an REB refused to provide ethics clearance for this study, describe why:

If not applicable, enter 'N/A' 'Refused to approve' means that an REB has reviewed the study and determined that it doesn't meet the standards for ethics clearance, and revision is unlikely to enable the REB to reach a positive determination.

2.1) \* 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, hospital 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 Student\*
- Doctoral Student\*
- Medical Student\*
- Medical Resident\*
- Postdoctoral Fellow\*
- Clinical Fellow\*
- Queen's Employee
- Hospital Employee (KHSC or PCC)
- Queen's Faculty
- External Applicant

2.2) If the PI status is indicated by an asterisk (\*) in question 2.1, list your Research Supervisor(s):

Also, make sure to add your supervisor(s) to 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 (e.g., transcriber, statistician). 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?](#)'.

2.3) Attach a letter/email from your Research Supervisor stating that they have reviewed and approved your application. You may attach a copy of your thesis committee approval in lieu of an email of support as applicable (select all that apply):

This letter/e-mail must include: a) the title of the study; b) the date of the letter/email; and c) your Supervisor's signature (written or electronic). Thesis committee approval should be sought prior to seeking ethics clearance, as any requested changes from the thesis committee should be implemented prior to the ethics review process.

- Yes, approval from my Supervisor is attached and they have been added as my Supervisor in the PROJECT INFO TAB
- Yes, thesis committee approval is attached and my Supervisor has been added in the PROJECT INFO TAB
- N/A

2.4) \* Attach a copy of the CORE completion certificate and/or GCP certificate for all research team members performing significant study-related duties, including those who have access to study data 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 may accept GCP, CORE or the Biomedical Research Ethics Tutorial (CITI) as evidence of ethics training. Please note that the Health Canada Division 5 - Drugs For Clinical Trials Involving Human Subjects CITI training module is not sufficient. Per KHSC and PCC Policies, all hospital researchers, research staff, medical and graduate students, post-doctoral fellows, clinic fellows, volunteers, and trainees conducting research with human participants must be trained in GCP or CORE. If you are conducting a clinical trial, all research team members who have a significant role in trial conduct must be trained in GCP. For additional information, refer to the KHSC Standard Operating Procedures for Clinical Research (11-152 and appendix C). The elements of the KHSC policy are similar to those found in the PCC Standard Operating Procedures for Health Research #ADM-RES-2. Hospital researchers must contact Lisa McAvoy (alternate) at 613-549-6666 ext. 3344 at Kingston Health Sciences Centre (KGH Site) for assistance with accessing the hospital training courses (CITI).

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

2.5) \* Has this protocol undergone an independent scientific peer review? (select all that apply):

The HSREB Scientific Peer Review Form is posted on the [HSREB website](#) under 'Resources'. Refer to [TCPS 2 \(2018\) Article 2.7](#) for additional information about peer/scholarly reviews.

- Yes, HSREB Scientific Peer Review Form attached
- Yes, external peer review attached
- Yes, per review by a funding agency attached
- N/A

2.6) \* At what site will the study procedures take place? (select all that apply):

If you are a St. Lawrence College student researcher, you will be required to complete the CORE tutorial and will also need to obtain ethics clearance from the [SLC REB](#)

- Queen's University Campus
- Kingston Health Sciences Centre (KHSC – KGH Site)
- Kingston Health Sciences Centre KHSC - HDH Site)
- Providence Care Center (PCC)
- Ongwanada
- KFL&A Public Health
- St. Lawrence College
- Other (specify below)

2.7) Describe any other study participant visits or procedures that will take place outside of the sites listed in 2.6 (e.g., local doctor's office). If 'other' selected above, specify and describe:

Do not include external testing or imaging (e.g., Lifelabs, Kingston MRI, KMI X-ray & Ultrasound).

2.8) \* Does your research need to comply with Queen's University's Off Campus Activity Safety Policy (OCASP)?

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.

- Yes, I have registered my off-campus activity using the OCASP on-line planning tool
- N/A

2.9) \* Does your research need to comply with the Office of Research Ethics Security Protocol?

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 – 6pm, 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 [HSREB 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).

- Yes, Security Protocol Form attached
- No, I am not conducting research on Queen's Campus outside of regular business hours

2.10) \* Are other approvals required (e.g., hospital approval, thesis committee approval, other REBs for multi-site research, school board approval, multi-jurisdictional approval, community approval when working with Indigenous peoples in Canada)? (select all that apply): This extends to Hospital approval via TRAQ DSS submission and criteria for the TRAQ DSS submission is listed in the information tab below.

If your research meets any of the following criteria you will need to seek hospital/departmental approval through the submission of a TRAQ DSS form: 1. Research occurs in a hospital setting; 2. Research utilizes or requires hospital staff, space, services, and/or other resources; 3. Research offices for yourself and/or your research staff/students/trainees are located in a hospital setting OR your research lab, unit, centre, space, and/or equipment is located in a hospital setting, even if your research project is occurring off-site; 4. Research involves obtaining or retrieving patient biological samples/specimens from patients seen (or samples stored) at one of the hospitals for lab projects and transported to your research lab located within OR outside of the hospital (e.g., Botterell Hall, Cancer Research Institute); 5. Research involves extracting patient data from hospital medical records; 6. Research involves purchasing supplies or equipment at/through the hospitals; 7. Research involves the use of hospital services and payment to hospital departments; 8. Research funds will be held within one of the hospitals/hospital research institutes. For more information, refer to the [HSREB's website](#) under 'Resources' or to the [KGH Research Institute \(KGHRI\) website](#).

- Yes, hospital approval required through the submission of a TRAQ DSS form only
- Yes, thesis committee approval required
- Yes, additional approvals required that are not captured by the TRAQ DSS form (e.g., school and school board approval, community approval, research licence, correctional/police services approval)
- No additional approvals required

2.11) If 'additional approvals' selected above, specify and describe. If you will be working with Indigenous populations, describe how you intend to engage the relevant community in your response:

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. Research involving Indigenous peoples in Canada may require community approval. Some jurisdictions require additional authorizations, approvals, and/or licenses for conducting research. For additional information see:

1. [Nunavut Research Institute approval](#).
2. [First Nations Information Governance Centre \(FNIGC\)](#).
3. [Yukon Scientists and Explorers License](#).
4. [Aurora Research Institute](#) (North West Territories).

For more information regarding research involving Indigenous peoples, refer to [TCPS2 \(2018\), Chapter 9](#).

3.1) \* Abstract: Summarize this study in plain language. 300 words maximum.

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3.2) \* Rationale: Explain in plain language why there is a need to conduct this study. 300 words maximum.

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3.3) \* Summarize the study design/methodology in plain language. 1000 words maximum.

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3.4) \* The study involves the use of (check all that apply):

- Surveys
- Questionnaires
- Interviews
- Focus Groups
- Sharing Circles
- Evaluations/Assessments
- Observation
- Secondary Data
- Conducting, administering or supervising tests that require professional credentials
- Audio/video recording
- Other (specify below)

3.5) \* Describe how each item selected in Question 3.4 will be implemented. If 'other' selected above, specify and describe:

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3.6) \* Attach all surveys, questionnaires, screen shots, interviews/focus group scripts, audio/video recording consent forms, copies of assessments/tests:

- Yes, attached
- N/A

3.7) If this study involves deception or partial disclosure, describe:

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 [TCPS2 \(2018\) Chapter 3 Article 3.7B](#)

3.8) If 'yes' above, attach a copy of your debriefing materials and outline your plan for debriefing participants. If you do not plan to debrief participants, provide justification as to why not based on the TCPS 2 2018 Article 3.7B:

If you do not plan on debriefing your participants, you must justify why not based on the [TCPS 2 \(2018\) 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"

3.9) If you will be using secondary data (data originally collected for a purpose other than the current research study), describe the source of the data:

For more information on the use of secondary data, refer to [TCPS2 \(2018\) Chapter 5](#).

4.1) \* How many participants will be recruited globally?

This number may be the same as the local recruitment if there is only one research site. 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

4.2) \* How many participants will be recruited locally?

This number may be the same as the global recruitment if there is only one research site.

4.3) \* Provide the sample size justification or indicate in which section of the protocol this information is provided:

Sample size involves the selection of a subset of individuals from within a statistical population to estimate characteristics of the whole population. Sample size can be small or large but the larger the sample size, the more accurate the results will be. The sample size should be statistically significant (i.e. power calculation), not just chosen randomly unless it is a pilot study



4.4) \* This study will target the following population(s) (select all that apply):

- Patients
- Healthy volunteers
- Students\*
- Staff\*
- People with mental health issues\*
- People institutionalized\*
- Prisoners/persons in detention\*
- People in poverty/economically disadvantaged\*
- Educationally disadvantaged people\*
- People who are unable to read or write\*
- Children\*
- People in medical emergencies \*
- People who lack capacity to consent\*
- Cognitively impaired individuals\*
- Individuals with physical disabilities\*
- People who have trouble understanding and/or producing speech (e.g., those who require special support including the use of assistive devices)\*
- Adult individuals who are temporarily unable to provide consent (e.g., unconscious)\*
- Pregnant women\*
- Elderly people\*
- People in palliative care\*
- People in long-term care\*
- Less than 6 participants (increased risk of identification/re-identification)\*
- Ethno-cultural minorities\*
- Data bank/registry
- Other, specify below

4.5) \* If you have selected participant populations with an asterisk (\*) above, justify the inclusion of all applicable participant populations. If you have selected 'Other,' specify the participant population and justify the inclusion of the participant population:

If not applicable, enter 'N/A'. Historically, researchers have not sufficiently considered the ethical rights of certain populations. For additional guidance, see: [TCPS2 \(2018\), Chapter 4.](#)

4.6) \* If this study excludes any participants based on culture, language, religion, race, disability, sexual orientation, gender, ethnicity, linguistic proficiency, competency/capacity, or age, describe the exclusion and justify why these participants have been excluded:

If not applicable, enter 'N/A'. Historically, researchers have not sufficiently considered the ethical rights of certain populations. These populations may include individuals who identify as First Nations, Inuit, or Metis; children; prisoners; elderly; those participants who have experienced a mental illness; and those with diminished capacity for self-determination. For additional guidance, see: [TCPS2 \(2018\), Chapter 4](#)

4.7) \* Describe the overall strategies for minimizing coercion or undue influence for the participant population(s) as indicated by an asterisk (\*) in Question 4.4:

If not applicable, enter 'N/A'. If you are an instructor who will be conducting research on your own students, refer to 'Ethical Considerations for Instructors Conducting Research on their Students' on the [HSREB website](#) under 'Guidelines' for additional guidance. This guidance document may also be useful for those researchers in a 'power' or influential position.

4.8) \* Provide the inclusion criteria:

If not applicable, enter 'N/A'.

4.9) \* Provide the exclusion criteria:

If not applicable, enter 'N/A'.

4.10) \* If material incidental findings are likely, include your plan for disclosing such findings to participants:

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. Example: If abnormal findings are noted on a cognitive functioning assessment, the participant will be referred to their local doctor for additional follow up

5.1) \* Describe how potential participants will be identified for recruitment:

If not applicable, enter 'N/A'. Personal Health Information (PHI) that is contained in the medical records for all of Kingston Health Sciences Centre (KGH and/or HSH Sites) and/or Providence Care Centre patients is allowed to be used for research purposes UNLESS patients have opted out by completing and submitting the "Withdrawal of

Consent Form” found on the “[My Healthcare Information](#)” webpage on the [Kingston Health Sciences Centre website](#) or equivalent form for Providence Care Centre. All researchers must check the electronic medical record to ensure participants have not opted out of research prior to using any personal health information for research purposes. For instructions refer to the KHSC Research Road Map for [Assessing Patient Data for Research](#) that is posted on the [KGHRI website](#).

5.2) \* Describe how permission will be obtained from potential participants to be contacted for research purposes and specify how (e.g., by phone, in person, email) and by whom (e.g., research coordinator, study nurse) initial contact will be made:

5.3) \* Summarize who will recruit participants into this study and how they will do so:

5.4) \* What recruitment materials are being used? Attach a copy of all recruitment notices, emails, scripts, advertisements, or information sheets (select all that apply):

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 [HSREB website](#) under ‘Guidelines’

- None
- Word of mouth, snowball sampling
- Brochures, flyers, posters
- Recruitment database
- Third-party recruitment
- Recruitment company
- Newspaper, radio ads
- Telephone call scripts
- Website
- Social Media (e.g. Facebook, Twitter)
- Video
- Other (specify below)
- N/A

5.5) If 'other' selected above, describe:

6.1) \* 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 \(2018\) Chapter 3](#).

- Written Informed Consent Form (active consent)
- Written Letter of Information with separate written Consent Form (active consent)
- Written Letter of Information with survey completion representing consent
- Written Assent Form
- Expression of assent (e.g., nodding of head)
- Verbal consent\*
- Implied consent\*
- Participant unable to provide consent\*
- Substitute decision maker
- Other (specify below)

6.2) If 'other' selected above, specify:

6.3) If you will be requesting a waiver or alteration to the consent process, justify your request:

Justification should be based on TCPS 2 (2018) [Article 3.7A/B](#). Refer to [Article 3.8](#) for guidelines regarding consent alterations due to medical emergencies. Refer to the [TCPS 2 \(2018\) Chapter 3, Section C](#) for guidance with respect to alternations to the consent process for those with diminished decision-making capacity

6.4) \* Describe the initial consent process, including when participants will be approached, the processes used to provide participants with new information which may affect their willingness to participate, and to obtain their ongoing consent. Lastly, describe the process by which participants can withdraw their consent:

If not applicable, enter 'N/A'. In addition to obtaining an ICF signature, it is also important to document the ICF process in the participant study file.

6.5) If you will be obtaining assent from any participants, describe how you will obtain assent:

If not applicable, enter 'N/A'. 'Assent is the expression of approval or agreement. For additional guidance on alterations to consent, refer to [TCPS2 \(2018\) Chapter 3](#) Article 3.7A.

6.6) \* Attach clean copies of all Letters of Information/Consent Forms/Assent Forms to the ethics application and any other materials that will be distributed to study participants (e.g., diaries, wallet cards):

Refer to the [HSREB website](#) under 'Informed Consent Form Resources' for NEW HSREB Letter of Information/Consent Form Checklist that outlines all of the Informed Consent Form required elements.

- Yes, attached
- N/A

6.7) \* Who will obtain the participant's signature on the consent form? If there is a relationship between the potential participants and the person obtaining the signature, explain the nature of the relationship (e.g., treating physician, employer, supervisor, instructor, etc.) and describe how you will minimize any undue influence/power imbalance:

If not applicable, enter 'N/A'. The healthcare provider should not be the individual obtaining the signature during the informed consent process. How, when, and where participants are approached, and who recruits them, are important elements in assuring (or undermining) voluntariness ([TCPS 2 \(2018\) Chapter 3](#)).

6.8) If there are 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), explain the procedures. If not, explain why not:

Participants should be made aware that if they do need to contact the HSREB for ethics concerns, they may need translation services, as the Ethics Office can only communicate to participants in English.

6.9) If this study permits/requires the enrollment of participants who are not capable of providing consent, describe who will assess capacity and how capacity (initial and ongoing) will be assessed (including assessment of attaining/regaining capacity):

For additional guidance, refer to Article 3.9 of the [TCPS 2 \(2018\)](#).

6.10) Describe how substitute decision-makers will be identified:

6.11) \* Attach all translated materials, including translation certificates (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.).

- Yes, attached
- N/A

7.1) \* Will study participants receive any incentives, compensation, reimbursement, or remuneration for expenses to participate in the study (e.g., compensation for time spent, gifts, reimbursement for research-related expenses such as parking, meals, travel, etc.)?

Incentives: Anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury). 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. 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 the [HSREB website](#) under 'Guidelines'.

- Yes
- No

7.2) \* Provide the incentives, compensation, and reimbursement details (amount, payment schedule, etc.) and justify why this is being provided:

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

7.3) \* Describe any anticipated expenses for participants associated with participation in the study (e.g., parking, food, travel) and comment on whether participants will receive remuneration for these expenses:

If not applicable, enter 'N/A' This information must be communicated on the ICF. Remuneration: Payment for out-of-pocket expenses such as parking, travel, day care, and meals. Expenses associated with local standard of care do not need to be included. Only include those expenses that are directly related to study participation.

8.1) \* Select all risks to participants (real or potential) associated with participation (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 to participants. For additional guidance, see: [TCPS 2 \(2018\)](#).

[Chapter 2: Section B, Concepts of Risks and Potential Benefits.](#)

- Physical risk
- Privacy Risk
- 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)
- Other (specify below)
- No known risks

8.2) \* List and describe all potential short-term/ long-term risks, foreseeable harms, contextual sensitivities, discomforts, and inconveniences for individual study participants, and any risks, any potential harms, etc., for study participants in general and/or the general population. Include approximate rates of occurrence, severity, and reversibility, as applicable. If 'other' selected above, specify and describe:

If not applicable, enter 'N/A'. All risks that result from study investigations that are not considered part of local standard of care (e.g., x-rays) must be communicated on the ICF. Ensure that you describe risks to all participant populations as applicable. If there are different risks, or different degrees of risk for different participant populations, ensure that this is clearly outlined in your response.

Privacy Risk: If you will be less than 6 participants 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 to the LOI/CF, suppressing small cells and/or giving participants to option to be identified.

8.3) \* Describe your plan to mitigate risks to participants, and how you will provide support to participants 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 as applicable. If there are different degrees of risk for different participant populations, ensure that all risk mitigation plans are clearly outlined in your response.

8.4) \* What is the overall anticipated public and/or scientific benefit of the study?

Outline what new knowledge will come from the research, how it will benefit society, and how it will have the potential to inform future work.



8.5) Describe any direct benefits that participants may receive from participating in this study? If there are no direct benefits to participants, this should be explicitly stated in the application form and the ICF:

Human participant research may result in benefits that positively affect the welfare of society as a whole through the advancement of knowledge for future generations, for participants themselves, or for other individuals; however, most research offers no direct benefit to participants. If there are no direct benefits to participants, this should be explicitly stated on the ICF. In some cases, participants 'may or may not' benefit from participation (e.g., drug trials). For additional guidance, see [TCPS2 \(2018\) Chapter 2](#).

9.1) \* What Personal Information (PI) and / or sensitive information and / or Personal Health Information (PHI) and / or Demographic information will be collected for research purposes? (select all that apply):

Include all information required for research purposes and you will need to explain your request to collect this information in your response below. '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. Personal Health Information extends to information about the 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. Demographic information relates to population based on factors such as age, race /ethnicity and sex.

- None (i.e. anonymous data and no collection of IP addresses as applicable)
- Anonymized/De-identified (Study Participant ID, WITH CODE for re-identification kept securely and separately from other study data)
- Full name / Full initials
- Partial initials
- Full date of birth
- Partial date of birth
- Full date of death
- Partial date of death
- Age
- Sex/gender
- Full postal code
- First 3 digits of postal code
- Pathology specimen number
- Medical device identifier



- Full Admission date
- Full Discharge date
- Medical record number
- Ontario health card number
- Driver's licence number
- Address
- Telephone number
- Fax number
- Email address
- Full face photograph / Video recording
- Voice/audio recording
- Other (specify below)

9.2) \* If Personal Information (PI), Personal Health Information (PHI) or sensitive information, including demographic information is required, explain why you need this information and how you will be using it for research purposes as selected above. If 'other' selected above, specify and explain

The collection of full dates of birth / death, admission dates, discharge dates and full postal code increased the risk for potential re-identification. The Board prefers only partial dates /postal codes are collected and that days calculated be used for admission / discharge information. If you do require this information in full a strong justification must be described below.

9.3) \* Attach a copy of the data collection forms/case report forms (CRFs):

Ensure the data collection forms/CRFs are limited to only collecting the information that you have described in sections 9.1 & 9.2

- Yes, attached
- N/A

9.4) \* Specify and describe what types of records and / or information sources need to be accessed for the purposes of this study as well as the source(s) of the records, and describe how permission to access this information will be obtained:

If not applicable, enter 'N/A'. Personal Health Information (PHI) that is contained in the medical records for all Kingston Health Sciences Centre Sites (KGH and/or HDH Sites) and/or Providence Care Centre is allowed to be used for research purposes UNLESS patients have opted out by completing and submitting the ['Withdrawal of Consent Form'](#) found on the 'My Healthcare Information' webpage of the [Kingston Health Sciences Centre Research Institute's website](#). All researchers must check the electronic medical record to ensure that participants have not opted out of research prior to using any personal health information for research purposes. For instructions refer to the KHSC Research Road Map for [Assessing Patient Data for Research](#) that is posted on the [KGHRI website](#).

9.5) \* Describe all persons who will have access to the information, why their access is necessary, their roles in relation to the research, and their related qualifications:

The HSREB does require access to participant information for quality assurance purposes. This requirement should be outlined on the ICF.

9.6) Attach confidentiality agreement templates (NOTE: Do not include signed documents, only a template updated for your study):

Confidentiality agreements are not required for Institutional staff that must abide by an institutional confidentiality agreement as a condition of their employment as long as their role is only directly related to research (i.e. KHSC biostatisticians, KSHC lab technologist)

- Yes, attached
- N/A

9.7) \* Indicate how research records will be stored. Describe for both electronic and paper records (select all that apply):

If not applicable, enter 'N/A'. Ontario's Information and Privacy Commissioner has mandated encryption for all Personal Health Information (PHI) stored on a mobile device. For more information regarding electronic data security, refer to the HSREB Research Ethics Data Security Recommendations posted on the [HSREB website](#) under 'Guidelines'. Refer to the 'Policies and Forms' section of [KGHRI's website](#) for additional information regarding Access to Personal Information and Disclosure of Personal Health Information, Personal Health Information Protection, and the Health Research Policy. Refer to the Queen's University's [IT Policies and Procedures website](#) for additional guidance with respect to policies regarding information technology.

- Access to medical records and study data will be limited to authorized personnel
- Access to electronic data will be password protected and auditable (e.g., EDC)
- Electronic data will be stored on a hospital or other institutional network with firewalls and other security and back-up measures in place
- Data stored on laptops or mobile devices will be encrypted
- Paper copies of study data will be stored in locked filing cabinets in a secure location
- A master linking log with identifiers will be stored separately from the study data
- Other (specify below)
- N/A

9.8) Provide the specific details of both written and electronic data storage measures. If 'other' selected above, specify:

9.9) \* 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'.

9.10) \* Indicate the measures in place to protect the confidentiality and security of the study data in the event that the data is transferred:

Information transferred outside your research group should not contain any personal identifiers (e.g., full date of birth, hospital numbers, initials, and names must be removed). This must be communicated on the ICF. 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.

- Fax
- Electronic data collection (EDC)
- Private courier
- Canada post registered mail (priority or other secure shipping method)
- Data transfer agreement
- Secure network
- Other (specify below)
- N/A, not transferring and data outside of my institution

9.11) \* Specify and describe the details of the data transfer. Include details about the method of encryption/secure file transfer process and if a data transfer agreement (DTA) or material transfer agreement (MTA) will be used. All agreements must be submitted via a TRAQ DSS for review by the Research Contract Unit. If 'other' selected above, specify and describe:

If not applicable, enter 'N/A'.

NOTE: All agreements must be reviewed by the [Research Contract Unit](#).

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 Encryption Security](#) website for additional guidance with respect to data security. 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 than password protected. The encryption key typically remains with the sender. 2. The sender would provide the password to open the encrypted spreadsheet ideally by phone directly to the receiver or in a separate email (that should not have an identifying subject heading such as "Here is your password"). Additional examples are noted below: a) Study data may be transferred electronically via secured servers between

Site and Sponsor, Sponsors and Vendors. They use 256bit SSL encryption. b) Participant data is transferred electronically via secured servers between Sponsor and the vendors. The cryptographic protocols used to secure transmission of data in transit between a Rave end user's web browser and the Sponsor's servers are Transport Layer Security/TLS and Secure Socket Layer/SSL.

9.12) \* If data is being transferred in another format, what measures will be used to ensure participant confidentiality and privacy?

Indicate 'N/A' if not applicable.

9.13) \* If any of the locally collected data will be entered into a database for future use, describe where it will be stored, who will be the custodian, who will have access to the database, and the security measures that will be in place to protect the confidentiality of the data:

Indicate 'N/A' if not applicable.

9.14) \* Outline any plans to link the database with any other databases (e.g., another study site, ICES, etc.). Describe the types of data that will be linked. Describe the likelihood that identifiable data will be created through the linkage. Discuss the plan to protect the confidentiality of the information:

Indicate 'N/A' if not applicable.

9.15) \* If there are any foreseeable risks/harms and/or benefits that may arise from the collection of the Personal Health Information (PHI), provide information on how you intend to mitigate those risks/harms and provide details on how participants may experience benefits:

Indicate 'N/A' if not applicable.

9.16) \* Who will conduct data collection and analysis? (select all that apply):

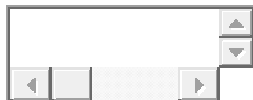
- Local Investigators/Research Staff/Students/Trainees/Delegates
- Sponsor/Contract Research Organization (CRO)
- External Academic Institution/Research Institution
- Other (specify below)

9.17) If 'other' selected above, specify:



9.18) \* How long will the data exist in an identifiable form and why?

Indicate 'N/A' if not applicable. This would extend to any information that is included in master lists/keys held on site and for ICFs.




9.19) \* What will happen to the data at the end of the study (e.g., anonymized, destroyed)?

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 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.



9.20) \* Include details regarding the length of time study records will be stored and outline how confidentiality will be maintained during long term storage of study data. NOTE: Queen's policy dictates study data must be retained for 5 years and this must be stated in the application and Letter of Information / Consent Form (LOI/CF).

Queen's University requires that all research materials be stored securely for a minimum of 5 years. Health Canada requires storage for 25 years. Ensure your storage plan is in line with applicable policies and regulations. For assistance with developing a secure data management plan, visit Research Data Management at Queen's University on the [Library website](#).



9.21) \* State what will happen to the data and study records after the storage period (e.g., archived indefinitely a suitable repository, permanently erase electronic data / securely shredded paper data per institutional policy. etc.) and indicate who will be responsible for this.

Since study data must be maintained for 5 years, students should not be responsible for this, as likely not to be affiliated with Queen's.

10.1) \* How will the results be communicated to participants and other stakeholders (e.g., advocacy groups, scientific community)? (select all that apply):

- Individual debriefing at the end of test session
- Publication (e.g., journal article)
- Presentation
- Group debriefing
- Letter of appreciation at end of study
- Clinicaltrials.gov
- Other (specify below)

10.2) If 'other' selected above, describe:

10.3) \* Attach copies of study letters, end of study letters, and the publication plans as applicable.

- Yes, attached
- N/A

10.4) \* If there is a contract involved with this study has the contract/research agreement been submitted for review and signing through the submission of a TRAQ DSS Form?

For assistance in contract related issues, contact the Queen's University [Contracts Office](#). Queen's also administers all hospital-based contracts on behalf of the University and Kingston hospitals, when both are a party to the contract/agreement. For assistance with contracts only involving Kingston General Health Research Institute, contact Veronica Harris-McAllister at 613-549-6666 ext. 3653. For assistance with contracts only involving Hotel Dieu Hospital Kingston Research Institute, contact Vic Sahai at 613-544-3400 ext. 3642. For assistance with contracts only involving Providence Care Centre, contact Kathleen Fitzpatrick at 613-544-4900 ext. 53370.

- Yes, approved
- Yes, pending review
- No
- N/A

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

- Funding still required
- Funding application submitted
- Funding obtained
- No funding required

10.6) \* Study funder(s) or material support providers (select all that apply):

Note: All Tri-Agency funded research is subject to the Tri-Agency Open Access Policy on Publications. For additional information, refer to the [Tri-Agency Open Access policy](#).

- Industry (e.g., pharmaceutical or biotechnology company)
- Tri- Council (e.g., CIHR, SSHRC, NSERC, NCE)
- Government (e.g., Ministry of Health and Long Term Care, Department of National Defence)
- Canadian Government Funding Agency
- Charitable foundation
- Internal funding
- US Federal Funds or support (e.g., NIH)
- Other (specify below)
- N/A

10.7) If 'other' selected above, specify:

10.8) \* If you are receiving industry funding, have you included the HSREB ethics review fee of \$4,000 into your budget?

Fees for submitting to Queen's University HSREB apply only to all industry- sponsored/supported studies and are invoiced upon receipt of the submission by Research Ethics. For more information, refer to the HSREB [Fee section](#) on the HSREB website.

- Yes
- No
- N/A

10.9) If yes above, provide the name of the industry contact or the name of the researcher to whom the invoice should be sent, the contact's email address and telephone number, and the sponsor agency's mailing address:

10.10) \* Will the investigator or sub-investigators, or anyone connected to them through their interpersonal relationships (including their partners, family members, or their former or current professional associates), receive any personal financial benefit in connection with this study?

Sources of personal financial benefit may include but are not limited to: patent or intellectual property rights; royalty income; employment; share 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 [HSREB SOPs 105A-C Conflicts of Interest \(COI\)](#) or [TCPS2 \(2018\) Chapter 7](#).

- Yes
- No

10.11) If 'yes' above, specify and describe. Include information about any financial payments with respect to the direct costs associated with doing this research, and describe the management plan for all conflicts of interest associated with this study:



10.12) \* Does the Principal Investigator (or their Research Supervisor, if the PI is a student, resident, or fellow) have appropriate credentials to carry out all procedures described in the protocol?

- Yes
- No

10.13) \* Is the Principal Investigator (or their Research Supervisor, if the PI is a student) a member in good standing with his or her respective regulatory authority?

- Yes
- No

10.14) \* 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

10.15) If 'no' selected in any question above, explain: