

HSREB Non-Recruitment Application Form

Use for research studies that are NOT ACTIVELY RECRUITING participants with the exception of case reports. Form activated January 12, 2019, updated May 2019.

1. Case Reports
2. Chart Reviews
3. Biological Samples
4. Secondary Data/Databases

Section 1: Study Overview

1.1) * Does your research involve the active recruitment of participants?

The HSREB Non-Recruitment Application form in [TRAQ](#) should be used for all research projects that are not actively recruiting participants or for case reports (e.g., chart reviews, secondary use of data, case reports, biological samples, etc.). All research studies that are actively recruiting participants must be submitted using the HSREB Standard Application Form or the HSREB Intermediate Application Form. The HSREB Intermediate Application Form should be used for research studies involving interviews, surveys, questionnaires, focus groups/sharing circles and evaluation/assessment. The HSREB Standard Application Form should be used for all clinical trials, interventional research, and studies involving invasive contact or the performance of a physical task (e.g., exercise, KINARM, motion capture).

- Yes – close this form, delete this draft and complete the HSREB Standard Application Form or the HSREB Intermediate Application Form
- Yes - but I am conducting a case report, continue completing this form
- No, continue completing this form

1.2) * Is this study receiving any funding or support from the United States Federal Government (e.g., funds, study supplies, etc.)?

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.

- Yes
- No

1.3) * Is this a multi-site research study?

If the study is conducted at more than one research site in Ontario, you should submit using the [Clinical Trials Ontario](#) (CTO) Streamlined Research Ethics Review System or to the [Ontario Cancer Research Ethics Board](#) (OCREB). OCREB is an expert central oncology REB that reviews multi-centre clinical cancer trials for almost every hospital in Ontario. CTO and OCREB's centralized models mean that once a study has received ethical clearance, participating study sites can receive a delegated ethics review. "This streamlines the review process, minimizes redundancy, ensures harmonization and consistency, and saves the time and cost of having the study reviewed by an REB at every participating institution (study site)" (OCREB).

- Yes, more than one site in Ontario – close this form, delete this draft and apply using CTO Stream
- Yes, National and/or International sites but only one site is in Ontario
- Yes, but one of last site(s) to be activated
- Yes, but the lead site is not using CTO
- No, not multi-site research

1.4) * Is this an investigator-initiated study?

Investigator-initiated: refers to a study that is not initiated by a commercial sponsor. The investigator assumes all responsibilities for the study including protocol design, data collection, safety monitoring, analysis and dissemination.

- Yes
- No

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

- Yes
- No
- No, not multi-site research

1.6) * Indicate the planned start date at your site:

[Open
the
calendar
popup.](#)

1.7) * When is the study expected to end at your site?

[Open
the
calendar
popup.](#)

1.8) * 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
- Unsure

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

A retrospective chart review requires access to existing data for research purposes. A prospective chart review requires access to medical charts to collect future data (i.e. data that does not yet exist). [A registry](#) is an organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition, or exposure.

- Use of Biological Specimen(s)
- Secondary Data
- Retrospective Chart Review
- Prospective Chart Review
- Observation
- Registry
- Case Study
- Other (specify below)

1.10) If 'other' selected above, specify:

1.11) * If this study will be registered in a public registry provide the name of the registry and the registration number:

If not applicable enter N/A. All clinical trials MUST BE registered per the [TCPS 2 \(2018\) Chapter 11, Article 11.10](#). All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE). The HSREB is using the National Institutes of Health's definition of a clinical trial. Please refer to the [NIH website/decision tree](#) to determine if your research meets the NIH's definition of a clinical trial.

1.12) * 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.

Section 2: Study Details & Description

2.1) * What is the current Rank of the Principal Investigator (PI)?

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.

- Queen's Faculty Member
- Undergraduate Student*

- Master's Student*
- Doctoral Student*
- Medical Student*
- Medical Resident*
- Postdoctoral Fellow*
- Clinical Fellow*
- Queen's Employee
- Hospital Employee (KHSC or PCC)
- KFL&A Employee
- Ongwanada
- 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'.

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):

If you are conducting a clinical trial, a peer review may be required depending on the level of risk. A peer review by a funding agency may also be sufficient. 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, peer 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 Centre (PCC)
- Ongwanada
- KFL&A Public Health
- St. Lawrence College
- Other (specify below)

2.7) Describe any other study 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) * 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)
- Yes, Environmental Health & Safety approval (e.g., cannabis, biohazard)
- No additional approvals required

2.10) 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 or justify why this community engagement is not required as per the TCPS 2 2018 Chapter 9:

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 with [cannabis](#) requires approval from [Environmental Health and Safety](#).

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.](#)



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

This section should be written to communicate your research purpose/objectives in plain language.



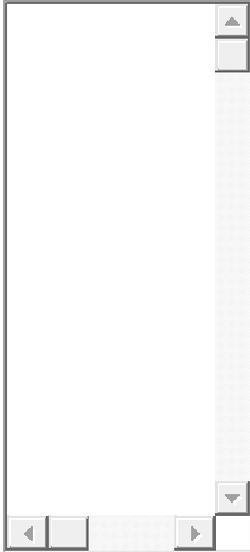
2.12) * Rationale: Explain in plain language why there is a need to conduct this study. 300 words maximum.

This section should be written to communicate your research purpose/objectives in plain language.



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

Give specific details of your data collection as it relates to human ethics. This section should be written to communicate your methods in plain language. This section should be written in such a way that an individual who is not an expert in the field should be able to replicate your methods. 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.



2.14) If there are any associated sub-studies or companion studies that will be conducted at this site, specify and describe. Attach any relevant documentation associated with the sub-studies:



2.15) 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.](#)

Section 3: Biological Specimen Collection

3.1) * Select the purpose(s) for which the specimens will be collected, accounting for current and future use (select all that apply):

Human biological materials include tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, stem cells, skin, hair, nail clippings, urine, saliva and other body fluids. In addition, the following materials relating to human reproduction including embryos, fetuses, and fetal tissues. For more information refer to [Chapter 2 of the TCPS 2 \(2018\)](#). Genetic tests are medical tests that can identify changes in your chromosomes, genes, or proteins. If you will be conducting genetic testing, refer to the HSREB's LOI/CF Checklist that is posted on [HSREB](#)

[website](#) and ensure that you include the appropriate language as applicable in the

ICF.

- For the purposes of this study (excluding specimens taken as part of normal care or for safety)
- For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA/RNA/mtDNA screening)
- To be stored, retained, or banked for any future testing
- N/A, skip the rest of this section

3.2) Describe what type and amount of biological specimen(s) will be used for research purposes? If stem cells will be used in this study, describe the stem cell component of the study:

Describe all aspects of biological specimen collection as it relates to the research project. If you will be using stem cells in your research you may require approval from the [Stem Cell Oversight Committee \(SCOC\)](#). The SCOC reviews research applications involving human pluripotent stem cells that have been derived from an embryonic source and/or will be transferred into humans or non-human animals to ensure compliance with [Chapter 12, Section F of the TCPS 2 \(2018\)](#).

3.3) Indicate where the specimens will be obtained, stored, analyzed and sent as applicable (e.g., name & address, including country):

3.4) Will a Material Transfer Agreement (MTA) or similar contract be implemented to ensure the secure transfer and storage of specimens?

If you will be using an MTA or similar contract this should be reviewed by the Research Contracts Unit through the submission of a TRAQ DSS form.

- Yes
- No
- N/A

3.5) If there is no transfer agreement in place, explain why not:

3.6) What information will be included on the specimen's label?

3.7) Indicate how long the specimens will be retained:

Ensure this information is also communicated on the ICF.

3.8) Describe what will happen to the specimens at the end of that period (e.g., destroyed, returned):

Ensure this information is also communicated on the ICF.

3.9) Indicate to what extent the study participant is able to withdraw specimens collected for the purposes of the study, and any limitations to the withdrawal:

Ensure this information is also communicated on the ICF.

3.10) If biological samples will be stored, linked, retained, or banked for any future use, specify and describe. Include relevant security information about how the samples will be stored (e.g., anonymized):

Ensure this information is also communicated on the ICF.

3.11) Where will the biobank(s)/repositories be located (e.g., name of bank & address, including country)?

Ensure this information is also communicated on the ICF.

3.12) Where will the associated data be located (e.g., name & address, including country)?

Ensure this information is also communicated on the ICF.

3.13) Who will be the custodian of the specimens that will be stored, retained, or banked, for any future testing?

Ensure this information is also communicated on the ICF.

3.14) Who will have access to the banked specimens?

Ensure this information is also communicated on the ICF.

3.15) Describe what will happen to the specimens (e.g., destroyed, returned) at the end of the banking period or if a participant withdraws their consent:

Ensure this information is also communicated on the ICF.

3.16) If study participants, their family members, or their health care providers will be informed of any genetic testing results describe a) what information will be shared and with whom; b) how consent will be obtained to release this information, and; c) whether participants will be given the option of not receiving information:

'Incidental findings' is a term that describes unanticipated discoveries made in the course of research that are outside the scope of the research. Participants should be given the option to find out about any unanticipated genetic testing discoveries. Ensure this information is also communicated on the ICF.



3.17) If incidental findings are likely due to the genetic testing component of the study, include your plan for disclosing/not disclosing such findings to participants:

'Incidental findings' is a term that describes unanticipated discoveries made in the course of research that are outside the scope of the research. Participants should be given the option to find out about any unanticipated genetic testing discoveries.



3.18) Do you plan to obtain ethics clearance for future use of samples? If no, explain why not:

Ensure this information is also communicated on the ICF.

Section 4: Imaging & Other Health Related Interventions

4.1) * Indicate the type(s) of imaging (select all the apply):

Computed Tomography Scan: CT scan Position Emission Tomography: PET Scan
PET-CT: A medical imaging technique that combines PET and CT for added precision. Magnetic Resonance Imaging: MRI Electroencephalography (EEG): is an electrophysiological monitoring method used to record electrical activity of the brain. Magnetoencephalography (MEG): is an electrophysiological monitoring method used to record electrical activity of the brain. Imaging biomarkers are defined as anatomic, physiologic, biochemical, or molecular parameters detectable with imaging methods used to establish the presence or severity of disease.

- CT Scan
- PET Scan
- PET-CT Scan
- MRI
- Ultrasound
- X-Ray

- EEG/MEG
- Imaging Biomarkers
- Other (specify below)
- N/A

4.2) Describe how the type(s) of imaging will be used in the study. If 'other' selected above, specify and describe:



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

A retrospective chart review requires access to existing data for research purposes. A prospective chart review requires access to medical charts to collect future data (i.e. data that does not yet exist). A registry is an organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition, or exposure.

- Secondary Data
- Retrospective Chart Review
- Prospective Chart Review
- Observation
- Registry
- Case Study
- Other (specify below)
- N/A

4.4) * Describe how each item selected in Question 4.3 will be implemented. If 'other' selected above, specify and describe:



4.5) * Attach copies of study related materials:

- Yes, attached
- N/A

Section 5: Informed Consent

5.1) * Does your research require you to obtain informed consent?

- Yes
- No
- N/A, skip the rest of this section

5.2) * 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. Per the TCPS 2 (2018) Article 12.3A Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials will only be permitted to not seek consent if the following can be justified: per the [TCPS 2 \(2018\) Article 12.3A](#).

5.3) If you require informed consent for this study, describe how it was or will be obtained? (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*
- Assent (e.g., nodding of head)*
- Verbal consent*
- Implied consent*

- Passive consent*
- Other (specify below)*

5.4) If the response to 5.3 includes an asterisk (*), justify your request for the use of an alteration to the standard consent process and/or for a waiver of consent based on TCPS 2 2018 Articles 3.7A/B:

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 alterations to the consent process for those with diminished decision-making capacity.



5.5) Describe the initial consent process, including when participants will be approached and outline the process for participant withdrawal:

In addition to obtaining an ICF signature, it is also important to document the ICF process in the participant study file.



5.6) 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:

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](#)).



5.7) 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.



5.8) 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 \(2018\)](#).



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



5.10) If you will be obtaining informed consent for genetic testing (mandatory or optional), describe the processes used for obtaining and documenting informed consent:

If you will be conducting genetic testing, refer to the HSREB's NEW HSREB Letter of Information/Consent Form Checklist posted under 'Resources' and ensure that you include the appropriate language as applicable in the ICF.



5.11) 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's website](#) under 'Resources' for the NEW HSREB Letter of Information/Consent Form Checklist and/or CTO's Clinical Trial Consent Form Checklist that outlines all of the Informed Consent Form required elements.

- Yes, attached
- N/A

5.12) 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

Section 6: Risks and Benefits

6.1) * 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:

Ensure that you describe risks to all participant populations. If there are different risks, or different degrees of risk for different participant populations, ensure that this is clearly outlined in your response.

6.2) * Describe your plan to mitigate these risks:

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

6.3) * What is the overall anticipated public and/or scientific benefit of the study and specify any direct benefits for participants?

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. If no direct benefits for participants, this should be stated.

Section 7: Privacy & Confidentiality

7.1) * 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)

7.2) If 'other' selected above, specify:

7.3) * 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.

7.4) * Attach a copy of the data collection forms:

Ensure the data collection forms are limited to collecting ONLY the information that you have described in section 7.1 & 7.2.

- Yes, attached
- N/A

7.5) * 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](#).

7.6) * 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:

If not applicable, enter 'N/A'. The HSREB does require access to participant information for quality assurance purposes. This requirement should be outlined on the ICF.

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

Note: 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

7.8) * 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 [ITS 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

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

7.10) * If there will be a code linking identifiers to the study participants, describe who will have access to the code. If any biological specimens will be linked to participant-identifying information directly or indirectly, via code or link, describe who will have access to the code or link:

If not applicable, enter 'N/A'.

7.11) * 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 other Queen's users. Additionally, 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 any data outside of my institution

7.12) * 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

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

If not applicable, enter 'N/A'.

7.14) * 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:

If not applicable, enter 'N/A'.

7.15) * Outline any plans to link the database with any other databases (e.g., another study site, IC/ES, 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:

If not applicable, enter 'N/A'. NOTE: merging data with other sites in a multi-centre trial is the same as linking databases. This would not include linking current study data with the master log.

7.16) * 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:

If not applicable, enter 'N/A'.

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

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

7.18) If 'other' selected above, specify:

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

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

7.20) * 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.

7.21) * 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](#).

7.22) * 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.

Section 8: Publication/Dissemination/Study Contract/Study Funding/Budget

8.1) * 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)

8.2) If 'other' selected above, describe:

8.3) * Is there an agreement between the investigator and the sponsor regarding use, publication, or disposal of the data?

- Yes
- No
- N/A

8.4) If 'yes' to above, describe any restrictions the funding agency or sponsoring company has placed on the publication of findings or on the reporting of interim results?

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 Open 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.



8.5) * Attach copies of study letters, end of study letters, and the publication plans as applicable:

- Yes, attached
- N/A

8.6) * Is a contract involved with this study?

For assistance in contract related issues, contact the [Research Contracts Unit](#). 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
- No

8.7) * Has the contract/research agreement been submitted for review and signing through the submission of a TRAQ DSS Form?

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

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

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

8.9) If 'funding application submitted', indicate expected date of decision:

[Open
the
calendar
popup.](#)

8.10) * 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

8.11) If 'other' selected above, specify:

8.12) * A copy of the study budget is attached:

- Yes
- No
- N/A

8.13) If 'no' above, explain why the budget was not submitted or not required if you are conducting a clinical trial:

8.14) * 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
- N/A

8.15) * If research is industry funded, 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:

If not applicable, enter 'N/A'.

8.16) * If the funds are presently available or applied for and do not cover all the requirements expenses to conduct the study project, explain how the shortfall will be made up:

If not applicable, enter 'N/A'

8.17) * Describe 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.):

If not applicable, enter 'N/A'.

Section 9: COI & PI Attestation

9.1) * 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

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



9.3) Describe any financial incentives or financial pressures associated with the study (e.g., recruitment incentives) that might compromise or influence the conduct of the study:

9.4) If funds will be transferred to a department research trust, or to any other type of account, indicate where the money will be transferred and include details on whether investigators will directly or indirectly benefit from the transfer of funds. Describe the management plan:

9.5) * 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?

All staff must have hospital credentials specifically to allow involvement in clinical research activity. Clinicians with hospital patient care credentials need nothing further. But other hospital or university staff, such as nurses or research assistants, do need to apply for hospital credentials for their research activities.

- Yes
- No

9.6) * Attach a copy of the Principal Investigator's (PI)/Co-PI's current Curriculum Vitae (CV):

This is not required for applicants that have listed a research supervisor as indicated with an asterisk (*) in question 2.1 (e.g., students, medical residents).

- Yes, attached
- N/A

9.7) * Is the Principal Investigator (or their Research Supervisor, if the PI is a student, resident, or fellow) entitled to provide health care (if applicable) under the applicable laws?

- Yes
- No

9.8) * 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

9.9) * 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

9.10) If 'No' selected in any question above, explain: