

Section 1: Study Overview

Use this form for all clinical trials, interventional research, studies involving invasive contact or the performance of a task. Form activated in May 2018, updated May 2019.

1. Clinical trials

2. Interventional research

3. Invasive contact

4. Performance of a physical task (e.g., exercise, KINARM, motion capture)

1.1) * The research involves 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 local participants and for case reports (e.g., chart reviews, secondary use of data, case reports, biological samples, etc.). All research and studies that are actively recruiting participants must be submitted using the HSREB Standard Application Form or the New HSREB Intermediate Application Form.

- Yes
 No

1.2) * Are you conducting a clinical trial and/or a study subject to the Health Canada Food and Drug Regulations and/or the U.S. Code of Federal Regulations (FDA)?

A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes ([Chapter 11, TCPS 2 2018](#)). A clinical trial may involve the assignment of participants to one or more health-related interventions (e.g., drugs, surgical procedures, devices, behavioural treatments, exercise interventions, dietary interventions, and process-of-care changes) in order to evaluate an outcome (e.g., effectiveness of a drug/device/diagnostic tool and/or improvement in quality of life). Contact the [Ethics Office](#) if you are unsure about the type of study you are conducting.

- Yes
 No

1.3) * If 'No' to 1.1, close this form, delete this draft and complete the HSREB Non-Recruitment Application Form in TRAQ.

The HSREB Non-recruitment Application form in [TRAQ](#) should be used for all research projects that are not actively recruiting local participants and for case reports (e.g., chart reviews, secondary use of data, case reports, biological samples, etc.). All research and 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 to 1.1 and/or 1.2 (continue completing the HSREB Standard Application Form)
 No to 1.1 and 1.2, delete this draft and complete HSREB Non-recruitment Application Form or the HSREB Intermediate Application Form

1.4) * Is this a multi-site research study? (select all that apply):

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 (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

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

- Yes
- No

1.6) * When is local enrollment expected to start?

[Open the calendar popup.](#)

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

Format YYYYMMDD (e.g., 2018JAN01). This date may be the same as the local enrollment end date if there is only one research site.

1.8) * When is local enrollment expected to end?

Format YYYYMMDD (e.g., 2018JAN01). This date may be the same as the global enrollment end date if there is only one research site.

1.9) * 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

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

Pharmacokinetics (PK) characterizes the absorption, distribution, metabolism, and elimination properties of a drug.
 Pharmacodynamics (PD) defines the physiological and biological response to the administered drug. The term
 'disinfectant' includes bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants, or
 combinations of these. A disinfectant without specific target organisms indicated on the product label is regarded only
 as a bactericide.

- Drugs, Biologics (including vaccines), Genetic Therapies, or Radiopharmaceuticals
- Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))
- Medical Devices
- Biological specimen collection for research purposes (e.g., blood/tissue for PK/PD, biomarker, biobanking, genetic testing, etc., excluding specimens taken as part of normal care or for safety)
- Imaging/Radiation (including tests involving exposure to radiation)
- Surveys/Questionnaires/Interviews/Focus Groups
- Audio/Video Recording
- Registry
- Observation
- Other (specify below)

1.11) If 'other' selected above, specify:

1.12) * Does this study require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)? (select all that apply):

- Yes - A Clinical Trial Application under the Food and Drugs Act
- Yes - A Clinical Trial Application under the Natural Health Products Regulations
- Yes - A Clinical Trial Application under the Medical Device Regulations
- No

1.13) * 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

1.14) * If this study has been or will be submitted to the US Food and Drug Administration (FDA) under an Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application, provide the US IND/IDE number:

If not applicable, enter 'N/A'. Some pharmaceutical trials may be conducted in Canada under a US Food and Drug Administration (FDA) Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application. In such instances, U.S. FDA regulations may apply to drug trials conducted in Canada.

1.15) * 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](https://www.eugdpr.org/) for additional guidance. <https://www.eugdpr.org/>

- Yes
 No
 Unsure

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

All clinical trials MUST BE registered. If not applicable, enter 'N/A'. The preferred registry for clinical trials is <https://clinicaltrials.gov/>. Registration of a clinical trial must be done before any participant is recruited. Contact Veronica Lloyd (main contact) at 613-549-6666 ext. 8171 or Lisa McAvoy (alternate) at 613-549-6666 ext. 3344 at Kingston Health Sciences Centre (KGH Site) if you require assistance with the clinical trial registry process. Veronica and Lisa handle the clinical trial registry process for all researchers affiliated with Queen's University, Kingston Health Sciences Centre, and Providence Care Centre (PCC).

1.17) * 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

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*
- Doctoral*
- 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):

If you are conducting a regulated clinical trial, a peer review is mandatory. If you are conducting an interventional study, 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)
- KHSC (HDH Site)
- Providence Care Centre (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 – 6:00pm, excluding observed holidays, ensure that you refer to the Office of Research Ethics Security Protocol and attach a copy of the Security Protocol Form, as applicable to your application. These documents are available on the [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/departamental 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 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 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 [TCPS 2 \(2018\), Chapter 9](#).

Section 3: Study Description

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

This section should include the purpose, brief rationale, and a short summary of the method in plain language.

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

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

Give specific details of your data collection as it relates to human ethics. Avoid cutting and pasting extensive sections from the protocol. Ensure that all elements noted in this section are consistent with the other sections of this application and with supplemental documentation.

3.4) * What are the primary objectives of this study?

If not applicable, enter 'N/A'.

3.5) * What are the secondary objectives of this study?

If not applicable, enter 'N/A'.

3.6) If a placebo will be used in this study, provide the scientific justification for the use of the placebo control (e.g., no alternative standard treatment available) and explain how the use of the placebo does not compromise the safety or health of participants:

In a placebo-controlled trial, participants may be assigned to a test treatment or to an identical-appearing treatment that does not contain the test drug. Per [TCPS 2 \(2018\) Article 11.3](#): "A new therapy or intervention should generally be tested against an established effective therapy, unless the Researcher can justify the use of a placebo"

3.7) Describe the provisions that will be made to break the code of a double-blinded study in the event of an emergency situation:

A type of study in which the participants (single-blinded) or the participants and their doctors (double-blinded) do not know which drug or treatment is being given. The opposite of a blinded study is an open label study.

3.8) 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 [TCPS 2 \(2018\) Chapter 3 Article 3.7B](#).

3.9) 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 (Article 3.1)".

3.10) 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:

3.11) 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 [TCPS 2 \(2018\) Chapter 5](#).

Section 4: Health Canada Regulations

4.1) * State the type and phase(s)/classification that best describe your study (e.g., pilot study, Drug - Phase III, Drug - Phase I/II, Medical Device – Class III):

If not applicable, enter 'N/A'.

4.2) If there a Contract Research Organization (CRO) overseeing the study, specify the CRO:

4.3) * Attach copies of all Investigator Brochures (IB), Product Monographs (PM), or equivalents (select all that apply):

- Investigator Brochure(s) (IBs) or equivalent(s) attached
- Product Monograph(s) (PMs) or equivalent(s) attached
- N/A

4.4) * Does this submission require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)? (select all that apply):

- Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations
- Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations
- Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations
- No, skip the rest of this section

4.5) If your research involves the use of Drugs, Biologics (including vaccines), Genetic Therapies, or Radiopharmaceuticals, indicate the status of the product(s) covered under the Clinical Trial Application (CTA) with Health Canada (select all that apply):

- Approved (e.g., has Drug Identification Number (DIN)), but being used in the study outside the conditions of use approved by Health Canada
- Investigational

4.6) Describe how the above product(s) will be used in the study outside the conditions of use approved by Health Canada:

4.7) Indicate the status of the Health Canada Clinical Trial Application (CTA):

The No Objection Letter (NOL) is evidence of study authorization, and it lists the drugs that are required to be managed according to the regulations. If your NOL is pending, ensure this is submitted as soon as it has been obtained.

- No Objection Letter attached
- No Objection Letter pending

4.8) If your research involves the use of Health Products, indicate the status of the Health Product(s) covered under the Clinical Trial Application (CTA) with Health Canada(select all that apply):

The Natural Health Products Directorate (NHPD) has changed its name to the [Natural and Non-prescription Health Products Directorate \(NNHPD\)](#) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs).

- Approved (e.g., has Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM)), but being used in the study outside the conditions of use approved by Health

Canada

Investigational

4.9) Describe how the Health Product will be used in the study outside of the parameters of the conditions of use approved by Health Canada:

4.10) Indicate the status of the above Health Canada Clinical Trial Application (CTA):

If your NOA is pending, ensure this is submitted in the form of an amendment as soon as it has been obtained.

- Notice of Authorization attached
- Notice of Authorization pending

4.11) If using medical devices, name all device components, parts, and/or accessories as per the product label for devices covered under the Investigational Testing Application (ITA) with Health Canada:

Research involving the testing of a medical device is subject to the [Medical Devices Regulations](#) and may require the submission of an Investigational Testing Application (ITA) to Health Canada

4.12) Indicate the status of the device(s) with Health Canada (select all that apply):

- Licensed (e.g., has Medical Device License (MDL)), but being used outside of current Health Canada authorization
- Investigational

4.13) Describe how the device component, parts, and/or accessories is/are being used in the study outside of the parameters of the conditions of use approved by Health Canada:

4.14) If this device contains a drug, specify and describe:

Section 5: Biological Specimen Collection

5.1) * 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 guidance document titled, “Statements for HSREB Informed Consent Forms” (ICFs) that is posted on [HSREB’s website](#) under ‘Resources’ 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

5.2) Describe what type and amount of biological specimen(s) will be collected from the study participants for research purposes? If stem cells will be collected or 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. You do not need to describe biological specimens that are taken as part of Standard of Care (SOC) or for safety purposes. 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 and 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 \(2018\)](#).

5.3) Indicate whether the specimen collection for the purposes of this study are:

- Optional
- Mandatory
- Mandatory and Optional

5.4) Specify the components that will be mandatory and/or optional and describe how the specimens will be used in this study:

5.5) Indicate where the specimens will be sent (e.g., name & address, including country) and specify if a Material Transfer Agreement (MTA) or similar contract will be implemented to ensure the secure transfer and storage of specimens. If there is no transfer agreement in place, explain why not:

Ensure this information is also communicated on the ICF.

5.6) What information will be included on the specimen’s label?

5.7) Indicate how long the specimens will be retained:

Ensure this information is also communicated on the ICF.

5.8) 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.

5.9) 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:

Ensure this information is also communicated on the ICF.

5.10) If material 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.

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

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

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

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

5.15) Who will have access to the banked specimens?

5.16) 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:

5.17) Indicate to what extent the study participant is able to withdraw banked specimens, and any limitations to the withdrawal:

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

Section 6: Imaging

6.1) * 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, skip the rest of this section

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

6.3) If research participants will be exposed to radiation/radiopharmaceuticals over and above what they would receive with local standard of care, describe the radiation exposure that is above local standard of care:

Examples: a) Participants will be exposed to two additional x-rays that are outside of the local standard of care for this population. b) Participants will have to undergo an MRI, which is outside of the local standard of care for this population.

6.4) If material incidental findings are likely, describe your plan for disclosing such findings to participants:

'Incidental findings' is a term that describes unanticipated discoveries made in the course of research, which are outside the scope of the research. Example: If abnormal findings are noted on an MRI, the participant will be referred to their local doctor for additional follow up.

Section 7: Other Health Canada Interventions

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

There are many psychological tests such as personality, intelligence, or emotional functioning assessments that may be restricted for use based on credentials (e.g., only to be used by Registered Psychologists). Controlled acts are defined in the [Regulated Health Professions Act, 1991 \(RHPA\)](#). For more information refer to the Delegation of Controlled Acts policy on the [College of Physicians and Surgeons of Ontario's website](#). If you plan to delegate a controlled act the following considerations must be made: 1. In every instance of delegation, the primary consideration must be the best interests of the participant. 2. An act undertaken through delegation must be as safe and effective as if it had been performed by the delegating physician. 3. Responsibility for a delegated controlled act always remains with the delegating physician. 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).

- Surveys
- Questionnaires
- Interviews
- Focus Groups
- Cognitive Behavioural Therapy (CBT)
- Surgery
- Exercise
- Observation
- Registry
- Retrospective Chart Review
- Prospective Chart Review
- Audio/Video Recordings
- Conducting, administering or supervising tests that require professional credentials
- Delegation of a “controlled act” as specified in the Regulated Health Professions Act, 1991 (RHPA)
- Other (specify below)
- N/A, skip the rest of this section

7.2) Describe how each item selected in Question 7.1 will be implemented. If ‘other’ selected above, specify and describe:

If you have selected ‘Conducting, administering or supervising tests that require professional credentials’ and/or ‘Delegation of a “controlled act” as specified in the Regulated Health Professions Act, 1991 (RHPA)’ ensure you include the following information in your response: 1. Name of the test/act; 2. Description of the test/act; 3. Information regarding the credentials necessary to administer and interpret the test/act; 4. Information concerning who will be administering and interpreting the test/who will performing the controlled act; 5. If a controlled act is to be delegated describe who will be performing the controlled acts.

7.3) Attach all surveys, questionnaires, screen shots, interviews/focus group scripts, audio/video recording consent forms, copies of assessments/tests, SOPs for delegated procedures:

- Yes, attached
- N/A

Section 8: Participants

8.1) * 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.

8.2) * How many participants will be recruited locally?

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

8.3) * 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.

8.4) * 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

8.5) * 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 [TCPS 2 \(2018\) Chapter 4](#).

8.6) * Describe the overall strategies for minimizing coercion or undue influence for the participant population(s) as indicated by an asterisk (*) in Question 8.4:

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.

8.7) * 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: [TCPS 2 \(2018\), Chapter 4](#).

8.8) * If 'patients' selected above as a population group, from which hospital(s)/clinic(s) will you be recruiting participants (select all that apply):

Hospital researchers must check the electronic medical records to determine if potential participants have opted out of research participation. For instructions refer to the KHSC Research Road Map for [Assessing Patient Data for Research](#) that is posted on the [KGHRI website](#).

- KHSC – KGH Site
- KHSC – HDH Site
- PCC
- Other (specify below)
- N/A

8.9) If 'other' selected above, specify:

8.10) * Will participants be hospital inpatients?

- Yes
- No

8.11) * Will participants be hospital clinic patients?

- Yes
- No

8.12) * If participants designated incompetent, why do you consider the participants incompetent?

If not applicable, enter 'N/A'.

8.13) * Provide the inclusion criteria:

If not applicable, enter 'N/A'.

8.14) * Provide the exclusion criteria:

If not applicable, enter 'N/A'.

8.15) * What is the accepted local standard of care for this/these population(s)?

If not applicable, enter 'N/A'.

8.16) * What study-related procedures will be done that are not part of local standard of care?

If not applicable, enter 'N/A'.

8.17) * If participants will be withdrawn from or denied usual therapy for any condition in order to participate in this study, explain and justify:

If not applicable, enter 'N/A'.

8.18) * Describe the care that will be available in case of an emergency:

8.19) * Describe what will happen if participant suffers an injury from participating in the study. Include information regarding whom participants contact in the event of a study-related injury, as well as whom will be covering reasonable out-of-pocket expenses to ensure that immediate medical care is provided:

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

8.20) * List any stopping rules or criteria for premature withdrawal of participants from the study due to safety concerns:

If not applicable, enter 'N/A'. Before a research participant enters a sponsored study, the research team should explain that the sponsor may stop a study prematurely for a number of reasons. The participant should also be informed that, in the event of a premature discontinuation, appropriate follow-up care will continue to be provided.

8.21) * Describe the criteria for stopping the study early due to safety concerns or for other reasons:

If not applicable, enter 'N/A'. Before a research participant enters any study/trial, the study staff should explain that, although it happens rarely, the sponsor may stop the trial early. The participant should also be informed that, in the event of a premature discontinuation, appropriate follow-up care will continue to be provided.

8.22) * If participation in this study could positively or negatively affect participants' current and future care or eligibility for future research, explain:

If not applicable, enter 'N/A'. Participation in a research study should not negatively affect a participant's future care as a patient. This information needs to be communicated on the ICF.

8.23) * 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.

Section 9: Recruitment

9.1) * 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](#).

9.2) * 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:

If not applicable, enter 'N/A'.

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

If not applicable, enter 'N/A'. The HSREB prefers that participants are not recruited or consented to participate in a research study by someone in a 'power-over' position. Undue influence and manipulation may arise when prospective

participants are recruited by individuals in a position of authority. This may include study doctors recruiting their own patients, or instructors recruiting their own students. How, when, and where participants are approached, and who recruits them, are important elements in assuring (or undermining) voluntariness ([TCPS 2 \(2018\) Chapter 3](#)). If you plan to use recruitment techniques that may involve power imbalances, you must justify how you will minimize undue influence. For additional guidance, refer to the guidance document titled, 'Ethical Considerations for Instructors Conducting Research on their Students' which is posted on the [HSREB website](#) under 'Guidelines' or refer to [TCPS 2 \(2018\) Chapter 3](#).



9.4) * 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

9.5) If 'other' selected above, describe:

Section 10: Informed Consent

10.1) * 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)

10.2) If 'other' selected above, specify:

10.3) 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.

10.4) * 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.

10.5) * 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](#)).



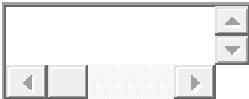
10.6) * If there are procedures in place for participants who may have communication difficulties (e.g., who may need translation, who are illiterate, who have trouble understanding or producing speech and require special support including the use of assistive devices), explain the procedures. If not, explain why not:

If not applicable, enter 'N/A'. 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.

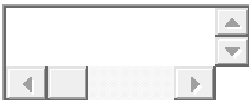


10.7) If this study permits/requires the enrollment of participants who are not capable of providing consent, describe who will assess capacity and how capacity (initial and ongoing) will be assessed (including assessment of attaining/regaining capacity):

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



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



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

'Assent' is the expression of approval or agreement. For additional guidance on alterations to consent, refer to [TCPS2 \(2018\) Chapter 3](#) Article 3.7A.



10.10) 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 guidance document titled, "Statements for HSREB Informed Consent Forms" (ICFs) that is posted on [HSREB's website](#) under 'Resources' and ensure that you include the appropriate language as applicable in the ICF.

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

- Yes, attached
- N/A

10.12) * 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 11: Incentives and Reimbursement for Participants

11.1) * 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

11.2) * 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.

11.3) * 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.

Section 12: Risks and Benefits

12.1) * 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 (e.g., drug side effects, injury)
- Privacy Risk (e.g., sending genetic testing samples outside of Canada)
- Psychological or emotional risk
- Questions about sensitive or personal issues
- Economic risk
- Social risk
- Dangerous location, such as war-torn country
- Risks to participants due to power imbalance (e.g., Instructor/Student)
- Cultural sensitivities
- Third party risks (e.g., risks to family)
- Reproductive Risks
- Other (specify below)
- No known risks

12.2) * 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.



12.3) * 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.

12.4) If there are any known reproductive risks associated with participation in the study, or risks to third parties, provide a summary of the relevant information (e.g., teratogenicity or embryotoxicity, risks related to breastfeeding or birth defects, risks to female partners of male participants, risks related to a male participant fathering a child, infectious risks to third parties):

Reproduction risks or third party risks generally include toxic or teratogenic effects of pharmaceutical agents and may also include infectious risks.

12.5) In the event that the partner of a participant taking the study drug becomes pregnant, and the participant's involvement in the study presents risk to the fetus, explain whether access to the pregnant partner and the baby's medical records will be required, and outline your plan for obtaining informed consent:

12.6) * 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.

12.7) * 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 [TCPS 2 \(2018\) Chapter 2](#).

Section 13: Confidentiality and Privacy

13.1) * 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)

13.2) If 'other' selected above, specify:

13.3) * 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.

13.4) * 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 13.1 & 13.3.

- Yes, attached
- N/A

13.5) * 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](#).

13.6) * 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.

13.7) * 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

13.8) * 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 [IT Policies and Procedures website](#) for additional guidance with respect to policies regarding information technology.

- Access to medical records and/or 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

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

13.10) * 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'.

13.11) * 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 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 any data outside of my institution

13.12) * 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.

13.13) * 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.

13.14) * 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:

Indicate 'N/A' if not applicable.

13.15) * 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:

Indicate 'N/A' if not applicable. 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.

13.16) * 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:

13.17) * 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)

13.18) If 'other' selected above, specify:

13.19) * 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.

13.20) * 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.

13.21) * 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](#).

13.22) * 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 14: Publication/Dissemination of Results

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

Indicate 'N/A' if not applicable.

- 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)

14.2) If 'other' selected above, describe:

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

- Yes
- No
- N/A

14.4) * 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?

Indicate 'N/A' if not applicable. All Tri-Agency funded research is subject to the Tri-Agency Open Access Policy on Publications. For additional information, refer to the [Open Access Policy](#). All National Institutes of Health (NIH) funded studies must abide by the [NIH 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.

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

- Yes, attached
- N/A

Section 15: Investigation Agent

15.1) * Will you be using an investigational agent in your research study?

- Yes
- No, skip the rest of this section

15.2) Will you require the use of the affiliated hospital pharmacy, and has approval from the pharmacy been obtained?

- Yes
- No

15.3) Outline if the sponsor will cover the cost of the investigational agent(s) and/or the comparator drugs used in the study for the duration of the study:

15.4) Describe if there are mechanisms in place to provide ongoing access to the investigational agent post-study if the participant is benefiting from treatment. If not, explain why:



15.5) Describe the steps for the ordering of study drugs including shipping, packaging, receipt and record keeping:

Where a cold chain must be maintained, details for temperature monitoring are required at each step.




15.6) Describe the storage requirements for the study drugs, including where the study drugs will be stored and how the study drugs will be stored (refrigerator, freezer, locked cupboard), and how the temperature of the study drug will be monitored:

Investigational agents must be stored in a secure location that is accessible only to authorized personnel. Each product should be stored and accounted for through use of the protocol-specific investigational product accountability log (i.e. DAL) with temperature monitoring in place.



15.7) Describe any process associated with labelling the study drug when it is received and dispensed:



15.8) Attach a sample label of all drug labels (Include information in English and French):

Refer to "Investigation Drug Labeling Requirements for Health Canada and US Regulated Studies," which is posted on the [HSREB website](#) under 'Guidelines'.

- Yes, attached
- Not attached, will submit in the form of an amendment

15.9) Describe how the study drugs are prepared for patients on active and placebo treatment arms, and identify who is responsible for study drug preparation and dispensation:



15.10) Describe the process for providing information to study participants regarding how to take study medications, including precautions and other instructions:

15.11) Describe the process for return of study drugs from the patients and for disposal of returned or unused study drugs at the study site:

15.12) Describe the records that will be maintained for all study drugs and outline who is responsible for maintaining these records:

Section 16: Safety and Monitoring

16.1) * Will you be implementing a safety/monitoring component for your study?

ICH GCP E6, as adopted by Health Canada; 5.18.1 Purpose, states that the purposes of trial monitoring are to verify that: a) The rights and well-being of human subjects are protected. b) The reported trial data are accurate, complete, and verifiable from source documents.c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

- Yes
- No, skip the rest of this section

16.2) Describe the procedure for safety monitoring, including during serious adverse events (SAEs). Include information concerning how the study investigator will be contacted if an SAE is experienced by a research participant. Include a description of the response mechanism in place for the study:

The research plan should include a definition of a serious adverse event (SAE), how SAEs will be identified, and how research staff will be trained to identify potential SAEs and report them to the Principal Investigator.

16.3) Describe plans to perform an interim analysis:

16.4) If there is a data and safety monitoring board (DSMB) or committee (DSMC), describe the DSMB/C, including its purpose, membership, relationship to the sponsor (e.g., independent of sponsor), how often the committee meets, and whether they will review un-blinded data, OR attach a copy of the DSMB/C charter. If none, justify why this is not required:

16.5) Who will conduct the on-site monitoring of the study?

Section 17: Study Contract

17.1) * Is a contract involved with this study?

For assistance in contract related issues, contact the Queen's University Research Services Contracts Office at 613-533-6081. 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

17.2) * 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

Section 18: Study Funding/Budget

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

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

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

Format YYYYMMDD (e.g., 2018JAN01).

18.3) * 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

18.4) If 'other' selected above, specify:

18.5) Describe the type of industry support, e.g., unrestricted, restricted, in-kind (e.g., supply of drug, device, biologic):

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

Submission of a budget is mandatory for all clinical trials.

- Yes
- No

18.7) If 'no' above, explain why the budget was not submitted or not required:

18.8) * 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
- N/A

18.9) * 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:

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

Section 19: Conflict of Interest Disclosure

19.1) * 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 [TCPS 2 \(2018\) Chapter 7](#).

- Yes
- No

19.2) 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:

19.3) 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:

19.4) 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:

Section 20: Principal Investigator Attestation

20.1) * 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

20.2) * Attach a copy of the Principal Investigator'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

20.3) * 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

20.4) * 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

20.5) * 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

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

Section 21: Checklist

21.1) * Protocol, peer review

- Yes, attached
- N/A

21.2) * Informed Consent Form (ICF), Assent Forms

- Yes, attached
- N/A

21.3) * IBs/PMs/Device Manuals/Safety Information

- Yes, attached
- N/A

21.4) * Participant Recruitment Materials (email scripts, posters, radio advertisements, social media ads, website links, etc.)

- Yes, attached
- N/A

21.5) * Participant Information Materials (Participant diaries, contact cards, wallet cards, etc.)

- Yes, attached
- N/A

21.6) * Budget

- Yes, attached
- N/A

21.7) * Debriefing Materials

- Yes, attached
- N/A

21.8) * PI's/Co-PI's CVs and/or other documentation evidencing qualifications

- Yes, attached
- N/A

21.9) * CORE, GCP training, CITI Ethics training certificates

- Yes, attached
- N/A

21.10) * Data Collection forms

- Yes, attached
- N/A

21.11) * Interview, focus group scripts

- Yes, attached
- N/A

21.12) * Any other documents that the REB may need to review?

- Yes, attached
- N/A