The Royal's
Institute of Mental Health Research
affiliated with the University of Ottawa

RESEARCH ETHICS BOARD - APPLICATION INSTRUCTIONS

**Please note that we only accept electronic submissions.*

The REB application forms have been designed to ensure the information we collect is compliant with TCPS2 and all regulations that govern the REB as well as clinical research conduct.

While this form may seem lengthy, numerous sections simply require the applicant to click on a checkbox to provide the requested information. The application must be all-encompassing. In other words, many sections may not apply to your study, but must be included in the application. Once an electronic format is available, programming rules will be incorporated that will allow us to ensure only applicable content appears based on the information you enter (e.g. an if-then scenario).

An ethics application provides an overview of the content of the study proposal/protocol. It is important to keep in mind that the text fields should be brief and in lay language. Where possible, you can use point form and in other sections that require more explanation, ensure the explanation you provide is brief, accurate and to the point. Reviewers will always need to look at the protocol for further information. **Do not copy and paste entire sections from your protocol.** Investing time in your application will make the entire process proceed more smoothly! Text boxes are formatted to have limited space – this is intentional. Be succinct and only provide what is necessary.

Instructions are included throughout the form!

Pay close attention to the details, instructions and guidance provided throughout the form in shaded areas. This information is to assist you in completing the application and ensuring that the correct information is entered. Do not automatically assume that the information does not apply to your study. It is especially important to take note of definitions and requirements related to interventional studies, regulated studies and studies using radiopharmaceuticals. Understanding the information will reduce the risk of having an application returned to you for corrections.

Form Design

The form is designed in sections that group like information together. Sections that are optional will include a check box that can be selected if not applicable to your project. A section that does not have a check box means that it is mandatory for all study types and must be completed.

An incomplete application will be returned to the investigator.

Blue tabs indicate the start of a new section.

SECTION 3 – STUDY DESIGN

3.1 Study Type

☐ **Interventional (check all that apply)**	☐ **Observational/No Intervention (check all that apply)**
☐ Pilot Trial ☐ Open-Label ☐ Single-Blind ☐ Double-Blind (or more) ☐ Randomized Control (RCT)	☐ Case Control ☐ Cohort ☐ Cross-sectional ☐ Decision Rule Research ☐ Longitudinal ☐ Qualitative (surveys, interviews, etc.) ☐ Registry ☐ Involves biological specimen collection ☐ Involves imaging/radiologic procedure ☐ Positron Emitting Radiopharmaceutical – for basic clinical research studies under Health Canada Division 3.

Check boxes allow you to select one or more options with the click of your mouse

NOTE: *The definition of a **REGULATED** (Health Canada approval required) research study:*

- *All clinical trials from phase I to phase III for new Investigational products (drug, natural health product, biologic) as well as any unlicensed medical devices (class 2 and up)*
- *Marketed products (drug, natural health products, biologic) being researched outside of their approved indication (i.e. new age group, new disease entity or new dosage range)*
- *Exception* - Phase IV trials do not require approval from health Canada however sponsors are mandated to conduct the trial according to section C.05.10, Good Clinical Practice, and keep the required records as*

Review gray shaded areas when completing the application. Following this guidance will help ensure the information entered on your application is accurate!

A checkbox indicating "Not Applicable" indicates that this section may not apply to your study. Completion of this section is not mandatory.

SECTION 8 – BIOLOGICAL SPECIMEN COLLECTION
(blood/tissue, biomarker, bio banking, genetic testing) – excludes specimens taken as part of normal care.

☐ **Section 8 – Not Applicable**

a) What type of specimen(s) will be collected from the study participants?

Click or tap here to enter text.

b) How will the specimens be collected? (check all that apply)

☐ Previously acquired clinical specimens (e.g. leftover or archived specimens)

☐ Prospectively collected for the study (e.g. not yet collected

Application Process

Preliminary Review: To ensure applications are completed accurately, the REB office will conduct a **preliminary administrative review** of each submission. During this process, the submission will be reviewed to ensure all sections of the application are complete, there are no major inconsistencies between the application, and the protocol and/or ICF. Grammar and spelling will also be reviewed for errors. Once the application is deemed to be ready for the REB review process, the study will be assigned an REB#, the investigator will be contacted and further instructions will be provided.

Supporting Documents: In addition to the required documents outlined in the application (e.g. protocol, informed consent form, participant handouts, etc.), you must submit the following with the final application:

☐ Checklist of resources
☐ Study Information Sheet
☐ TCPS2 certificates for the PI and all staff listed on the application/protocol

General Tips for Success

- Carefully review and read the application form to understand what information is required.
- Do not assume that a section is not applicable to your research – the application is designed to meet regulatory requirements. If a section of the application is considered "mandatory," there is a reason it must be completed.
- When submitting documents for review, you must ensure that they are version dated and paginated. This includes, but is not limited to: protocols, informed consent forms, and recruitment materials. Documents that do not include this information will be returned to the investigator.
- Incomplete applications will be returned to the investigator and will not be forwarded to the REB for review.

Important Points

CO-INVESTIGATORS – REBs across the province are adopting an approach whereby only one co-investigator is listed on the REB application. This co-investigator is the person who is responsible for the study in the absence of the Principal Investigator. Listing only one co-investigator eliminates the numerous amendments and notifications to the REB office when staff/investigators are added to or removed from a study. It is important to note that it is the Investigator's responsibility to list co-investigators and research staff on the study delegation log and to ensure all research staff are appropriately trained for the research activities that they are conducting.

FUNDING – The REB retains the right to delay REB review and approval until funding has been secured for a study. Funding should be secured prior to submitting an REB application. If you have questions or concerns about this, please reach out to the REB Administration Office.

DATA SHARING AGREEMENT(S) – The REB retains the right to delay REB review and approval until all data sharing agreements have been finalized for a study. If you have questions or concerns about this, please reach out to the REB Administration Office.

REGULATED RESEARCH – Research in which Health Canada Approval is required prior to commencing a trial that is using drugs, natural health products, devices or in some cases new radiopharmaceuticals. These trials are considered to be of

higher risk and are subject to Health Canada inspection. Please keep in mind that investigators and staff working on regulated trials must be able to provide evidence of training on applicable Health Canada regulations.

CLINICAL TRIAL REGISTRATION – This is applicable to ALL INTERVENTIONAL studies. REB approval may be withheld pending confirmation of trial registration. Please refer to section 4 of the REB application for further information.

RADIOPHARMACEUTICAL RESEARCH – Health Canada changed its requirements in order to make it easier for researchers to conduct scanning protocols using radiopharmaceuticals. This change allows investigators to use radiopharmaceuticals that have a predefined safety profile in humans. These are referred to as "Basic Clinical Research Studies" in which radiopharmaceuticals are used to advance scientific knowledge and are not intended to fulfill any immediate diagnostic or therapeutic purpose. A clinical trial application approval is not required by Health Canada. For trials, using a Positron-Emitting-Radiopharmaceutical (PER) that is first in humans, or a study that does not meet the basic clinical research definition, a Health Canada Clinical Trial Application (CTA) must be submitted.

Investigator Responsibilities

The Principal Investigator is ultimately responsible for all aspects of a clinical research study/trial. This includes but is not limited to ensuring REB approvals and regulatory approvals are in place prior to commencing a trial, ensuring staff are appropriately and adequately trained for the research activities that they will conduct, ensuring there is sufficient space, resources and staff to conduct the study/trial and ensuring investigator/medical oversight for all aspects of the study.

REB Approval

As per TCPS2, REB approval will be granted for a period of one year. It is the investigator's responsibility to ensure that approval does not lapse and that continuing review occurs on an annual basis. Each approval letter issued by the REB clearly indicates the date of expiry. Investigators must submit annual renewal forms 4 weeks prior to expiration to ensure timely review of the request to renew approval.

If there is a lapse in study approval, the REB will suspend the study, and all associated cost centres will be put on hold until approval is renewed. All study activities must cease during this period. If participants are recruited and/or consented during a lapse in REB approval, the REB will assess to determine if the data may be used in analysis, if the participants must be re-consented and/or if the lapse must be reported to the granting agencies as per their specific guidelines.

Continued failure to renew REB approval will result in the inability to submit new applications to the REB, and a requirement to renew and update TCPS2 training before new applications may be submitted.