IWK Research Ethics Board (REB) Application Process Guide

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APPLIES TO

The IWK research community, including employees, investigators, physicians, management, consultants, students, volunteers, and other personnel involved in conducting research with human subjects.

PURPOSE

This document provides guidance on completing the REB application process. The primary purpose of the application form is to give REB committee members a detailed overview of your study and the activities that will take place.

GUIDING PRINCIPLES AND VALUES

Research, education, and clinical care are the three essential activities of the Health Centre. The Research Ethics Board (REB) assists the research community in conducting ethically acceptable research involving humans.

All research that involves human subjects, their information or their tissue, requires review and approval by the REB before commencing. Research proposals are assessed for ethical acceptability using regional, national and international guidelines.

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2022 (TCPS2) defines research as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

APPLICATION

The IWK applications for both interventional and non-interventional studies can be found on the ROMEO Researcher Portal.

If you are not currently registered for the Research Portal, the homepage has information on how to register.

APPLICATION REQUIREMENTS

For the initial REB application, the following documents are required:

- Research protocol (If this is a multi-center study and the protocol has been modified for research at the IWK, both the original protocol and the IWK-specific version should be uploaded.)
- Data collection tools
- Signature page (template available in the attachment tab), see REB SOP 802 found here

- Delegation log (template available in the attachment tab), see REB SOP 803 found here
- Team contacts page (template available in the attachment tab)
- Departmental letter of support (template available in the attachment tab), see REB SOP 804 found here
- TCPS2: CORE-2022 Tutorial certificate for the PI and each team member (if previously submitted it does not need to be included)
- Curriculum Vitae (CV) for the PI and each team member (if previously submitted within the past three years it does not need to be included)

Depending on your study, the following documents may also be required:

- Informed consent/assent/authorization Form(s) (template available in the attachment tab)
- Case report forms
- Recruitment material
- Additional letters of support
- Registry use form
- REB Fee Form
- NOL, clinical trials only
- Good clinical practice (GCP) certification, clinical trials only
- OCAP training certificate for the PIs for research specific to Indigenous populations

Templates can be found in the attachment tab of the application forms and on pulse here and the IWK website here.

SOPs can be found in the attachment tab of the application forms and on the IWK website here.

Incomplete application packages will not be accepted and will be returned to the researcher.

Quality Assurance/Quality Improvement (QA/QI) Studies: The TCPS2 article 2.5 states "Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements **when used exclusively for assessment, management or improvement purposes**, do not constitute research and do not fall within the scope of REB review." However, the articles go on to say, "If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research and at that time may require REB review." Therefore, if you are conducting a QA/QI and if you know or anticipate that you will be extending the knowledge acquired to a broader community by presenting, broadcasting or publishing the results it is recommended that IWK REB review and approval is obtained before the start of your project, as approval cannot be given retroactively.

PROJECT INFO TAB

TITLE: Ensure that the study title is explicit and descriptive of the study. Ensure that the title matches on all documentation regarding the study/protocol.

START DATE: Can be completed if known but is not necessary.

END DATE: Can be completed if known but is not necessary.

KEYWORDS: Use keywords that best describe your study.

CLINCIAL TRIALS NO.: On Interventional application only, complete if known.

RELATED AWARDS: If your study involves an agreement or award and you have already submitted the application then please complete.

PROJECT TEAM INFO TAB

PRINCIPAL INVESTIGATOR: This section defaults to the project of the person who creates the file. Do not hand type this section. If you need to change PI, click the 'change PI' button, enter the last name of the new PI and click 'search', then select the correct PI.

OTHER PROJECT MEMBER INFO: All local team members must be added. Local is defined as IWK, NSH and Dalhousie. Use the 'add new' button to search for each team member's profile. Select the most appropriate role for each team member, e.g. co-PI, sub-investigator, research coordinator, administrative coordinator, study staff, research assistant, etc. If the team member does not currently have a ROMEO profile, please complete the new user registration request found on the homepage of the Researcher Portal website and send to research@iwk.nshealth.ca.

IWK INTERVENTIONAL STUDY – ETHICS APPLICATION FORM (EAF)

Tab 1: Guidelines For Submitting an REB Application

This section is a simplified version of this guide and serves as a reminder when completing the form. IWK Research Ethics Standard Operating Procedures 102 (found here) provides a detailed glossary of terms used throughout the Application.

Tab 2: Principal Investigator Attestation/Commitments

The Principal Investigator (PI) has the ultimate responsibility for the conduct of the research to ensure participant safety and data integrity. By clicking the "agree" check box the PI is agreeing to the outlined statements.

Tab 3: Administrative Information

This section provides background information on your study, including whether it is minimal risk or requires full board review, if it is multi-site, and if there is a contract the REB needs to be aware of. It also covers funding details. Investigators conducting research on IWK Health property, using IWK Health resources, or involving IWK Health researchers/participants **must** hold and administer funds from an IWK account. For more information, please review the Research Jurisdiction Policy.

If your study is multi-site, provide details of who has reviewed the protocol and attach a copy of the review.

Tab 4: Research Summary

The Research Summary section outlines the core aspects of your research project. Begin with the background and rationale, providing the scientific context and justification for the study. Clearly state your primary research question or hypothesis, as this will guide the entire study. Describe your study design and methods in detail, ensuring that your methodology aligns with your research question. Define your primary and secondary outcome measures and explain how your data will be analyzed to address the research question. Do not copy and paste directly from the protocol. Spell out all acronyms when first used. Remember that this section must be in lay language.

It's crucial to discuss both the potential benefits and risks to participants, ensuring that the benefits outweigh the risks. This aligns with the TCPS 2 principle of Concern for Welfare. Specify the expected timeline for your study, and if applicable, describe any sub-studies and their specific objectives.

Sub studies need to have a direct relationship with the main study and must be clearly outlined. If necessary, a separate copy of the EAF can be downloaded and completed for the sub study and added to the attachment tab.

Tab 5: Research Protocol Information

The Research Protocol Information section delves into the specifics of how your research will be conducted. Start by specifying where the research will take place and provide both local and global enrollment targets. If your research focuses on underrepresented groups, describe the research team's expertise and how you've engaged with the community. This addresses the TCPS 2 principle of Justice.

Justify any inclusion or exclusion criteria that may appear to violate the principle of inclusiveness. Describe how participants will be assigned to study arms and explain how your study deviates from standard care, if applicable. Identify any extra visits, tests, or data collection that will be done purely for research purposes. Have a plan for managing potential incidental findings and describe this plan in your application.

If your study uses placebos or involves any form of deception, provide strong justification for these approaches and describe how you will debrief participants. This is particularly important in adhering to the principle of Respect for Persons. Explain how participant safety will be monitored, including any data safety monitoring board. Describe how new safety information will be communicated and explain mechanisms for withdrawing participants for safety reasons. Outline systems for handling medical emergencies outside working hours and explain provisions for follow-up care after the study ends.

Tab 6: Compensation/Conflict of Interest

In the Compensation and Conflict of Interest section, address financial aspects of study participation and potential conflicts. Describe any financial costs to participating and justify any reimbursement for participant expenses or additional compensation. Disclose any honoraria or incentives for the research team. Declare any financial interests in the research, product, or sponsor, as well as any other actual or perceived conflicts of interest. Transparency in this section is crucial for maintaining the integrity of the research and aligning with all three TCPS 2 principles.

Tab 7: Participant Identification and Informed Consent

The Participant Identification and Informed Consent section focuses on recruitment and consent procedures, directly addressing the TCPS 2 principle of Respect for Persons. Describe your target population and explain how potential participants will be identified. Specify who will first approach potential participants and describe the informed consent process, including who will conduct it. Note that while the PI or someone within the circle of care may introduce the study, someone outside the circle of care should obtain consent (e.g. research assistant, other study staff).

Provide details on consent procedures, especially for participants with limited literacy or capacity. Explain how capacity to consent will be assessed and describe procedures for ongoing consent throughout the study. This ensures that participants' autonomy is respected throughout the research process.

Tab 8: Privacy and Confidentiality

The Privacy and Confidentiality section is a critical component of your ethics application, addressing both the TCPS 2 principles of Respect for Persons and Concern for Welfare. This section must be completed if you are collecting any personal information or personal health information. Personal information encompasses a broad range of data, including but not limited to email addresses, phone numbers, and other identifiable details.

Begin by specifying exactly what personal information will be collected and from what sources. This could include information directly provided by participants, extracted from health records, or obtained from other databases. Be comprehensive in your description, as transparency is key in ethical research. Next, explain how this information will be used in the research. If your study

involves data matching - combining data about an individual from two or more sources - you must justify why this is necessary for your research objectives.

Describe in detail the processes you will use for de-identifying data. This is crucial for protecting participant privacy and minimizing the risk of unauthorized disclosure. Specify who will have access to personal information and provide a clear rationale for why each person needs this access. This might include members of the research team, data analysts, or other collaborators.

Outline where and how data will be stored, including both physical and digital safeguards. If data will be transferred outside the IWK, you must explain the process and describe the safeguards that will be in place to protect the information during transfer and at its destination. It's important to note that if data will be transferred outside the IWK, a contract or Data Transfer Agreement (DTA) will be required. This agreement ensures that the receiving institution or organization will maintain the same level of privacy protection as the IWK.

When describing your plans for long-term data storage and eventual destruction or de-identification, it's crucial to adhere to the IWK's specific data retention policies. For adult clinical trial studies, data must be stored for 25 years. For pediatric studies, data should be stored for either 25 years or 10 years past the age of majority, whichever is longer. For minimal risk studies, data should be retained for five years. Clearly specify in your application how you will comply with these retention periods, how data will be securely stored during this time, and the methods that will be used for destruction or de-identification at the end of the retention period.

Tab 9: Other Ethical Issues

The Other Ethical Issues section allows you to address any additional ethical concerns not covered in previous sections. Use this opportunity to demonstrate your comprehensive consideration of ethical implications in your research.

Tab 10: Application for Access to Personal Information and Personal Health Information for Research Purposes

If your research requires access to personal health information (PHI), use this section to specify the types of records and software systems you need to access. Examples of personal information (PI) include name, address, email address, etc. Examples of personal health information (PHI) include health card number, medical diagnosis, treatment, etc. Indicate the time period for the records to be reviewed and provide expected start and end dates for the project. Attach a specific field/variable list of data to be collected.

Tab 11: Request for Waiver of Consent

The Tri-Council Policy Statement (TCPS 2) provides guidance allowing the REB to approve requests for waiver of consent if they are satisfied that: the research poses no more than minimal risk, there is no likelihood of adverse events, it is impossible or impracticable to obtain

consent, and, when possible and appropriate, participants will be debriefed about the waiver. Under the Nova Scotia Personal Health Information Act (PHIA) waiver of consent for research may be granted if ALL of the following conditions are met:

(i) The research cannot be conducted without the use of the PHI.
(ii) PHI is strictly limited to that necessary to accomplish the research.
(iii) PHI is in the most de-identified form possible for the conduct of the research.
(iv) It must be used in a manner that ensures its confidentiality.
(v) It is impracticable to obtain consent. With the exception "impracticability", consideration of these concepts is a necessary component for all research and as such, these details are requested as part of the ethics application.
(vi) Item (v) above, regarding impracticability, is unique to considerations for waiver of consent. Impracticability is described as "a degree of difficulty higher than inconvenience or impracticality but lower than impossibility".

Please see the REB guidance document 'IWK Research Ethics Board – Impracticability Guide' (found here in the Privacy section) for further details.

Tab 12: Research Registry

If your study will use the IWK research registry to identify participants, describe the type of registry access needed in this section. Specify the criteria for selecting potential participants from the registry and explain how registry participants will be contacted. The research registry planning form needs to be completed and attached. The form can also be found in the attachment tab.

The IWK research registry is a mechanism for patients at the IWK to indicate their willingness to be contacted about potential research participation. When attending clinic, registration staff inquire whether patients are interested in being contacted about future studies. Their preferences are documented in Meditech. Researchers can access this list of possible participants when recruiting for their study.

If your study intends to utilize the research registry for participant identification, please provide the following information in this section:

1. Specify the type of registry access required for your study.
2. Clearly outline the criteria for selecting potential participant from the registry.
3. Describe the process for contacting registry participants, adhering to TCPS2 guidelines on privacy and confidentiality (Chapter 5).

Researchers must complete and attach the registry use form, available in the attachments tab. This form helps ensure compliance with ethical standards for secondary use of information for research purposes (TCPS2 Article 5.5). Note: when using the registry, researchers should be mindful of the ongoing nature of consent (TCPS2 Article 3.3) and respect participants' right to withdraw at any time.

Tab 13: Checklist

The final Checklist section ensures that all necessary documents are attached to your application. This includes the study protocol, information and consent forms, study measures and data collection forms, recruitment materials, scripts and other participant communications, and any other relevant documents such as the Investigator's Brochure, budget, REB fee form, letters of support, consent SOP, CVs for team members, and various certificates (TCPS2, GCP, OCAP). Ensure all required signatures are obtained and that you've attached the delegation log.

If you fail to upload all required documents this could result in the REB delaying the review.

ATTACHMENT TAB

The Attachments tab section is a crucial part of your ethics application process. This section not only provides you with the necessary documents to complete your application but also serves as the platform where you will upload your study documents. Understanding this section thoroughly will ensure a smooth and complete submission of your ethics application.

To begin, familiarize yourself with the essential documents required to complete your study. These include the delegation log, signature page, letter of support template, and research team contact page. These documents form the backbone of your application and provide critical information about your research team and study structure.

Depending on the nature of your study, you may also need to complete additional documents. These might include the REB fee form if your study requires payment of fees, or a self-declared income statement. Be sure to check whether these apply to your specific research project.

To guide you through the application process, several Standard Operating Procedures (SOPs) and guidance documents are available. These include instructions on how to complete the IWK REB application process, a consent template, and SOPs for the delegation log, signature page, letter of support, record management, and review process. These resources are designed to help you navigate the application process effectively and ensure that you meet all necessary requirements.

When it comes to attaching documents to your application, you'll need to provide, at minimum, your study protocol and all required documentation. To add a file, locate and click the "add attachment" button. This will open a separate dialog box where you'll provide details about the document you're uploading.

In the description field, enter the name of the file. It's important to note that this file name will be listed on the approval letter, so choose a clear and descriptive name. Use the browse button to locate and upload the file from your computer.

You'll also need to enter the version date of the document being uploaded. It's crucial that this date matches exactly with the version date listed on the document itself. This ensures version control and helps track any revisions to your documents.

Finally, select the type of document you're uploading from the provided options. This might be a paper consent form, protocol, or any other type of study document.

By carefully managing your documents and following these submission guidelines, you'll help ensure that your ethics application is complete, accurate, and ready for review. Remember, a well-organized and thorough application not only facilitates the review process but also demonstrates your commitment to conducting ethical, well-planned research.

APPROVALS

This section is not currently used by the IWK REB.

LOGS

This section tracks significant activities related to the study file. Three radio buttons allow you to toggle between different logs, each capturing distinct aspects of the file's history:

- **Application Workflow Log**: This log details the workflow and significant activities during the initial application process, including the date and time each activity occurred.
- **Application Log**: This log provides a timeline of key activities that have occurred on the study file after the study's approval. It includes events such as changes to study personnel, submission of amendments, renewals, and other relevant actions, along with the corresponding date and time.
- **Shared Communication**: This section contains a list of all email communications sent from ROMEO. These emails can be accessed using the magnifying glass icon.

ERRORS

This section provides a comprehensive list of all required questions that have not yet been answered. Please ensure these questions are addressed to proceed further. The application cannot be submitted until all the errors have been corrected.

DEFINITIONS

Assent Form: Any child 7 years of age or older should be considered for an Assent form. For ages 7-12, an Assent should be provided for the participant. For ages 13-16, an adolescent

Assent should be provided. Please note age groupings are not firm but are dependent on the children's capacity to consent. Assent should be given whenever possible and the participant should be able to sign the document. Please see Consent and Authorization Documents – Information Sheet and Assent (found here) for guidelines on assent/consent.

Case report forms: Case Report Forms (CRFs) are standardized documents used in clinical research to systematically collect data from each participant in a study. These forms capture a wide range of information, including patient demographics, medical history, treatment details, and outcomes, ensuring that all relevant data is recorded consistently across all participants. CRFs are essential for maintaining the integrity and accuracy of the data collected, as they provide a structured way to document study findings in compliance with regulatory requirements. The information recorded on CRFs is later analyzed to assess the safety and efficacy of the investigational product or intervention being studied. Properly designed and completed CRFs are critical for ensuring the reliability of clinical trial results and supporting the study's overall validity.

Data Collection tools: Data collection tools are instruments or methods used to gather information systematically for research, analysis, or evaluation purposes. These tools vary depending on the nature of the data and the research objectives and can include surveys, questionnaires, interviews, observation checklists, sensors, or software programs. Each tool is designed to capture specific types of data, whether quantitative (e.g. numerical data, measurements) or qualitative (e.g. opinions, behaviors, experiences). The choice of data collection tool is crucial, as it directly impacts the accuracy, reliability, and validity of the data collected, and ultimately influences the findings and conclusions of the research.

Informed Consent Form: A document detailing the necessary information needed for a participant to make the decision as to whether they wish to participate in the proposed study. Informed consent is an ongoing process, and a person's ability to provide consent may change throughout a study's lifetime.

NOL: A Health Canada No Objection Letter (NOL) for research is an official communication issued by Health Canada, indicating that the regulatory body has reviewed a proposed clinical trial or research involving investigational products, such as drugs or medical devices, and has no objections to the study proceeding as described. This letter is a critical step in the regulatory process, ensuring that the research meets safety, ethical, and scientific standards before it begins. The NOL signifies that Health Canada is satisfied with the trial's design, risk assessment, and proposed measures to protect participants, though it does not constitute formal approval or endorsement of the study. Researchers must obtain this letter before commencing the trial in Canada.

***Principal Investigator (PI)*:** A Principal Investigator (PI) is the lead researcher responsible for the design, conduct, and management of a research project, typically in an academic or clinical setting. The PI holds the primary responsibility for ensuring that the research adheres to scientific, ethical, and regulatory standards, and is accountable for the project's overall progress, including the supervision of team members, data integrity, and budget management. Additionally, the PI often serves as the main point of contact for funding agencies, institutional review boards, and other stakeholders involved in the research.

Protocol: The protocol is your comprehensive outline of your study. This is where you detail the scientific aspect of your study and provide the most information. The protocol describes the objective(s), design, methodology, statistical considerations and organization of the study. The protocol describes, among other things, what types of people may participate, the schedule of tests (questionnaires, etc.), and the length of the study.

Recruitment materials: Recruitment material refers to any communication tools or resources used to attract and inform potential participants about a research study. This material can include flyers, brochures, advertisements, social media posts, emails, and websites, all designed to provide key details about the study, such as its purpose, eligibility criteria, potential benefits, and risks. The goal of recruitment material is to engage and motivate individuals to consider participating in the research while ensuring they are fully informed about what participation entails. It's crucial that recruitment material is clear, accurate, and compliant with ethical and regulatory guidelines to protect participants' rights and ensure they can make an informed decision about joining the study.

Researchers: Anyone who conducts research activities falling under the jurisdiction of the IWK Research Ethics Board. A researcher is an individual who systematically investigates and studies materials, sources, or data to establish facts, draw conclusions, and contribute new knowledge or insights to a particular field. Researchers work in various disciplines, including science, social science, humanities, and more, using methods such as experiments, surveys, or qualitative analysis to explore specific questions or hypotheses. They play a critical role in advancing understanding, solving problems, and driving innovation by critically analyzing information, publishing findings, and often collaborating with other experts in their field. Researchers can work independently or as part of a larger team in academic, governmental, or private sector settings.