IWK Research Ethics
Standard Operating Procedures

Document # **RE 8.801**	Title: **Responsibilities of Investigators / Investigator Qualifications and Responsibilities**	Effective Date: **November 19, 2024**
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POLICY STATEMENT

IWK investigators are required to produce evidence of satisfactory completion of the following:

- *TCPS2 certification*
- *OCAP certification (for research involving Indigenous peoples)*

Before approving any research application, the REB must be satisfied that the research will be conducted by individuals appropriately qualified by education, training, and experience to guarantee proper conduct of the research and protection of participants' welfare.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to Investigators, REB Chair, Manager, REB members, and Research Ethics Office (REO) staff

PROCEDURES

Principal Investigators Responsibilities

The Board will require Principal Investigators (PI) assume responsibility and accountability for:

- The personal conduct and/or supervision of the research, and that the research is conducted in compliance with the approved protocol and applicable regulations, guidelines and policies
- Ensuring each member of the research team is appropriately qualified for their role, and that necessary supervision and guidance be available throughout the research project
- Ensuring that for all clinical trials or for research that is considered to be more than

minimal risk, there is at least one appropriately qualified co-investigator or sub-investigator capable of deputizing for the PI in periods of absence

- Adequacy of resources to ensure the research is properly conducted following written standard operating procedures
- Disclosure of any conflicts of interest arising in the course of the research and to follow a management plan agreed with the Chair of the REB
- Ensuring that no part of the research involving actual subject participation will take place prior to REB review and approval
- Ensuring that all study-related correspondence requiring formal approval or other official correspondence with the REB is properly signed and forwarded to the REO. If there is uncertainty about any contract/agreement or other issue, the PI should contact IWK Research & Innovation Advancement for advice
- Ensuring that clinical trials are registered in a registry approved by the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE), and that the details of registration are provided to the REB
- Ensuring that express informed consent, when required, is obtained from participants prior to their enrolment and this be documented using the most current informed consent document approved by REB
- Ensuring adequate, accurate, and secure project records (see 'Record Keeping' below for additional detail)
- The prompt reporting to the Board of any unanticipated problems arising during the research, including protocol deviations, serious unexpected adverse events and privacy breaches
- Ensuring no changes are made in the approved research without first obtaining the Board's approval for such changes, except where necessitated by the need to avoid immediate hazard to participants
- Prompt notification of the Board in cases of premature termination or suspension of the research
- Submission of written summaries of the study status to REB at least annually, or more frequently if required by REB, along with application for continuing review prior to the expiration of current approval, and notification when the research has been completed
- Ensuring the Board is kept apprised of any safety communications received, from any source, relevant to the project (e.g. Safety Monitoring Board Reports)
- Ensuring the REB is kept informed of any material changes which might have bearing on risk or other consideration in the research
- Ensuring the REB is kept informed of any material changes in the status of any member of the research team, such as temporary or permanent departure from the institution; institution of disciplinary procedures; change in medical staff privileges, etc.

Protection of the Rights, Safety, and Welfare of Research Subjects

The PI or other identified qualified individual(s) must be available to provide study subjects with reasonable medical care for any medical problems that arise during participation in the research. Additionally, when participation in the research might impact the subject's health

and/or medical care, the PI should, with the subject's agreement, inform the subject's primary care physician.

When protecting the rights, safety, and welfare of research subjects, the PI must ensure that:

- Either the PI or other identified, qualified person is available to provide reasonable medical care for any untoward event taking place during execution of the research protocol, irrespective of whether or not the event seems immediately related to the research
- Either the PI or another specific qualified person is available to study subjects to answer questions or provide care during the conduct of the research
- All members of the research team adhere closely to the research plan and protocol
- If, for whatever reason, adequate resources to enable safe continuing conduct of the research become unavailable, the research should be suspended forthwith until the deficiencies have been resolved

Principal Investigator Qualifications

Every investigator submitting an application for ethics approval to the REB is required to attach a copy of their current CV, and this CV will be retained by REO.

Where an Investigator's application is required to be signed by the Department/Division/Program Head, the REB will interpret this signature as attesting that the Head:

- Is aware of, and supports, for the project in question
- Considers the project to be feasible and appropriate
- Confirms that the PI responsible for the conduct of the study is qualified by education training and experience

Clinical Trials Regulated by Health Canada

For clinical trials regulated by Health Canada, the REB must be satisfied that there is a Qualified Investigator (QI), that is, the PI must meet Health Canada's criteria for the person responsible to the Sponsor for the conduct of the clinical trial at a particular site, including being entitled to provide health care under the laws of the province where that clinical trial site is located. Further:

- In the case of a clinical trial of a drug to be used for dental purposes only, be a physician or dentist and a member in good standing of a professional medical or dental association
- In any other case, be a physician and a member in good standing of a professional medical association

In the case of an Investigator-Initiated Clinical Trial Application or Investigational Testing Authorization to Health Canada, the PI applying to the REB does not need to be the QI as defined above. There must, however, be a QI for the clinical trial. This person must be clearly designated on the REB application (i.e. listed as a Sub-Investigator).

Record Keeping

The principal investigator must maintain appropriate research-related records, and these records and files must be readily available for inspection by authorized representatives of regulatory agencies, the sponsor, and the IWK REB. These records should include:

- All documents submitted to the REB for approval, along with evidence and date of approval
- A list of qualified persons to whom the principal investigator has delegated research-related duties
- Training documentation for delegated research-related duties
- Signed and dated consent forms for all participants
- All completed data collection forms
- All records of receipt, use, and disposal of investigational drugs or devices
- A participant enrolment log, including the names and research ID numbers of all those who volunteered to participate whether or not they actually ended up or remained as active participants
- Signed and dated CVs for investigators and research staff
- A signature sheet showing signatures and initials of all persons authorized to obtain consent and make entries or corrections on data collection forms
- Reports from internal or external monitors

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 11.3;
2. Health Canada, Division 5, Part C.05.001 of the Food and Drug Act;
3. Health Canada Guidance for Clinical Trial Sponsors: Clinical Trial Applications;
4. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 1.56, 3.1.3 and Section 4.

Revision	Date	Description of changes
0.0	April 01, 2017	Initial Release
0.1	September 01, 2022	Updates as per CHEER Qualification requirements
0.2	February 1, 2023	Updated logo
0.3	August 15, 2024	Updates to Policy Statement, addition of OCAP
0.4	November 19, 2024	Added note regarding compliance with US regulations where applicable & update to responsibility (RIA)