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Documented Institutional Ethics Requirements
[Izaak Walton Killam (IWK) Health Centre]

Scope

The IWK Health Research Ethics Board (REB) is mandated by IWK Health to ensure all research involving human participants carried out under the auspices of IWK Health is of the highest quality, protects the interests of the human participants and of society generally, and complies with the Tri Council Policy Statement Ethical Conduct for Research Involving Human Subjects (TCPS2 - 2022).

Missions and Values

Recognizing the importance of research and the need to ensure the ethical conduct of research, the REB is built upon the guiding core ethical principles of the TCPS2 - 2022: respect for persons, concern for welfare, and justice. The independent functioning of the REB requires REB members and IWK researchers to navigate a course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research through a transparent and accountable process for review of the ethical acceptability of research.

Privacy Considerations

IWK is subject to the provisions of the Nova Scotia Personal Health Information Act ("PHIA") and the Personal Information International Disclosure Protection Act ("PIIDPA").

PIIDPA generally prohibits the access, disclosure, transfer or storage of personal information outside of Canada except with consent of the individual or institutional CEO approval in required circumstances. Any access, disclosure, transfer or storage of research participant personal information outside of Canada should be specifically authorized in the informed consent process. Should an REB of Record identify any circumstances involving a non-consensual access, disclosure, transfer, or storage of personal information outside of Canada related to an IWK study, consultation should be made with the IWK Research and Innovation Advancement office to ensure compliance with PIIDPA.

In considering the collection, use and disclosure of personal health information ("PHI") under PHIA, the REB of Record will review the research submitted to determine if the investigator has access to and/or is using PHI and whether sufficient protections are in place in relation to the PHI including ensuring the research plan addresses the following:

- The purpose for which the PHI will be used
- Limits on the use, disclosure, and retention of the PHI including a description of all individuals who will have access to the information, and why their access is necessary, their roles in relation to the research, and their qualifications, risks to participants should the security of the data be breached, including risks or reidentification of individuals

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- How accountability and transparency in the management of PHI will be ensured

Waivers of Consent

Exceptions to the institutional requirement for subject consent must be approved by the REB of Record in the form of documented approval of a waiver of the consent requirement. REB of Record must be satisfied that

- the research cannot be conducted without using PHI and the use of PHI is limited to that necessary to accomplish the research in the most de-identified form possible for the conduct of the research

Informed Consent Form Requirements

1. Insert the IWK Institutional logos on first and signature page of consent and assent forms
2. Insert IWK's local research coordinator contact on the first page of the consent form (under "Study Doctor")
3. If deidentified data and/or samples will be transferred to other sites for future research, add the following bullet point under the Signatures page: "I consent to the transfer of my deidentified data and/or biological samples to institutions other than this study site"
    a. If applicable regarding data transfer outside Canada, revise sentence "By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside Canada." *Replace disclosure with transfer ("you are consenting to the transfer of your coded information").*
4. Indicate length of time study data will be retained
5. If the study includes future uses of data, add the following bullet point in the signature section:

    I agree that my data collected (note that biological samples are not considered participant data) for this research may be used in future research, that I may or may not be contacted about, within or beyond the general area of research of the current study.

When the statement "In the case of research-related side effects or injury, medical care will be provided by your doctor" (or variations of it) is present in the provincially-approved consent form, it must be deleted from the IWK consent and replaced with the following language or equivalent approved by the REB of Record: *"Nothing written here about treatment or compensation in any way alters your right to claim damages. Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. If you become ill or injured as a direct result of participating in the study, necessary medical treatment will be available at no additional cost to you. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-7879, Monday to Friday between 8:00 a.m. and 4:00 p.m."*

6. Under the confidentiality section, revise the sentence "The research ethics board who oversees the ethical conduct of this study in Ontario" to *"The research ethics board who oversees the ethical conduct of this study in Canada"* (*Replace "Ontario" with "Canada"*)

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Assent Consent Form Requirements

For studies with participants under the age of 16 where there is pregnancy testing, assent forms for individuals undergoing the testing must include the following:

*"*For a positive pregnancy test, the study doctor will contact you. Your family will not be informed without your permission. The study doctor will discuss test results and ensure you have information to make an informed decision about any follow up that may be needed.

If you are pregnant, the study doctor may need to contact appropriate authorities or clinics at this institution to discuss this with them to ensure you receive appropriate care.

If you become pregnant during the study, you may be withdrawn from the study. We may be required to continue to collect some of your health information."

1. Under the "Will any part of the study hurt or be scary?" section of the assent form template, when applicable, **add** the following statement to report any harm that may be revealed as a result of the research"

> *"Please note that, in the rare event that we should learn anything during the course of your participation in our study that would cause us to believe that you are in danger of harming yourself or others, Dr _____ would follow-up with you directly. Further, in accordance with provincial laws, in the rare event that we learn anything during the course of your participation in our study that would cause us to believe that you are being harmed, we would be required to report this to a child protection agency. If any issues do arise as a result of your participation in our study, you are encouraged to contact Dr. _____ at (902) 470-_____"*

Capacity assessments cannot be based on age. The ability to consent must be based strictly on the individual's capacity to consent. In addition, capacity assessments must be conducted by a NS-licensed medical practitioner (physician/resident). As consent is an ongoing process, capacity for consent may change.

Access to Medical Records and Obtaining Consent

Requests to review IWK participant's health records or obtain de-identified data for research purposes must be directed to Decision Support Services at the IWK in keeping with IWK policies and procedures.

Research Agreements

All research studies that involve: (1) the collection and disclosure of IWK staff and/or patient information, and/or (2) the participation of IWK staff and/or patients requires an agreement that at minimum provides provisions for the protection of staff and/or patient information and protection of staff and/or patients throughout the conduct of the study. IWK must enter into an agreement for the research before it can participate in such a study. The review, negotiation and execution of all research agreements (including confidentiality agreements/confidential disclosure agreements and non-disclosure agreements) is managed through Research & Innovation Advancement

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(RIA) Contracts. All new agreements and applicable amendments should be submitted to the RIA Contracts team via ROMEO contracts.

Data Storage and Retention

Data storage and retention will follow IWK's policy on managing health information and research records. For clinical trials, data must be retained for 25 years after close of the clinical trial. For non-interventional research the standard retention period is 5-years post publication or 5 years following close of the study, whichever is longer.

Ownership, Control, Access and Possession (OCAP)

The IWK respects and supports First Nations' information governance. If the research involves a First Nation and their community members the investigator must have completed the Fundamentals of OCAP course.

Clinical Trials Ontario

CHEER
Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research
Collaboration pancanadienne pour la santé des enfants: Efficacité et excellence dans la révision éthique de la recherche

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SRERS Administration
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Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CHEER/CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial/CHEER Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: frank.macmaster@iwk.nshealth.ca
Role: Institutional Representative

Email: kathleen.leadon@iwk.nshealth.ca
Role: Institutional Representative

Email: joanne.street@iwk.nshealth.ca
Role: Institution Admin

This access is automatically granted when the Centre Initial Application is created. **When Izaak Walton Killam (IWK) Health Centre is the Provincial/CHEER Applicant site the research team should immediately create the CIA for Izaak Walton Killam (IWK) Health Centre (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CHEER/CTO Stream:

Title:	Mrs.
First Name:	Kathleen
Surname:	Leadon
Organization:	IWK Health
Address:	5850/5980 University Avenue, PO Box 9700
City:	Halifax
Province/State:	Nova Scotia
Postcode/Zip:	B3K 6R8
Telephone:	902-470-3706
Fax:	N/A
Email:	Kathleen.leadon@iwk.nshealth.ca

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The Secondary Institution Representative must be indicated as follows in the applications within CHEER/CTO Stream:

Title:	Dr.
First Name:	Frank
Surname:	MacMaster
Organization:	IWK Health
Address:	5850/5980 University Avenue, PO Box 9700
City:	Halifax
Province/State:	Nova Scotia
Postcode/Zip:	B3K 6R8
Telephone:	902-470-6958
Fax:	N/A
Email:	Frank.macmaster@iwk.nshealth.ca