IWK Research Ethics
Standard Operating Procedures

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Term / Acronym	**Definition**
Ad hoc advisor	A person with relevant and competent knowledge and expertise consulted by a research ethics board for a specific research ethics review, and for the duration of that review, in the event that the board members lack specific expertise or knowledge to review with competence the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the research ethics board and is not counted in the quorum or allowed to vote on board decisions. (TCPS2)
Adverse event (AE)	Any untoward medical occurrence in a research participant administered an investigational product, including an occurrence which does not have a causal relationship with this product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.
Amendment	A written description of a modification or change(s) to or formal clarification of the previously approved research.
Applicable Regulatory Requirement(s)	Any law(s) and regulation(s) addressing the conduct of clinical research, including U.S. regulations as applicable.
Approval Period	For annual reviews, the approval period is calculated as the one-year anniversary from the date of the letter confirming that the research was reviewed and approved at a convened REB meeting

	or through a delegated review procedure. When the REB determines that review more frequently than annually is required, the approval period will be determined by the REB
Audit	A systematic and independent examination of research related activities and documents to determine whether the evaluated research related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Assent of the Child	An expression of the minor's willingness to participate in the proposed research.
Audit Trail	Documentation that allows reconstruction of the course of events.
Authorized Signatory/Signing Authority	Individual authorized to sign documents on behalf of the REB.
Blinding/Masking	A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).
Canadian Institutes of Health Research (CIHR)	The Canadian Institutes for Health Research is Canada's federal funding agency for health research. CIHR is composed of 13 Institutes.
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
Clinical Trial/Study	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
Compliance	Adherence to all the study-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity. (ICH)
Conflict of Interest (COI)	The incompatibility of two or more duties, responsibilities or interests (personal or professional) of an individual or an institution as they relate to the ethical conduct of research, such that one

	cannot be fulfilled without the other. (TCPS2) A conflict of interest may arise when activities or situations place an individual (i.e., researcher or REB member) or institution in circumstances that create a risk that an independent observer would reasonably question whether professional judgments or actions regarding a primary interest may be unduly influenced by a secondary interest thereby creating a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests.
Data safety monitoring board (DSMB)	A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of research study procedures, and monitoring the overall conduct of a research study. (TCPS2)
Delegated Review	Under a delegated review procedure, the review may be performed by the Research Ethics Board (REB) Chair or delegated to one or more reviewers from among the REB members. Delegated review procedures may be used for certain kinds of research involving minimal risk, and for minor changes in approved research.
Direct Access	Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor’s proprietary information.
Essential Documents	Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced
Expedited review (also referred to as delegated review):	The level of REB review assigned to minimal risk research studies. Expedited review procedures also may be used for the review of: centre-specific applications for which the main provincial submission already has undergone full REB review; researcher responses/affirmation that conditions of REB approval have been met; minor changes in approved research; and, continuing review applications that meet the expedited review criteria. Under an expedited review procedure, one or more qualified reviewers are selected from among the REB membership to conduct the review.
External Safety Report	A Report of a serious unexpected adverse drug reaction that occurs at any other centre involved in a study using the same investigational agent.
Food and Drug Administration (FDA)	U.S. federal agency that oversees trade in and the safety of food and drugs in the United States.

Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Human genetic research	The study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.
International Conference of Harmonisation: Good Clinical Practice Guidelines (ICH:GCP)	An international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
International Air Transportation Association (IATA)	An international industry trade group of airlines with the mission to represent, lead, and serve the airline industry.
Identifying information	Information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual.
Impartial Witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.
Impracticable	Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. (TCPS2)
Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in the biorepository program, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. (ICH definition)
Informed Consent Form (ICF)	A process by which a subject voluntarily confirms his or her willingness to participate in a particular research study, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Inspection	A systematic examination and evaluation of study-related activities and documents in comparison to specified requirements and standards.
Investigational product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Investigator/Principal (PI) Investigator	A person responsible for the conduct of the study or clinical trial at a site. If a study or trial is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the principal investigator.
Legally Acceptable Representative	An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical study.
Local adverse event	Those adverse events experienced by study participants enrolled by the Investigator at the centre under the jurisdiction of the REB.
Manager	This refers to the manager who oversees operations of the IWK Research Ethics Office (REO) and administrative functions of the IWK REB.
Medical device trials	Clinical trials that test the safety and/or efficacy of one or more instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition or the restoration, correction or modification of body function or structure. (TCPS2)
Minimal risk research	Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Multicentre Study	A clinical study conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
Noncompliance	Failure to follow applicable guidelines and regulations governing human research; failure to follow the protocol approved by the REB, or failure to follow stipulations imposed by the REB as a condition of approval.
Non-local adverse event	Those adverse events experienced by research participants enrolled by Investigators at other centres/institutions outside the

	REB's jurisdiction.
Participant	An individual whose data or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as "human participant" and in other policies/guidance as "subject" or "research subject." (TCPS2)
Periodic safety update or summary report	A summary report, created by the sponsor, listing all of the reported unexpected serious adverse events that have occurred in a given reporting period, and which includes any significant areas of concern and the evolving safety profile of the investigational product. Adverse events that are considered to be unanticipated problems should be reported immediately.
Personal health information (PHI)	Identifying health information about an individual in either an oral or in a recorded form.
Personal Health Information Act (PHIA)	Nova Scotia's Privacy Legislation pertaining to personal health information.
Principal Investigator (PI)	The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. (TCPS2)
Proportionate review	Given that research involving humans spans the full spectrum of risk, from minimal to significant, a crucial element of REB review is to ensure that the level of scrutiny of a research project is determined by the level of risk it poses to participants. A reduced level of scrutiny applied to a research project assessed as minimal risk does not imply a lower level of adherence to the core principles. Rather, the intention is to ensure adequate protection of participants is maintained while reducing unnecessary impediments to, and facilitating the progress of, ethical research.
Protocol deviation	Divergence or departure from the expected conduct of an approved study not consistent with the current REB approved version of the research protocol, consent document or addenda.
Qualified Investigator	The person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located and who is: (a) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case, a physician and a member in good standing of a professional medical association.
Quorum	The minimum number of REB members that must be present in order for the IWK REB to review and make its determination regarding submitted research. A minimum of five members are required, including men and women:

	- 2 members with expertise in relevant research - 1 members knowledgeable in ethics - 1 member in relevant law - 1 community member
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Recusal	Conflicted REB members leave the REB meeting before the vote on the item with which they have a conflict.
Research	An undertaking intended to extend knowledge through a disciplined inquiry or investigation. (TCPS2)
Research ethics board (REB)	A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices. (TCPS2)
Research Ethics Board Chair (REB Chair)	Chair of the Research Ethics Board (REB) will be nominated by the REB membership, and approved by the appropriate Board as outlined in the REB Terms of Reference for each institution.
Research Ethics Office (REO)	Refers to the IWK Research Ethics Office.
Research Ethics Office Manager	This refers to the manager who oversees operations of the IWK Research Ethics Office (REO) and administrative functions of the IWK REB.
Research Ethics Office (REO) staff	Refers to the staff of the IWK Research Ethics Office.
Risk	The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties. (TCPS2)
Serious Adverse Event (SAE)	Any adverse event that is medically significant that: - results in death - is life-threatening - requires inpatient hospitalization or prolongation of existing hospitalization - results in persistent or significant disability/incapacity - is a congenital anomaly/birth defect - other medically important condition
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies,

	microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical study).
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor-Investigator	An individual who both initiates and conducts, alone or with others, a clinical study, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
Standard Operating Procedures (SOPs)	Detailed, written instructions to achieve uniformity of the performance of a specific function.
SOP Index	List of the current, finalized standard operating procedures.
SOP Template	Document used to standardize the format of all standard operating procedures.
SOP Training Record	Document used to record SOP training.
Sponsor-Investigator	An individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a research participant. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
Subject Identification Code	A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other study related data.
Suspension	A temporary halt to all research activities pending future action by the REB, by the sponsor and/or by the Investigator.
Termination	A permanent halt by the REB, by the sponsor and/or by the Investigator to all or some research activities.
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans(TCPS2)	A joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada(NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC).
Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the

	pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Forms/Records:

Form #	Form/Record Name
SOP 102	Glossary

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added US regulatory compliance requirements & update to responsibility (RIA)