Aboriginal peoples: Persons of Indian (First Nations), Inuit, or Métis descent, regardless of where they reside and whether or not their names appear on an official register. In the international context, the term comparable to Aboriginal peoples is Indigenous peoples.

Ad hoc advisor: a person with relevant and competent knowledge and expertise consulted by an Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review, in the event that the REB 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 REB and is not counted in the quorum or allowed to vote on REB decisions.

Adverse event (AE): any untoward medical occurrence in a research participant, administered 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.

> **Local adverse event:** those adverse events experienced by research participants enrolled by the Investigator at the centre(s) under the jurisdiction of the Research Ethics Board (REB).
>
> **External (non-local) adverse event:** those adverse events experienced by research participants enrolled by Investigators at other centres/organizations outside the REB's jurisdiction.

Amendment: a written description of a modification or change(s) to the previously approved research study. Amendments include any changes to the protocol or related research documents, such as changes to the consent form, revisions to the Investigator Brochure, updated participant material, etc.

Anniversary date (also referred to as expiry date): the first day that the Research Ethics Board (REB) approval of the research is no longer valid without further review and approval by the REB. When the REB determines that review more than annually is required, the anniversary date will be determined by the REB.

Appeal: A process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research.

Approval period: For annual renewals, 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 Full Board 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 (i.e., six months from the date of the approval letter).

Assent: affirmative agreement to participate in research by an individual unable to provide consent.

Audit: A systematic and independent examination of study-related activities and documents, to determine whether the evaluated activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol and all applicable standards.

- **External Audit**: An audit performed by an external party such as the study sponsor (or its agents) or the IWK Research Ethics Board.

Authorized signatory: individual(s) authorized to sign documents on behalf of an organization.

Authorized third party: Any person with the necessary authority to make decisions on behalf of the prospective participant who lacks the capacity to consent to participate, or to continue to participate, in a particular research project. (Also known as a "legally acceptable representative" or "substitute decision-maker").

Biobank: a collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected.

Capacity: The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.

Circle of Care: Regulated health professionals who are part of an individual's healthcare team.

Confidentiality: refers to the agreement between the Investigator and the participant as to how personal data will be managed and used, and an ethical and/or legal responsibility to safeguard information from unauthorized use, disclosure, modification, loss or theft. The term also refers to the REB's ethical and/or legal responsibility to safeguard information in its custody from unauthorized use, disclosure, modification, loss or theft.

Conflict of Interest (COI): circumstance of a person (e.g., Investigator or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

Example: COI may occur when an individual's judgments and actions or an organization's actions in relation to research are, or could be, affected by personal, organizational or other interests, including, but not limited to, business, commercial or

financial interests, whether of individuals, their family members, their friends, or their former, current or prospective professional associations or of the organization itself.

Examples of secondary interests for an Investigator include the following:

- Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;
- Acts as an officer, director, or agent of the sponsor;
- His/her job status or compensation is impacted by the research (e.g., payment for speaking or leading study groups on behalf of the sponsor);
- Is receiving a finder's fee for the recruitment of research participants;
- Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;
- Has (or family, spouse, close relationships) any equity interest in the sponsor;
- Receives payments of other sorts, which are made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);
- Is intending to recruit his/her own patients as research participants;
- Has identified him or herself for any other reason as having a conflicting interest (i.e., organizational conflict that may impact the research).
- Examples of secondary interests for an REB member include the following:
- Is an Investigator or sub-investigator on the protocol;
- Is directly involved in the conduct of the research;
- His/her job status or compensation is impacted by the research (e.g. research coordinator, payment for speaking/leading study groups on behalf of the sponsor);
- Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;
- Acts as an officer, director, or agent of the sponsor;
- Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;
- Has any equity interest in the sponsor that when aggregated for the member and the member's spouse and dependent children;
- Any equity interest in the sponsor (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices);
- Significant payments of other sorts, which are payments made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);
- Is in direct competition with the Investigator of the research project for limited resources, funding, sponsorship, or research participants; acts as a consultant for the sponsor; is considered a personal or professional adversary of the Investigator;

- Has identified him or herself for any other reason as having a conflicting interest.

Consent: See Informed Consent.

Continuing research ethics review (also referred to as "continuing review"): any review of ongoing research conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.

Controlled forms: documents that require formal change control, and that form part of the permanent record of Research Ethics Board (REB) operations and processes.

Custodian: An individual or organization listed in the Personal Health Information Act and its regulations including, but not limited to:

- A regulated health professional in private practice;
- A District Health Authority/IWK;
- A pharmacy licensed in Nova Scotia;
- A continuing care facility.

Data linkage: the merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes.

Data and 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 procedures, and monitoring the overall conduct of the research.

De-identification: means to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.

Delegated review (also referred to as expedited review): the level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from among the REB membership to conduct the review.

Designee: may refer to a member of the Research Ethics Board (REB) or to the REB Office Personnel depending on the context of the statement and the accompanying requirements of the organization**.**

Electronic Signature (e-signature): Any electronic means that indicates either that a person adopts the contents of an electronic message, or more broadly that the person

who claims to have written a message is the one who wrote it (and that the message received is the one that was sent by this person).

- **Scanned Signature:** A digital copy of a signature (converted to an electronic image file) derived from an original hand-written version.

Embryo: A human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended. It also includes any cell derived from such an organism that is used for the purpose of creating a human being.

Emergency preparedness plan: Plans that detail an institution's policies and procedures for addressing research ethics review during public health outbreaks, natural disasters, and other publicly declared emergencies.

Full Research Ethics Board (REB) review: the level of Research Ethics Board (REB) review assigned to above minimal risk research studies. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving human participants.

Fetal tissue: membranes, placenta, umbilical cord, amniotic fluid, and other tissue that contains genetic information about the fetus.

Fetus: a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.

Human biological materials: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.

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.

Human reproductive materials: a sperm, ovum, or other human cell, or a large gene, including part of any of them.

Identifiable information: information that may reasonably be expected to identify an individual, alone or in combination with other available information; also referred to as "personal information."

Impartial: without prejudice or bias, fair; a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person over another.

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.

Incentive: anything offered to research participants, monetary or otherwise, to encourage participation in research.

Incidental findings: unanticipated discoveries made in the course of research that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are discovered, Investigators have an obligation to inform the participant.

Informed Consent: The voluntary, knowledgeable agreement of the individual or, if the individual lacks capacity, their SDM with what is being done or proposed in relation to PHI. Consent can be express or implied. Express consent is given either verbally or in writing.

Informed Consent Form (ICF): A document confirming the research participant's willingness to participate in a particular research study.

Inspection: a systematic examination and evaluation of study-related activities and documents in comparison to specified requirements and standards.

Institutional conflicts of interest: an incompatibility between two or more substantial institutional obligations that cannot be adequately fulfilled without compromising one or another of the obligations

Investigational product: refers to new or new uses of drugs, biologics, medical devices or natural health products.

Investigator/Principal Investigator: the 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 a research team who is responsible for the conduct of the research, and for the actions of any member of the research team (also known as "Qualified Investigator" or "Researcher").

Mature minor: is an individual who demonstrates adequate understanding and decision-making capacity.

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.

Minimal risk: 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.

Minor change: any change that would not materially affect an assessment of the risks and benefits of the research or the integrity of the data, and does not substantially change the specific aims or design of the study.

Multi-centred: multi-centre means that the research is reasonably expected to be conducted at more than one centre.

Natural health product (NHP) trial: a clinical trial testing the safety and/or efficacy of one or more natural health products (NHP). The term NHP is used to describe substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines.

Noncompliance: failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.

Non-controlled forms: documents that are not part of the permanent record of Research Ethics Board (REB) operations and processes. Non-controlled forms also will contain version dates.

Ongoing research: research that has received Research Ethics Board (REB) approval and has not yet been completed.

Organizational Official: a senior official who signs an organization's human participants' assurance, making a commitment on behalf of the organization to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human participants, and with Health Canada regulations.

Participant: A person about whom a researcher obtains (1) data through intervention or interaction with the individual or the individual's cadaver, remains, tissues, biological fluids," embryos or fetuses, or (2) identifiable private information (e.g., health information). The term "subject" may also be used.

> **Local Participant:** a research participant enrolled by the investigator at one or more centres under the jurisdiction of the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

Patient safety events: all patient related healthcare adverse and near miss occurences (excuding staff occupational health and safety events) are investigated and analysed by the Risk Management team. Serious occurrence reviews are conducted as necessary. The occurrence reporting system is managed and monitored by the Risk Management team. Patient safety events must be entered in the Nova Scotia Health Authority (NSHA) Patient Safety Reporting System as per policy CH 100-035.

Periodic safety update report (PSUR): 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.

Personal Health Information (PHI): Identifying information, (i.e. information that identifies or could reasonably be used to identify an individual either alone or with other information), whether living or deceased, and in both recorded and unrecorded forms, if the information relates to:

- The physical or mental health of the individual, including information that consists of the health history of the individual's family,
- The application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,
- Payments or eligibility for health care in respect of the individual,
- The donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
- The individual's registration information, including the individual's health-card number,
- Identification of an individual's substitute decision-maker.

Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

Personal Health Information Act (PHIA): Nova Scotia's legislation that governs the access, storage, disclosure and transportation of personal information outside of Canada, including personal health information.

Personal information (also referred to as "identifiable information"): information that identifies an individual and/or for which it is foreseeable that may reasonably be expected to identify an individual, alone or in combination with other available information.

> **Directly identifying information**: the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
>
> **Indirectly identifying information:** the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic).
>
> **Coded information:** direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Investigator retains a list that links the

participant's code name with their actual name so data can be re-linked if necessary).

Anonymized information: the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

Anonymous information: the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Placebo-controlled trials: a clinical trial designed to test the safety and/or efficacy of a pharmaceutical product.

Pharmaceutical product: is any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of disease, disorders, or other illness.

Placebo: an inactive substance or intervention that resembles the comparable active substance or intervention.

Policy: a written statement that provides direction for decision-making, prescribes limits, identifies responsibility and accountability, and is secondary to existing legislation and bylaws.

Principal Investigator: see Investigator.

Privacy: an individual's right to be free from intrusion or interference by others. In the context of personal information, privacy is about having the ability to control or influence the way in which information about you is collected, used and disclosed by consenting to or withholding consent for, the collection, use and/or disclosure of information.

Privacy breach: Inappropriate or unauthorized access, collection, use, disclosure, copying, modification, retention, or disposal of personal health information. Privacy breaches may be accidental or intentional. Examples include, but are not limited to:

- Loss and theft of PHI;
- Faxing PHI to the wrong fax number;
- Viewing PHI without a work related reason, even though the PHI was not shared with others, etc.

Proportionate approach to research ethics review: the assessment of foreseeable risk to determine the level of scrutiny the research will receive (i.e., delegated review for minimal risk research or full Research Ethics Board (REB) review for research above minimal risk), as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.

Protocol deviation (minor): is considered to be any deviation from applicable regulatory requirements or REB-approved documents, policies, and/or processes that does not impact participant safety, confidentiality, or willingness to continue in the study, and/or the integrity of study data. Examples include visits / tests conducted outside specified windows, date errors on consent forms, or failure to meet reporting timelines.

Protocol violation (major): are deviations from applicable regulatory requirements or REB-approved documents, policies, and/or processes that impact data integrity or participant safety, privacy / confidentiality, or willingness to continue in the study. Examples include: obtaining informed consent with an outdated or unapproved version of the consent form; beginning study procedures before consent was obtained; enrolling participants who didn't meet eligibility criteria; omitting key protocol-required tests or procedures; medication errors, including prescribing a contraindicated medication; using the wrong survey instrument; or using or releasing personal information without the participant's consent.

Publicly available information: Any existing stored documentary material, records or publications, which may or may not include identifiable information, and that has no restrictions on its use or distribution, or that may be released under certain legal conditions.

Publicly declared emergency: An emergency situation which, due to the extraordinary risks it presents has been proclaimed as such by an authorized public office (in accordance with legislation and/or public policy). Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. Examples include hurricanes and other natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies.

Qualitative research: an approach that aims to understand how people think about the world and how they act and behave in it. This approach requires researchers to understand phenomena based on discourse, actions, and documents, and how and why individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter.

Quorum: a simple majority of Research Ethics Board (REB) members (50% + 1), who collectively have sufficient expertise in the scientific, methodological and clinical areas of the research under review and are knowledgeable about relevant ethical and legal matters. The quorum will include at least one community member and a member whose primary experience and expertise are in a non-scientific discipline. Quorum includes REB members participating by telephone or video conference.

Reportable event: includes anything that could significantly impact the conduct of the research or alter the Research Ethics Board's (REB) approval or favourable opinion to continue the research.

Research Ethics Board (REB) of record: the Research Ethics Board that has been delegated authority for the ethics review and ethical oversight of a research study.

Research Ethics Board (REB): a body of Investigators, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an organization to review the ethical acceptability of all research involving humans conducted within the organization's jurisdiction or under its auspices.

Research Ethics Office Staff: refers to the staff of the Research Ethics Office including the Manager, Ethics Coordinator(s), and Administrative Coordinator.

Research Misconduct: Actions that have been committed intentionally, knowingly, recklessly or without due consideration deemed reasonable in the circumstance and that have been proven by a preponderance of evidence. Research Misconduct includes any practice that seriously deviates from commonly accepted principles and standards for proposing, conducting or reporting Research, including:

- Deception
- Fabrication
- Falsification
- Destruction of Research records
- Plagiarism
- Redundant publications
- Invalid authorship
- Inadequate acknowledgement
- Mismanagement of Conflict of Interest
- Noncompliance with relevant policies, laws or regulations
- Failure to obtain appropriate approvals, permits, or certifications.

Research: an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Researcher: 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. (Also known as "Qualified Investigator").

Researcher's Portal (ROMEO database): the ROMEO Researcher Portal is a web based system established to provide electronic submission, review and approval processes for the NSHA REB and grant/award applications. It may be accessed by research team members and supports collaborative editing and development of applications, REB submission, review and approval processes, and ongoing oversight of REB related activities.

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.

Secondary use: the use in research of information or human biological materials originally collected for a purpose other than the current research purpose.

Suspected Unexpected Serious Adverse Reaction (SUSAR): An adverse event that is serious (resulted in death, required hospitalization or prolonged an existing hospitalization, resulted in incapacity or disability, birth defect or jeopardized the participant or required intervention to prevent one of these criteria) and unexpected (not consistent with risks described in the study documents) and related or possibly related to participation in the research.

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.

Standard operating procedure (SOP): document used to standardize the format of all standard operating procedures. Written statements that typically describe a series of steps required to complete various tasks.

Substitute Decision Maker (SDM): The legally appointed substitute decision maker able to make treatment decisions when the patient is incapable. (For more information on determining the appropriate SDM, refer to the Consent to Treatment policy, CH 30-045).

Suspension: a temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor and/or by the Investigator or his/her research team.

Termination: a permanent halt by the Research Ethics Board (REB), by the sponsor and/or by the Investigator to all or some research activities.

Unanticipated issues: issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the Investigator in the research proposal submitted for research ethics review.

Unanticipated problem: any incident, experience, or outcome (including an adverse event) that meets **all** of the following criteria:

- ***Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the Research Ethics Board (REB) approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the research participant population being studied; **and**

- **+Related or possibly related** to participation in the research, (possibly related means there is a reasonable possibility that the incident, experience, or outcome

may have been caused by the [investigational product(s)] or procedures involved in the research); **and**

• Suggests that the research **places research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

***Unexpected:** an event is “unexpected” when its specificity and severity are not accurately reflected in the protocol-related documents such as the Research Ethics Board (REB) approved research protocol, the Investigator Brochure, or the current REB approved informed consent document, or other relevant sources of information such as product labelling and package inserts; or when the event is not associated with the expected natural progression of any underlying disease, disorder, predisposing risk factor, or condition of the participant(s) experiencing the adverse event.

+Related to the research procedures: an event is “related to the research procedures” if in the opinion of the Investigator or sponsor, the event was more likely than not to be caused by the research procedures.