Glossary of Terms

Above minimal risk health research: research in which the probability and magnitude of possible harms implied by participation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research.

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

Adverse event (AE): an unfavourable medical occurrence in a research participant. The adverse event does not necessarily have a causal relationship with the intervention or investigational product. An AE can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of an intervention or investigational product, whether or not directly related.

- **Local adverse event:** those adverse events experienced by research participants enrolled by the Researcher at the centre(s) under the jurisdiction of the Health Research Ethics Board (HREB).
- **Non-local (external) adverse event (EAE):** those adverse events experienced by research participants enrolled by Researchers at other centres/organizations outside the HREB's jurisdiction.

Alternate member: a formally appointed voting member of the Health Research Ethics Board (HREB) who may substitute for a regular member of the HREB but who is not expected to attend every HREB meeting. An alternate HREB member's presence at the HREB meeting in the place of an absent regular HREB member is used to establish quorum.

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.

Appeal board: a board consisting of 5 members of the appeal panel that may consider the matter of an appeal.

Appeal panel: a panel of persons appointed under section 17 of the Health Research Ethics Act to act as members of appeal boards.

Application for reconsideration: the process by which a principal investigator who is dissatisfied with a decision of the research ethics board or a research ethics body may request that it reconsider its decision.

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

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").

Board of record: the qualified research ethics board that has been delegated authority for ethics review and ethical oversight of a research study.

Business day: "business day" means a day that is not a Saturday, Sunday or a holiday;

Competent Canadian research ethics body: means a body that

(i) is constituted in a Canadian jurisdiction,

(ii) is affiliated with a university, hospital, government or government agency,

(iii) is a not-for-profit body,

(iv) adheres to the requirements of the tri-council policy statement, and

(v) consists of at least 5 members, of whom at least

(A) 2 persons have expertise in relevant research disciplines, fields, and methodologies covered by the body,

(B) one person is knowledgeable in ethics,

(C) one person is knowledgeable in the law and is not the legal counsel or risk manager of the university, hospital, government or government agency with which the body is affiliated, and

(D) one person has no affiliation with the university, hospital, government or government agency with which the body is affiliated;

Confidentiality: refers to the agreement between the Researcher 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 HREB'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., Researcher or Health Research Ethics Board (HREB) 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.

Continuing research ethics review (also referred to as "continuing review; continuing oversight"): any review of ongoing research conducted by the Health Research Ethics Board (HREB) occurring after the

date of initial HREB approval, or HREA acknowledgement and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with sections 13-20 of the HRE Act.

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

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.

Debriefing: The full disclosure of the research purpose and other pertinent information to participants who have been involved in research employing partial disclosure or deception. Debriefing is typically done after participation has ended, but may be done at any time during the study.

Delegated review (also referred to as expedited review): the level of Health Research Ethics Board (HREB) 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 HREB membership to conduct the review.

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

Documented Institutional Ethics Requirements: specific ethical, privacy, and operational requirements that must be met before a research study can proceed at a given site.

Expiry date: the first day that the Health Research Ethics Board (HREB) approval of the research is no longer valid without further review and approval by the HREB. When the HREB determines that review more than annually is required, the expiration date will be determined by the HREB (e.g., six months from the date of the approval).

Gender diversity: representation of people of different gender identities and expressions

Health research: means research activities in relation to human health, health care and health care systems involving

(i) human beings as research participants,

(ii) health care information respecting human beings, and

(iii) human biological material;

Health Research Ethics Board: the research ethics board established by section 8 of the Health Research Ethics Act.

Full Health Research Ethics Board (HREB) review: the level of Health Research Ethics Board (HREB) review conducted by the full membership of the HREB.

Health Research Ethics Act (HRE Act): the law governing ethics review of human health research in Newfoundland and Labrador.

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.

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, Researchers have an obligation to inform the participant.

Indigenous peoples: In Canada, the term "Indigenous peoples" refers to persons of Indian (First Nations), Inuit, or Metis descent, regardless of where they reside and whether their names appear on an official register. In Canada, a comparable term, "Aboriginal peoples," is also used in certain contexts.

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.

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.

Multi-jurisdictional research: research involving multiple institutions and/or multiple research ethics boards. It is not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or under the auspices of a single institution.

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.

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

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

Notification Process: Process by which a person seeking to conduct health research activities in Newfoundland and Labrador where the activities do not exceed minimal risk, are subject to a current research ethics approval, demonstrated by an approval letter granted by a competent Canadian research ethics body issued within the previous 6 months. The health research will come within the supervisory jurisdiction of the HREA.

Ongoing research: research that has received Health Research Ethics Board (HREB) 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: 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."

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.

Person knowledgeable in privacy: a person who is knowledgeable in privacy is someone who has worked professionally in the field of privacy for 3-5 years and who has had significant involvement with either health research or health information privacy.

Personal health information: Personal health information (PHI), is a subset of **Personal information** which is identifiable information about an individual. (See "Identifiable information" which also is "personal information")

Personal health information is identifying information about an individual in either an oral or in a recorded form, if the information:

- Relates to the individual's physical or mental health, including family health history;
- Relates to the provision of health care, including the identification of persons providing care;
- Is a plan of service for an individual requiring long-term care;
- Relates to payment or eligibility for health care;
- Relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances;
- Is the individual's health number; or
- Identifies 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 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 Researcher 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.

Principal investigator: means the person who has the principal responsibility for initiating and overseeing the conduct of a health research project.

Privacy: an individual's right to be free from intrusion or interference by others.

Privacy refers to persons and their interest in controlling the access of others to themselves (their personal information).

Privacy breach: the unauthorized collection, use, or disclosure of personal information or personal health information (PHI) in the custody and control of an individual or a Health Information Custodian (HIC) or in the custody and control of the organization or its affiliated partners.

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 Health Research Ethics Board (HREB) 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: the term protocol deviation is not well defined by regulations or guidelines, but deviations are identified as any unplanned or unforeseen change to a Health Research Ethics Board (HREB) approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol.

Quorum:

Quorum shall include at least five (5) voting members, including (at minimum):

- two (2) members with expertise in the relevant disciplines, fields and methodologies covered by the HREB
- one (1) member knowledgeable in ethics
- one (1) member from the community who has no affiliation with the organization(s), and who is not part of the immediate family of a person who is affiliated with the organization
- one (1) member knowledgeable in the law related to health research involving human subjects. This person must not be legal counsel or risk manager for the institution where the research will be conducted

For research subject to the US Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.

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

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 or Principal Investigator").

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 organization to review the ethical acceptability of all research involving humans conducted within the organization's jurisdiction or under its auspices.

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

Research ethics body: a not-for-profit, TCPS2 adherent, independent committee operating within Newfoundland and Labrador that reviews research involving human participants to ensure that it meets ethical standards and protects participants' rights and that has been approved by the HREA under section 9 of the HRE Act.

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.

Substantive changes: any modifications to a research project that:

i. may result in an increase of risk to research participants and may affect their rights, safety, or well-being.
ii. substantially alter the nature of the approved research.

Summary Review: a shortened review process by the HREB for health research that has received prior approval from a not-for-profit Canadian research ethics body in another jurisdiction. The health research will come within the supervisory jurisdiction of the HREA for all purposes if approval is granted.

Suspension: a temporary or permanent halt to all research activities pending future action by the Health Research Ethics Board (HREB), by the sponsor and/or by the Researcher.

Termination: a permanent halt by the Health Research Ethics Board (HREB), by the sponsor and/or by the Researcher 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 Researcher 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 Health Research Ethics Board (HREB) 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 Health Research Ethics Board (HREB) approved research protocol, the Investigator Brochure, or the current HREB 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 Researcher or sponsor, the event was more likely than not to be caused by the research procedures

Vulnerability: a diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances.