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

Alternate member: a formally appointed voting member of the Research Ethics Board (REB) who may substitute for a regular member of the REB but who is not expected to attend every REB meeting. An alternate REB member's presence at the REB meeting in the place of an absent regular REB 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: is a process that allows researchers to request a review of a research ethics board/committee (REB/REC) decision when, after reconsideration, the REB has refused ethics approval of the research.

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").

Compensation: anything offered to research participants, monetary or otherwise, to encourage participation in research. Also referred to as **incentive** (see below).

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 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., Researcher 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.

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

Conflict of Interest (COI) disclosure: Formal acknowledgement of the Researcher's or REB member's COI to the REB.

Conflict of Interest (COI) management plan: Formally proposed and approved plan to address the COI, thereby resolving or removing it. The plan may be approved by the Researcher's one-up supervisor, COI committee or REB, as per Organizational policy.

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.

Course-based research: Research involving human participants undertaken by students as part of an educational institution-recognized course for a pedagogical purpose. This does not include research undertaken by graduate students for a research thesis.

Creative Practice is a process through which an artist makes or interprets a work of art. It may also include a study of the process of how a work of art is generated. Creative practice activities do not require REB review, but they may be governed by ethical practices established within the cultural sector. (TCPS2 – 2018 Article 2.6)

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.

Delegated 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: person to whom a duty has been delegated 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**.**

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 expiration date will be determined by the REB (e.g., six months from the date of the approval).

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.

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.

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.

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 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.

Non-REB reviewer: a reviewer for a course-based research protocol that is not a member of the REB.

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

Organizational Official: a senior official ultimately responsible for ensuring that the institution or organization complies with all required laws, regulations and standards for research involving human participants. This may include signing memoranda of agreements or other documentation on behalf of the organization to formalize assurance of compliance.

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.

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/de-identified 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.

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.

Privacy regulations: Laws and rules created at the federal or provincial/territorial level outlining

measures that must be taken to ensure that person's privacy is maintained when collecting, using, sharing or storing their personal information.

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: any unplanned or unforeseen change in the execution of research that differs from the Research Ethics Board (REB) approved protocol or protocol procedures.

Publicly-declared emergency: An emergency situation which, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public office

Quorum: An REB meeting 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 REB,
- 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 relevant law (for biomedical research)
- additional representation as required by applicable legislation or guidelines

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 Research Ethics Board's (REB) approval or favourable opinion to continue the research.

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

Researcher (Principal Investigator): 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. May also be known as Principal Investigator or PI. The researcher is responsible for communicating any changes to the study, material incidental findings, new information and/or unanticipated events to their own REB as well as to the local site researchers for multi-site studies, who must then inform their respective local REBs.

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) Office: the unit, whether independent or part of a larger unit dedicated to providing administrative support to the REB.

Research Ethics Board (REB) Office Personnel: (an) administrative staff member(s) of the REB office.

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 Misconduct: any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community.

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.

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 Researcher.

Termination: a permanent halt by the Research Ethics Board (REB), 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.

1. Personal Information Protection and Electronic Documents Act
2. United States Code of Federal Regulations: 45 CFR 46
3. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS2 2018
4. World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
5. Canadian Association of Research Ethics Boards. Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada (July 2010)
6. U.S. Department of Health and Human Services, Office for Human Research Protections, and FDA Institutional Review Board Written Procedures Guidance for Institutions and IRBs (May 2018)
7. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on Reporting Incidents to OHRP (May 2011).
8. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (January 2007)
9. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on IRB Continuing Review of Research (November 2010)
10. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on the Use of Expedited Review Procedures (August 2003)
11. U.S. Department of Health and Human Services, Office for Protection from Research Risks. Memorandum re: IRB Meetings Convened via Telephone Conference Call (March 2000)
12. U.S. Department of Health and Human Services, Office for Protection from Research Risks and Food and Drug Administration. Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure. Federal Registrar: November 9, 1998 (Volume 63, Number 216)
13. U.S. Department of Health and Human Services, Food and Drug Administration. A Guide to Informed Consent – Information Sheet; Guidance for Institutional Review Boards and Clinical Investigators
14. U.S. Department of Health and Human Services, Food and Drug Administration. Sponsor-Investigator-IRB Interrelationship – Information Sheet; Guidance for Institutional Review Boards and Clinical Investigators
15. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research (April 2013)
16. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Industry; Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009).

17. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting to IRBs – Improving Human Subject Protection (January 2009)
18. U.S. Department of Health and Human Services, Food and Drug Administration. Institutional Review Boards Frequently Asked Questions – Information Sheet; Information Sheet – Guidance for Institutional Review Boards and Clinical Investigators
19. U.S. Department of Health and Human Services. Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection (May 2004)
20. U.S. Department of Health and Human Services, National Institutes of Health. NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research (November 2017)
21. U.S. Department of Health and Human Services, National Institutes of Health. Guidance on NIH Office of Extramural Research (OER) on-line tutorial Protecting Human Research Participants (PHRP) (February 2008)
22. U.S. Department of Health and Human Services, National Institutes of Health. Frequently Asked Questions; Human Subjects Research – Requirement for Education
23. Canadian Institutes for Health Research. Best Practices for Protecting Privacy in Health Research (September 2005)