Title	0.00 Glossary of Terms
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Ad hoc advisor: A person with relevant and competent knowledge and expertise consulted by a Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review. The ad hoc advisor is not a member of the REB.

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, updated recruitment material, etc.

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

Authorized third party: Any person with the necessary legal 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.

Compensation: Anything offered to research participants, monetary or otherwise, to encourage participation in research. Also referred to as an incentive.

Confidentiality: An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them from unauthorized access, use, disclosure, modification, loss or theft.

Conflict of Interest (COI): The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another.

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

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 Tri-Council Policy Statement on the Ethical Conduct for research Involving Humans (TCPS2).

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: 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: The person to whom a duty has been delegated. This may refer to a member of the Research Ethics Board (REB), to the REB Office Personnel, or to the Director, depending on the context of the statement and the accompanying requirements of the University.

Director: The Director of Human Research Ethics.

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.

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.

Identifiable information: Information that may be reasonably expected to identify an individual, alone or in combination with other available 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.

Information Types:

> **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).

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.

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).

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

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.

Non-compliance: Failure to follow applicable policies, 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.

Office of Human Research Ethics (OHRE) Personnel: Administrative staff members of the Research Ethics Board (REB) office.

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

Participant: An individual whose data or responses to interventions, stimuli, or questions by a Researcher are relevant to answering a research question.

Personal health information (PHI) - Manitoba: Means recorded information about an identifiable individual that relates to:

- The individual's health or health care history, including genetic information about the individual.
- The provision of health care to the individual.
- Payment for health care provided to the individual and includes the personal health information number (PHIN) and any other identifying number, symbol or particular assigned to an individual, and any identifying information about the individual that is collected in the course of, and is incidental to, the provision of health care or payment for health care.

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

Privacy breach: The unauthorized collection, use, or disclosure of personal information or personal health information (PHI).

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/Ethics Protocol: Information, documents or sets of documents describing how a research project involving human participants will be conducted to ensure compliance with all ethical requirements.

Protocol, Migrated: Protocols submitted to any of the Fort Garry Research Ethics Boards (REB) before the online Research Administration System (RAS) was implemented in July 2021.

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: 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 University
- one (1) member knowledgeable in the relevant law (advisable for areas of research other than biomedical).

Reportable event: 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: 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 the Principal Investigator (PI).

Research Ethics Board (REB): A body of Researchers, community members, and others with specific expertise established by the University to review the ethical acceptability of all research involving humans conducted within the University's jurisdiction or under its auspices.

Research Ethics Board Chair (REB Chair): The REB Chair provides overall leadership for the REB and facilitates the REB review process, based on University policies and procedures and the TCPS2. There may be more than one Chair of an REB, in which case

the Chairs may be referred to as Co-Chairs. References to REB Chair(s) include REB Co-Chairs.

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.

Secondary Use: The use in research of information originally collected for a purpose other than the current research purpose.

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.

University: University of Manitoba.

University Official: A senior official ultimately responsible for ensuring that the University complies with all required laws, regulations and standards for research involving human participants.