WCH Standard Operating Procedures Glossary of Terms

Ad hoc advisor: A person with relevant and competent knowledge and expertise consulted by a research ethics board for a specific research ethics review, and for the duration of that review, in the event that the board members lack specific expertise or knowledge to review with competence the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the research ethics board and is not counted in the quorum or allowed to vote on board decisions (TCPS2).

Adverse Event (AE): Any untoward medical occurrence in a research participant administered 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), 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 study participants enrolled by the investigator at the centre under the jurisdiction of the REB.
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> **Non-local (external) adverse event (EAE):** Those adverse events experienced by research participants enrolled by Investigators at <u>other</u> centres/institutions outside the REB's jurisdiction.

Alternate member: A formally appointed voting member of the REB who may substitute for a regular member of the REB but who is not expected to attend every meeting. An alternate member's presence at the WCH REB meeting in place of an absent regular member is used to establish quorum.

Amendment: A written description of a modification or change(s) to or formal clarification of the previously approved research study.

Authorized Signatory: Individual(s) authorized to sign documents on behalf the WCH REB.

Confidentiality: The obligation of an individual or organization to safeguard entrusted information and includes the obligation to protect information 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 an institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without the other (TCPS2). A conflict of interest may arise when activities or situations place an individual (i.e.,

researcher or REB member) or institution in circumstances that create a risk that an independent observer would reasonably question whether professional judgements or actions regarding a primary interest may be unduly influenced by a secondary interest thereby creating a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests.

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 (TCPS2).

Data Safety Monitoring Board (DSMB): A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of research study procedures, and monitoring the overall conduct of a research study (TCPS2).

De-identification: Removal of 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: A review performed by the Research Ethics Board (REB) Chair or assigned to one or more reviewers from among the REB members. Delegated review procedures may be used for certain kinds of research involving minimal risk, and for minor changes in approved research (see Delegated Review Procedure SOP)

Ex-Officio Member: Members on the REB by virtue of a particular office or position held.

Expiry Date: The first day that the REB approval of the research study is no longer valid without further review and approval by the REB. For annual reviews, the expiry date is the one-year anniversary of the date of the initial approval by either the convened REB or via delegated review, as applicable. 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).

External Safety Report: A report of a serious unexpected adverse drug reaction that occurs at any other institution involved in a study using the same investigational agent.

Full Research Ethics Board (REB) Review: The level of REB review assigned to above minimal risk research studies. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans (TCPS2).

Human Genetic Research: the study of genetic factors responsible for human traits and interaction of those factors with each other, and with the environment (TCPS2).

Identifiable Information (also referred to as "personal information"): Information 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).
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> **Indirectly Identifying Information:** The information can reasonably be expected to identify an individual though a combination of indirect identifiers (e.g. date of birth, place of residence, or unique personal characteristics).
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> **Coded Information:** Direct identifiers are removed from the information from which direct identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g. the principal Investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
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> **Anonymized Information:** The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
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> **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 (TCPS2).

Incentive: Anything offered to research participants, monetary or otherwise, to encourage participation in research (TCPS2).

Incidental findings: Unanticipated discoveries made in the course of research that are outside the scope of the research (TCPS2).

Institutional Official: A senior official who signs an institution's human subject assurance, making a commitment on behalf of the institution to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human subjects.

Investigator/Principal Investigator: A person responsible for the conduct of the study or clinical trial at a site. If a study or trial is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the principal investigator.

Investigational Product: Refers to new or new usages of drugs, biologics, medical devices or natural health products.

Legally Acceptable Representative: An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's involvement in a research study.

Manager: Refers to the manager who oversees operations of the WCH Research Ethics Office (REO) and administrative functions of the WCH REB.

Minimal Risk Research: Research in which the probability and magnitude of possible harm 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 Amendment/Change: Any change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study.

Multi-Centre: In the context of OCREB means that the research is reasonably expected to be conducted at more than one centre in Ontario.

Natural Health Product (NHP) Trial: A clinical trial testing the safety and/or efficacy of one or more natural health products. The term natural health product is used to describe substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines (TCPS2).

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

Notification/On-going Communication: Updates that do not accompany a change to the protocol and informed consent form such as a Data Safety Monitoring Report or updated Investigator Brochure.

OCREB Formal Relationship: Means that the institution (WCH) has signed a Letter of Intent and has registered OCREB under its Federal Wide Assurance. Once a formal relationship is established, the institution may delegate OCREB as the REB of Record on a study by study basis by executing a Board of Record Study Agreement.

Ongoing Research: research that has received REB approval and has not yet been completed (TCPS2).

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 documents as "subject" or "research subject" (TCPS2).

Personal health information (PHI): 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 Provincial 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.

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

Privacy: Refers to 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 a person is collected, used and disclosed by consenting to or withholding consent for, the collection, use and/or disclosure of information.

Proportionate Review: Given that research involving humans span the full spectrum of risk, a crucial element of REB review is to ensure that the level of scrutiny of a research project is determined by the level of risk it poses to participants. A reduced level of scrutiny applied to a research project assessed as minimal risk does not imply a lower level of adherence to the core principles. Rather, the intention is to ensure adequate protection of participants is maintained while reducing unnecessary impediments to, and facilitating the progress of, ethical research.

Protocol Deviation: Any unplanned or unforeseen change to a REB 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.

Qualified Investigator: The person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located who is:

(a) in case of a clinical trial respecting a drug to be used for dental purposes only a physician or dentist and a member in good standing of a professional medical or dental association; and
(b) in any other case, a physician and a member in good standing of a professional medical association.

REB of Record: The Research Ethics Board that has been delegated authority for the ethics review and ethical oversight of a research study

REB Standard Operating Procedure Committee: The WCH REB SOP Committee is comprised of:

- WCH REB Chair
- WCH Director, Research Operations
- WCH Manager, Research Operations (Manager)
- Hospital delegate

The WCH REB SOP Committee may meet to develop recommendations to the Vice President, Research with a quorum of three out of four members.

Renewal Form/Progress Report: Written summaries of the study/research status which may include: a recruitment summary, a summary of local serious adverse events, a notification of protocol deviations requiring conflict of interest information, relevant ethical and scientific information outside of an amendment, attachment of the current approved informed consent form, and Data Safety Monitoring Board reports.

Research Ethics Office (REO) Staff: Refers to the staff of the REO including Manager and the REB Chair. The Manager is accountable for determining staffing requirements and for hiring and evaluating the ongoing performance of REO staff in accordance with WCH's Human Resource policies. The REB Chair and/or Manager may delegate tasks to qualified staff as outlined in the SOP.

Standard Operating Procedure (SOP): Standard Operating Procedure – written statements that typically describe a series of steps required to complete various tasks.

Standard Operating Procedure Template: Document used to standardize the format of all standard operating procedures.

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 REB Review Package: Includes the meeting agenda, the minutes from the previous meeting, documents related to 'business carried' (e.g., investigator responses for deferred projects), standing agenda items (e.g. Update from the Research Ethics Office), REB applications (e.g., new projects, amendments, renewals), proposed consent documents, other study participant materials (e.g., questionnaires, diaries, recruitment materials, as applicable) and budget. Other documents associated with full REB reviews that are not part of the 'standard' review package include the protocol, Investigator Brochure(s), Product Monograph(s) and Package Inserts, Health Canada No Objection Letter.

Suspension: A temporary or permanent halt to all research activities pending future action by the REB or by the investigator of his/her study personnel.

Termination: A permanent halt by the REB to all or some research activities.