



Ad hoc advisor: An individual 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 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 formally appointed member of the REB and is not counted in quorum or allowed to vote on REB decisions.

Adverse event (AE): Any untoward medical **or study related** occurrence with 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 it is 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



Glossary of Terms



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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.

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: Research is reasonably expected to be conducted at more than one centre.



Glossary



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Privacy breach: The unauthorized collection, use, or disclosure of personal information

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

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.

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.

Suspension: 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: 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 welfare; and were not anticipated by the Researcher in the research proposal submitted for research ethics review.

Vulnerability: Diminished ability to fully safeguard 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.