Research Ethics Board

REB Guidance and Information Document

SOP File #	**REB.INFO.002**
Title	References for REB SOPs
Effective Date	June 2023
Next Review	2028
Next Administrative Review	2026

References

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4. World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
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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)
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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)
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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)

Acknowledgements

This document has been adopted directly from the Glossary of Terms document developed by the Network of Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB) and posted publicly on the N2 and CAREB website.

- Glossary of Terms (2021) for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER Glossary of Terms - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

Modification History

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REB.INO.002	Original document	April 2023