IWK Research Ethics
Standard Operating Procedures

Document #	Title:	Effective Date:
RE 1.104	**Activities Requiring REB Review**	**November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

All research involving human participants (as defined below), and all other activities, which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by the IWK REB. No intervention or interaction with human participants in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, recruitment materials, and consent/assent documents. Specific determinations as to the definition of "research" or "human participants", and their implications for the jurisdiction of the IWK REB are determined by the REB Chair or designate. Determination of exemption from REB review must be based on regulatory and institutional criteria.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to the REB Chair, Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES

Activities that require REB Review

Research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." The following require ethics review and approval by an REB before the research commences:

a. Research involving living human participants
b. Research involving human biological material as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Examples of types of research involving human participants include:

- Administering a drug, taking a blood sample, doing a test or performing a procedure, clinical, therapeutic or otherwise, upon the person of himself/herself or someone else, for research rather than treatment
- Asking people information whether by telephone, letter, e-mail, internet, survey, questionnaire or interview
- Using material derived from biological samples, cadavers, tissues, biological fluids, embryos or fetuses
- Using non-public records that contain identifying information previously gathered about anyone, either directly or indirectly
- Use information previously gathered about anyone (e.g., secondary data analysis)
- Observing anyone's responses or behaviour, either directly or indirectly.

All research involving people (patients and their family members, staff, students or members of the community), all research involving tissues, fluids or cadaveric remains, all research in which access to human participants involves any records maintained by the IWK Health Centre and all research involving data collected from human participants, which is to be carried out by researchers or staff with appointments at the IWK, or their students, shall be reviewed and approved in advance by the REB.

Research Exempt from REB Review

Research that relies exclusively on publically available information does not require REB approval IF:

a. The information is legally accessible to the public and appropriately protected by law or
b. The information is publically accessible and there is no reasonable expectation of privacy

Research involving the observation of people in public places does not require REB approval IF:

a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups
b. Individuals or groups targeted for observation have no reasonable expectation of privacy
c. Any dissemination of research results does not allow identification of specific individuals

Research that relies exclusively on secondary use of anonymous information or anonymous human biological materials does not require REB review so long as the processes of data linkage or dissemination of results do not generate identifiable information.

Activities Not Requiring REB Review

Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB.

- Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute

research for the purposes of this Policy, and do not fall within the scope of REB review

- Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review

Failure to Submit Project for REB Review

The implications of engaging in activities that qualify as research without obtaining REB review are serious. Results from such studies may not be accepted for publication unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of the Tri-Agency Framework: Responsible Conduct of Research. It is also against policy to use data derived from unapproved research protocols to satisfy thesis or dissertation requirements unless deemed exempt from REB review.

If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, and has changed in some fashion that requires further REB review, or that the researcher may wish to publish the results, the investigator must submit a proposal to the REB for review as soon as possible. If the REB does not approve the research, data collected cannot be used as part of a study, thesis or dissertation nor may the results of the research be publishable.

Note: US regulations will be applied as applicable.

REFERENCES

1. 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, 2018: (short name: TCPS 2), Article 2; 10.1; 6.11
2. US Food and Drug Administration (FDA) Code of Federal Regulations Title 45 Part 46.102; 21 Partb50.3

Revision History:

Revision	Date	Description of changes
0.0	April 01, 2017	Initial Release
0.1	May 01, 2017	Updates as per Tri-Council requirements
0.2	February 1, 2023	Updated logo
0.3	November 19, 2024	Added US regulatory compliance requirements