

SOP Title:	Activities Requiring REB Review		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review and research activities that do not.

2.0 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 SickKids 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 REB under SickKids policy are determined by the REB Chair or designate.

Determination of exemption from REB review must be based on regulatory and institutional criteria. When research is funded by a U.S. Federal agency, the U.S. Department of Health and Human Service definitions of research and human subject also apply. When research is regulated by the US Food and Drug Agency (FDA), the FDA’s definitions of clinical investigation and human subject also apply.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

5.0 PROCEDURES

5.1 Research that Requires REB Review

- 5.1.1 The following requires ethics review and approval by the SickKids REB before the research commences:
- (a) Research involving living human participants,
 - (b) Research involving human data and/or biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials and/or data derived from living and deceased individuals.

5.2 Research Exempt from REB Review

- 5.2.1 Research that relies exclusively on publicly available information does not require REB review when:
- (a) The information is legally accessible to the public and appropriately protected by law,
 - (b) The information is publicly accessible and there is no reasonable expectation of privacy;
- 5.2.2 REB review is not required for research involving the observation of people in public places where:
- (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, and
 - (c) Any dissemination of research results does not allow identification of specific individuals;
- 5.2.3 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;
- 5.2.4 The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

5.3 Activities Not Requiring REB Review

- 5.3.1 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;
- 5.3.2 Quality assurance and quality improvement studies, program evaluation activities, 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 SOP, and do not fall within the scope of REB review;
- 5.3.3 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.

- 5.3.4 REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.
- 5.3.5 Case reports involving no more than two (2) separate cases, provided that the case reports are void of private identifiable information. This activity is not to be confused with thesis or dissertation projects, which do require prospective REB review and approval.

5.4 Failure to Submit Project for REB Review

The implications of engaging in activities that qualify as research that is subject to REB review without obtaining such review are significant. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with SickKids policy. It is also against policy to use that data to satisfy thesis or dissertation requirements.

If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, and has changed in some fashion as to now require REB review, or that he or she may wish to publish the results, the investigator should 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 published.

6.0 REFERENCES

See References