

**Holland Bloorview Research Ethics Board (REB)
Standard Operating Procedures**

	REB REVIEW OF RESEARCH		
POLICY: REB-401	CRITERIA FOR PROJECTS NOT REQUIRING REB REVIEW		
This policy pertains to:	The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital		
Responsibility for executing this policy:	Chair, Holland Bloorview REB (or designate)		
Approval authority:	Research, Teaching & Learning Advisory Committee (RTLAC) of the Holland Bloorview Board of Trustees		
Effective date:	September 30, 2014	Superseded document date:	V2: January 2012
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE

The purpose of this SOP is to describe knowledge generating projects that do not require REB review because the activity does not constitute human research.

REFERENCES

2. POLICY

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

TCPS2 Article 2.1

- (a) research involving living human participants;
- (b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

For research funded or supported by the US government, human research is any activity that either: 1) meets the Department of Health and Human Services (HHS) definition of “research” and involves “human subjects” as defined by the HHS regulations or 2) meets the FDA definition of “clinical investigation” and involves “human subjects” as defined by the FDA regulation.

45 CFR 46.102(d)(f)
21 CFR 50.3(c)(g)

Some research does not require REB review and certain projects are exempt from REB review. Determination of exemption is based on regulatory and institutional criteria.

3. SPECIFIC POLICIES

The REB Chair and delegated REB members may determine that an activity does not meet the definition of human research. Investigators may submit an application to the REB to obtain an official

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determination.

The REB Office will review the application and supporting documents and forward it to the REB Chair or delegated member for a formal determination. If requested by the submitting party, the REB Chair will notify the Local Principal Investigator in writing if the proposed study/project does not meet the Institutional definition of human research.

The REB Chair or delegated member will consider the following criteria to make a formal determination:

TCPS2 Article 2.3, 2.4,
2.5, and 2.6

- 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.
- 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.
- REB review is not required for 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.
- REB review is not required for creative practice activities, in and of themselves. 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.
- REB review is not required for observations of behavior within a public gathering which cannot be associated with any particular individual or group of individuals (random people or an anonymous group with no known, identifiable membership); and
- REB review is not required for the use of information which is already in the public domain (e.g. autobiographies, diaries or public archives)

Revision History

V3/July2014: changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.