

SOP Title:	Alternate Research Ethics Board Review Arrangements		
SOP #:	I.08.001	Original Issue Date:	January 24, 2019
Category:	General Administration	Reviewed/Effective Date:	October 1, 2019
Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the types of research conducted at The Hospital for Sick Children (SickKids) that may use another qualified Research Ethics Board (REB) as a delegated REB of Record. This SOP also describes the procedures when the SickKids REB acts as a qualified Board of Record for an external institution.

2.0 POLICY STATEMENT

The SickKids Chief of Research may enter into joint review arrangements, rely upon the review of another qualified REB or make similar arrangements for duplication of effort as allowed.

Through a formal relationship and Board of Record Agreement, the SickKids REB may act as a REB of Record for external institutions or another qualified REB may be delegated as the REB of record for multi-centered research studies that are conducted by SickKids researchers. This decision will be made on a case-by-case basis by the SickKids REB (with the approval of the Chief of Research) in conjunction with the External Institution.

Where necessary the Institutional FWA will be appropriately modified, and Board of Record Agreements will be entered into.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

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

5.0 PROCEDURES

5.1 In deciding whether or not to review for or rely upon another REB of Record, the SickKids REB Chair (or delegate) will consider the following criteria:

- 5.1.1** Whether other external REB is qualified;
- 5.1.2** Risk level of study
- 5.1.3** Patient population included in the study
- 5.1.4** Sources of funding
- 5.1.5** Location of human research activities
- 5.1.6** Expertise & location of personnel involved (i.e. Principal Investigator (PI) to provide appropriate coordination and oversight of the study activities, expertise of the personnel, and location for primary appointment of the PI).
- 5.1.7** REB expertise: REB that has the most appropriate expertise to conduct the review.
- 5.1.8** Appropriate membership composition of external REB.

5.2 In order for the SickKids REB to consider becoming the REB of record for a research project conducted by an External Investigator/Institution:

- 5.2.1** The External Institution must enter into a Board of Record Agreement with SickKids and provide any requisite documents to the SickKids REB.
- 5.2.2** Agreements will specify the type(s) of research or the individual research project conducted under the agreement and outlines the duties and responsibilities of the SickKids REB and the External Investigator/Institution.
- 5.2.3** Copies of any agreements and any accompanying documentation must be retained by both the SickKids REB and the External Institution. The Manager of the REB or designee is responsible for maintaining copies of such agreements.
- 5.2.4** The REB Manager, REB Chair and Chief of Research (or delegate) make the final decision of whether to enter into an agreement allowing the SickKids REB to be the Board of Record for research conducted at an External Institution.

5.3 Review by another REB for a Single Project

- 5.3.1** If a research project is conducted entirely at an External Institution it may still require SickKids REB approval (e.g. an investigator is SickKids faculty, etc.).
- 5.3.2** If there is a qualified REB at the external institution, the SickKids REB (with the approval of the Chief of Research) may allow the External Institution's REB to be the REB of record for the single project. This will be addressed on a case-by-case basis.
- 5.3.3** SickKids must enter into a Board of Record Agreement with the External Institution in order for this to occur.
- 5.3.4** Copies of any agreements must be retained by both the SickKids REB and the External Institution. The Manager of the REB or designee is responsible for maintaining copies of such agreements.
- 5.3.5** The REB Manager, REB Chair and Chief of Research (or delegate) make the final decision of whether to enter into an agreement allowing for another REB to review research conducted at SickKids.

5.4 Determination of whether research falls within the scope of REB Review

- 5.4.1** The opinion of the REB should be sought whenever there is any doubt about the applicability of submitting a particular research project to the REB prior to completing an application form.
- 5.4.2** The SickKids REO Personnel will correspond with the investigator as needed to assist in the determination of whether their research falls within the scope of REB review and the applicability of using either an REB of Record or the SickKids REB acting as a REB of Record for a study.
- 5.4.3** When the determination of scope is unclear, the decision will be made by the SickKids REB Chair.

5.5 Notification of Board of Record Agreement and REB of Record Approval

- 5.5.1** Upon receipt of an REB approval, the Investigator or designee will send an electronic copy of the signed and executed Board of Record Agreement and REB Approval Letter to the SickKids REB on a study-by-study basis.
- 5.5.2** The SickKids REB logs the study and relevant approval information for tracking and reporting purposes.
- 5.5.3** The REB of Record maintains responsibility for ethical oversight of the conduct of the study.

6.0 REFERENCES

See References