

SOP Title:	Scientific Review for Research Ethics Applications		
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1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the scientific review requirements for research being conducted at or under the auspices of SickKids.

2.0 POLICY STATEMENT

While it is within the scope of the Research Ethics Board (REB) to review the scientific validity of research proposals, the primary focus of the SickKids REB in evaluating a research project should be ethical acceptability.

Researchers have a role to play in demonstrating to the SickKids REB whether, when, and how appropriate scientific review has been or will be undertaken for their research. The SickKids REB may request that the researcher provide full documentation of completed scientific reviews.

All applications for SickKids REB review (with the exception of some limited circumstances) must include a satisfactory scientific review. Evidence of a scientific review prior to submission to the SickKids REB will help to facilitate the Research Ethics Review and allow for the SickKids REB to focus their attention on the ethical acceptability of each project.

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 Scientific Review

5.1.1 A scientific review will be considered satisfactory when it includes the following:

- completion of the report on the SickKids Scientific Peer Review Form by peer reviewer(s);
- itemized responses to issues raised, and evidence of final approval by the Researcher's division/department/program head indicating support for the noted revisions;
- the names of all reviewers that contributed to the review (reviewers may be SickKids investigators or external reviewers).

5.2 Waivers of Scientific Review

5.2.1 The following scholarly reviews may generally be submitted in place of an approved SickKids Scientific Review Form. However, the SickKids REB reserves the right to request additional scholarly review documentation (e.g. the peer review submitted is non-scientific or the study is greater than minimal risk). Researchers should contact REO Personnel early in the process to confirm whether science review can be waived.

- In instances, when external scientific review has already occurred and a grant is awarded internal SickKids science review may be waived. Evidence of scientific review must be included in the application package.
- In instances when a research trainee (at the graduate or post-graduate level) is being supervised by a SickKids Investigator, supervisory committee meeting reports may be accepted in place of a SickKids Scientific Review Form for minimal risk studies. A response to the recommendations made by the supervisory committee must accompany the REB submission.
- In instances when a clinical trainee is being supervised by a SickKids Investigator, either a protocol review by the research course instructor or teaching assistant may be accepted in place of a SickKids Scientific Review Form for minimal risk studies. A response to the comments made by the reviewer must accompany the REB submission.
- Please note, trainee protocols which are greater than minimal risk must undergo a SickKids Scientific Review by a qualified expert who is not involved in teaching or supervising the trainee or trainee team.
- Retrospective chart reviews do not require a scientific review.

5.3 Scientific Review Process

5.3.1 Researchers are responsible for selecting potential scientific reviewers and coordinating the scientific review process. Selected reviewers shall have the appropriate credentials and may be internal or external to SickKids.

5.3.2 The reviewer(s) shall assess the research proposal using the scientific reviewer form as a guide (tracked changes may also be included). The reviewer shall make comments or suggestions on the scientific validity of the proposal.

5.3.3 Upon completion of the scientific review, the completed scientific review form shall be signed by the primary reviewer and returned to the Researcher.

5.3.4 It is the responsibility of the Researcher to respond to the reviewers' comments in a clear, itemized fashion.

- 5.3.5 Once satisfied with the responses and revised proposal, the scientific reviewer(s) and the division/department/program head shall sign off on the scientific review form indicating support for the Researcher's proposal and any noted revisions (email approval is acceptable).
- 5.3.6 The Researcher shall include the completed (including all signatures) science review form, including an itemized response to the issues raised, and revised proposal with his/her SickKids REB submission.

6.0 REFERENCES

See References