



THE HOSPITAL FOR
SICK CHILDREN

Research Ethics Board

Report on Scientific Peer Review

**PLEASE NOTE – Reviewers must include all substantive issues and/or recommendations on this form, whether or not they have been provided verbally to the investigator.*

PART A: GENERAL

Primary Investigator: _____ Co-investigator: _____

Co-investigator: _____ Co-investigator: _____

Co-investigator: _____ Co-investigator: _____

Project Title _____

Funding Agency _____ Deadline _____

Brief Description of Project (to be completed by reviewer)

PART B: BUDGET:

A) Approximate Budget - Year 1 _____ B) Is it justified in the application? _____

C) Are the sums requested adequate? _____ D) Do the items reflect the actual costs of the research interventions, excluding interventions that are part of routine clinical practice? _____

E) Is there a project contract or agreement (notice of award)? _____

PART C: REVIEW

Is the hypothesis reasonable? _____

Is the literature review appropriate? _____

Is the research protocol clearly described? _____ Is the stated significance of the study plausible? _____

Are the summary pages well prepared? _____

Are the research methods likely to deliver results to the stated objectives? _____

Is this study feasible? _____ If not, why? _____

Is the study likely to yield publishable results? _____

What is your overall assessment of the application?

Please list any specific recommendations (attach an additional page if necessary).

PART D: FOR HUMAN RESEARCH ONLY

Which of the following prior studies have been published?

Relevant animal studies _____

Studies of animals at a stage of development analogous to the subjects of the proposed study _____

Relevant adult human studies _____

If the answer to one or more of the above questions is negative, please comment on the feasibility and desirability of undertaking prior studies in animals and/or adult humans before proceeding to a pediatric study.

Are patient eligibility and exclusion criteria clearly delineated? _____

Are the following methods appropriate?

Ascertainment of potential subjects _____

Making contact with potential subjects _____

Obtaining consent (if needed) _____

Is the study comparative? _____

Are the study numbers discussed and justified? _____ If yes, are the study numbers sufficient to provide likelihood of an interpretable result? _____

Are the subjects likely to be enrolled in other studies? _____

Is the study descriptive? _____ If yes, is the information to be derived likely to be unique? _____

Does the study involve disruption of schedules (including school) for subjects/parents? _____

If yes, is the disruption justified? _____

Are the potential harms vs. potential benefits appropriate? (For research in children, potential harms must be estimated to be more than balanced by potential benefits; both are quantified in terms of the expected frequency of the harm or benefit, and the magnitude of the harm or benefit) _____

If this is a clinical trial comparing two or more treatment regimens, are the risk - benefit ratios of each regimen well balanced so that the average expert would not favour one regimen over the other (ie., equipoise exists)?

Yes _____ No _____ Don't Know _____

Is statistical analysis required? _____ If yes, is there a discussion of statistical methods and are they appropriate? _____

Is the plan for monitoring safety and efficacy (in the case of diagnostic or therapeutic trials) of the human subjects appropriate? _____

For clinical trials (diagnostic as well as therapeutic), is the plan for monitoring safety and if relevant, efficacy, appropriate? (see attachment for categories of research and the monitoring matrix) _____

Should extra-mural scientific peer review be obtained (e.g., for conflicts of interest of the researchers, the institution, and or the internal peer reviewers; for questionable risk - benefit ratio; for serious threats to the privacy of human subjects)? _____

Are there any major changes that need to be made before this proposal should be submitted for ethical review? _____

Assuming that this committee will accept any changes made to the protocol, is scientific merit including significance of the study adequate to justify its ethical consideration? _____

PART E: RANKING

Please rank the proposal as is, and the proposal if the proposed revisions are made.

Please use the two digit CIHR rating system: 4.5 - 4.9 outstanding, 4.0 - 4.4 excellent, 3.5 - 3.9 very good, 3.0 - 3.4 acceptable, but low priority, 2.5 - 2.9 needs revision, 2.0 - 2.4 needs major revision, 1.0 - 1.9 seriously flawed, 0 not acceptable.

Reviewer Signature Scientific Discipline Proposal As Is Proposal after Revisions Made

Date of Review: _____

disciplines involved in research	disciplines of investigators	disciplines of scientific reviewers

PART F: ITEMIZED RESPONSE

An itemized written response to all the issues raised by the reviewers noting where revisions were made in the revised protocol must be provided to the Research Committee Review Chair/Grant Review Committee Chair for final approval & signoff prior to submission to the REB for ethical approval.

Final Approval of Research Director/Committee Chair: _____

Date: _____

PART G: CONFLICT OF INTEREST DECLARATION (for reviewers):

Please confirm with your signature that all contracts and any conflicts of interest (actual, apparent, perceived, or potential)* relating to this project are disclosed to the Manager, Research Contracts for review.

Signature _____

* Conflicts of interest include but are not limited to the following situations:

Do you or any of the involved staff members or your/their dependents have,

(1) employment or consulting arrangements and/or a financial interest in the sponsor of the study, or with proposed subcontractors, vendors, or collaborators;

(2) a financial interest in the product/medical device that is the subject of the study?