WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Procedures

Scientific Review for Research Ethics Applications

SOP NO:	REB-SOP-IX-02.003	**Revision Date:**	January 11, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	January 11, 2017
SUB-CATEGORY	Section IX: Quality Assurance	**Original Issue Date:**	December 21, 2012
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

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 Women's College Hospital (WCH). 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 WCH REB in evaluating a research project should be ethical acceptability.

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

All applications for WCH 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 WCH REB will help to facilitate the Research Ethics Review and allow for the WCH REB to focus their attention on the ethical acceptability of each project.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB members and Research Ethics Office (REO) staff.

4.0 PROCEDURES:

4.1 Scientific Review

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

- Completion of the Report on the WCRI Scientific Peer Review Form by peer reviewer(s) (N.B. The peer reviewer(s) should not be affiliated with/or part of the research team);

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- Itemized responses to issues raised, and evidence of final approval by the investigator's division/department/program head indicating support for the noted revisions;

- The names of all reviewers that contributed to the review (reviewers may be WCH investigators or external reviewers).

4.2 Waivers of Scientific Review:

The following scholarly reviews may generally be submitted in place of an approved WCRI Scientific Review Form. However, the WCH 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). Please contact REO staff 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 WCH 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 WCH Investigator, supervisory committee meeting reports may be accepted in place of a WCRI 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 WCH Investigator, either a protocol review by the research course instructor or teaching assistant may be accepted in place of a WCRI 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 WCRI Scientific Review by a qualified expert who is not involved in teaching or supervising the trainee or trainee team.

- For Health Canada regulated studies, a No Objection Letter or Investigational Testing Authorization Letter will be accepted in lieu of a scientific review.

- Retrospective chart reviews do not require a scientific review.

4.3 Scientific Review Process:

4.3.1 Investigators are responsible for selecting potential scientific reviewers and coordinating the scientific review process. Selected reviewers shall have the appropriate credentials and

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may be internal or external to WCH. (N.B. The peer reviewer(s) should not be affiliated with/or part of the research team);

4.3.2 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.

4.3.3 Upon completion of the scientific review, the completed scientific review form shall be signed by the primary reviewer and returned to the principal investigator (PI).

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

4.3.5 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 investigator's proposal and any noted revisions (email approval is acceptable).

4.3.6 The investigator shall include the completed (including all signatures) science review form, including an itemized response to the issues raised, and revised proposal with his/her WCH REB submission.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2)
2. Sick Kids Scientific Peer Review Guidelines
3. Holland Bloorview Scientific Review Forms and Guidance Notes (April 2012)

Appendix 1: Women's College Research Institute Scientific Review Form
Women's College Research Institute Scientific Review Form

PLEASE NOTE - Reviewers must identify all substantive issues and recommendations on this form, regardless of if they have been provided verbally to the investigator, any substantive issues and recommendations must be stated in section D2, and the Principal Investigator must provide a written response. Other comments noted in section B and C are suggestions only.

PART A: GENERAL

Principal Investigator:				**Project Title:**
Sponsor:				
Reviewer Conflict of Interest				
Declaration	**Yes**	**No**	**NA**	**Comment/Clarification**
Do you or your immediate family have any financial interest in the Sponsor?	☐	☐	☐	If yes – please contact the Grants Manager, alex.willis@wchospital.ca
Have you had any involvement in a previous review or input into the protocol?	☐	☐	☐	If yes – please contact the Grants Manager, alex.willis@wchospital.ca
Are you or will you be taking on any role in this project?	☐	☐	☐	If yes – please contact the Grants Manager, alex.willis@wchospital.ca
Do you have any professional, academic, or other types of competing interest in this project or with the sponsor that needs to be declared?	☐	☐	☐	If yes – please contact the Grants Manager, alex.willis@wchospital.ca and declare in this box
Brief Description of the Project (to be completed by reviewer):				

PART B: REVIEW

1. Are the objectives clearly described?
2. Is the literature review appropriate?
3. Is there a theoretical or conceptual framework?
4. Is the rationale for the study clear?
5. Is the research innovative?
6. Are the methods clearly described?
    a. Are the inclusion/exclusion criteria clear?
    b. Are the outcomes clear?
    c. Is there an analytical plan?
7. Are the methods (design, measurement, analysis) appropriate to achieve the objectives?
8. Is this study feasible? If not, why?

9. Does the research team have the necessary clinical and research expertise to complete the study?

10. Is the study likely to yield publishable results?

11. Is there a knowledge translation and/or dissemination plan?

    a. If yes, does it include strategies to disseminate findings to non-scientific audiences?

12. Is the potential impact or significance of the proposed research clearly stated?

PART C: BUDGET

1. Is the budget amount justified in the application?

2. Are the sums requested adequate to cover the cost of conducting this research?

PART D: COMMENTS BY THE REVIEWER(S)

1. What is your overall assessment of the application (No concerns? Major Concerns? Minor Concerns)?

2. Please identify substantive issues and specific recommendations?

PART E: REVIEWER(S) INFORMATION

Name	Title	Contact Information

Date of Review:

PART G: ITEMIZED RESPONSE
An itemized written response to all of the issues raised in section D2, noting where revisions were made in the revised protocol, must be provided to the Primary Scientific Reviewer for final approval and sign-off.

PART H: APPROVALS

Final Approval of Primary Scientific Reviewer:

Name:	**Signature:**
Date:	

Final Approval of Division/Department Head:

Name:	**Signature:**
Date:	