Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Delegated Ethics Review
REB SOP # 010

Issued By: Research Ethics Board Office
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Purpose:
The purpose of this SOP is to describe the delegated (formerly known as expedited) review process of a proposed research submitted for ethics review and approval. The delegated review process involves review conducted by one member, or a subcommittee of the board. The main criterion that is used to determine whether a protocol may be reviewed through the delegated process is risk. Only research that meets the threshold of minimal risk may be delegated. Minimal risk is defined below.

Scope:
This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines

Description:
The REB tailors its level of scrutiny to the level of risk presented by the research, and assesses the ethical acceptability of the research through consideration of the foreseeable risks, the potential benefits and the ethical implications of the research, both at the stage of the initial review and throughout the life of the project (continuing ethics review). If the REB regards the research as posing only 'minimal risk' to participants, such research submitted to the REB normally receive delegated review by one or two REB members with the appropriate scientific expertise. 'Minimal risk' research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research." [TCPS2, Chapter 2, Section B]. The results of delegated review are ratified by the full board at a regular meeting.

Please complete the research intake process (SOP # XXX) with the research planning strategist before submitting the application to the REB. Also refer to SOP # 009 (Submission of a new research ethics application for REB review).

For delegated review, please submit 1 original paper copy plus an electronic version of the application. If required, REB office shall request additional one or two copies of the application from PI.

Procedure:
1) Completed application forms with all required signatures can be submitted for delegated review to the REB office any time. There is no deadline for submission. Please check the REB website on the shoreline intra or http://www.ontarioshores.ca for the application forms and guidelines.

2) Applications will not be considered until all relevant information for the review is complete. Please refer to SOP # XXX to verify the list of documents to include with the application.

3) The Principal Investigator (PI) may obtain a prior assessment to know if the project qualifies for a delegated review by submitting a copy of the protocol to the REB office. The Chair will review the protocol and determine if the research meets qualifications for a delegated review. Generally only minimal risk studies (questionnaires, survey, use of existing samples or treatments, studies reviewed by other REBs and chart review) are eligible for a delegated review. All other studies that are evaluated as posing above-minimal risk

shall receive a full REB review. PI may also directly request for a delegated review without first consulting REB. However the process remains the same.

4) The Chair's decision is final and will be communicated in writing to PI through the REB office. If delegated review is refused, the PI will have to submit the project for a full board review (see SOP # XXX).

5) Applications accepted for delegated review will be reviewed by the Chair and/or one or two REB members (chosen by the Chair) with expertise in the area of the proposed research. The reviewers chosen shall have no conflict of interest in the proposed research.

6) Reviewers may request clarifications or additional information from the PI to aid the review process. The reviewers will send a report on the scientific and ethical assessment of the protocol to the REB office within two weeks of receipt of the application with a recommendation for approval, modification or rejection of the proposed study.

7) REB Coordinator shall combine the reviewers report and draft an initial review letter listing the comments, questions, recommendations and required revisions. The final letter will be reviewed and approved by the Chair or the designate and/or REB reviewers before being sent to the PI by the REB office.

8) The REB Chair in consultation with delegated reviewers will review any revisions and PI response to REB questions/comments/concerns and has the authority to approve, require modifications, or defer the decision to a convened meeting. Rejection cannot be decided through the delegated review procedure. It must be reviewed by the full REB at a convened meeting (see SOP # XXX).

9) If approved, approval is effective on the date of the letter confirming the study is approved by the REB Chair. REB approval is granted for no greater than one year. The expiry date will be clearly indicated on the original approval letter and subsequent continuing ethics review. Studies requiring further modifications shall be approved only after the REB Chair/delegated reviewers and PI come to a satisfactory agreement regarding the changes suggested and made or not made by the PI.

10) The REB Chair is responsible for signing documents related to the REB review/approval of research. The REB Chair may delegate signing authority; however, the responsibility for oversight rests with the REB Chair.

Responsibility:
REB Chair, Acting Chair, REB members,
REB Coordinator and REB office.

References:

1) Shoreline REB intra:
https://shoreline/departments/REB/Pages/default.aspx

2) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, December 2010:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

3) The International Conference on Harmonization: Guidelines for Good Clinical Practice, Section 3: http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Parts 46.109, 46.111;
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Parts 50 & 56.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=50

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=56

6) OHRP Guidance on Written IRB Procedures:
http://www.hhs.gov/ohrp/policy/index.html

7) Health Canada Research Ethics Board:
http://www.hc-sc.gc.ca/sr-sr/pubs/advice-avis/reb-cer/index-eng.php