Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Full Board Research Ethics Review
REB SOP # 11

Issued By: Research Ethics Office
Date of Issue: 2014/03/28
Revised: 2014/08/27 (Version # 01)

Purpose:
This SOP outlines the procedures to be undertaken pertaining to full board ethics review of research submissions, the stakeholders involved in preparation of applications to the REB, timelines and required documentation.

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

Description:
1) 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).

2) For full board review, please submit 1 original and 11 paper copies plus an electronic version of the application.

Procedure:
1) Completed application forms with all required signatures must be submitted at least two weeks prior to the next scheduled REB meeting. Ontario Shores' REB meets on the first Wednesday of every calendar month except the month of August. Please check the REB website on the shoreline intra or www.ontarioshores.ca for the meeting dates, deadlines, 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) All REB members will be routinely provided with the complete application package for all studies 7-10 days before the REB meeting date. The REB Co-Ordinator in consultation with the Chair will appoint a primary and secondary reviewer for each protocol to be discussed at the meeting.
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4) The REB reviewers will present and discuss a detailed scientific and ethical assessment of the study protocol, consent forms, application and supplementary documents to the full board at the scheduled meeting. The discussion will be led by the primary and secondary reviewers appointed for each protocol.

5) On rare occasions the Principal Investigator (PI) or his/her representative may be invited to attend the review meeting. Alternatively, the PI may request attendance at an REB meeting, though the investigator will be asked to withdraw during deliberations.

6) If any REB reviewers have conflicts of interest with the protocol being discussed, it will be declared at the start of the meeting and recorded in the minutes. Members, who have recused themselves due to conflict of

interest, must withdraw from the meeting during deliberations and decision making.

7) The REB Co-Ordinator will take the minutes of the meeting noting the comments and the required revisions/clarifications suggested by the reviewers and agreed upon by the full board. The final decision of the board on the outcome of the review of the protocol will also be noted in the minutes.

8) All REB decisions are reached by consensus of the members present except those who have recused themselves due to conflict of interest. If consensus cannot be reached, a vote will be taken. The results of the voting will be recorded in the minutes. The REB will reach one of the following decisions as a result of its review and deliberation of research submitted for initial review

a) Approval by full board: If acceptable risks-benefits ratio exists and regulatory and other ethical criteria required for ethics approval are satisfied, the research may be approved as submitted.

b) Clarifications/revisions required: REB may suggest modifications to the research in order to meet acceptable risks-benefits ratio and satisfy regulatory criteria to secure ethics approval.

c) Defer decision: The REB may defer its decision pending receipt of clarifications/revisions of major issues at a subsequent convened meeting, when significant questions are raised during review of research.

d) Rejection/Not approved: The REB may reject a project when the research fails to meet its scientific or ethical standards. The REB chair will ensure that the reasons for rejection are identified at the meeting for communication to the PI and recorded in the minutes.

9) The results of the REB deliberations will be summarized in a formal letter to the PI. The REB coordinator will generate the first draft of the Initial Review Letter. The initial review letter listing the comments, questions, recommendations and required revisions/clarifications must be reviewed and approved by the REB Chair or the designate in consultation with the REB members who led the discussion, before being sent to the PI by the Research Ethics Office. The initial review letter must be sent to the PI within two weeks of the meeting date.

10) If the research is rejected, the principal investigator will be given an opportunity to respond in person or writing. Principal investigators have the right to appeal the decision of the REB.

11) If approved, the approval date is defined as the REB meeting date when the application was last reviewed by the full REB membership. REB approval will granted for no greater than one year. The expiry date will be clearly indicated on the original approval letter and subsequent continuing ethics review.

12) 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 Co-Ordinator 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: Ethics Review of Research Involving Humans - Administrative Policy and Procedures Manual
http://www.hc-sc.gc.ca/sr-sr/pubs/advice-avis/reb-cer/index-eng.php