Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP:REB Review Decisions
REB SOP # 012

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Purpose:
This standard operating procedure (SOP) describes the decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research for ethical acceptability

Scope:
This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

Description:
As a result of its review, an REB has the authority to approve, reject, or to require modifications to submitted research. If there are questions that must be addressed prior to a determination, the REB may defer its decision. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the REB members who are present at a Full Board meeting at which there is a quorum. REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the REB (if applicable), in accordance with the REB and Ontario Shore's conflict of interest policies. When the delegated review procedure is used, the REB Chair and/or REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to reject the research must be made by the Full Board. Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

REB Decisions:
REB decisions are made either by consensus or a majority vote of the REB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies. The REB Coordinator abstains from voting except to break a tie vote

The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

1) Approval (approve the application as submitted, including the consent form):

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted
- The approval date is defined as the date the final approval was granted by the full board or the REB Chair or his/her designee
- The expiry date of the REB approval is calculated one year from this date (e.g. if the approval date is March 11, 2015, the expiry date is calculated as March 11, 2016)

2) Approval with Modifications/Clarifications:

- When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may recommend "Approval with

Modifications/Clarifications"

- When the REB recommends "Approval with Modifications/Clarifications", the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the REB meeting and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following a) The REB Chair alone b) The REB Chair and the primary/secondary reviewer and c) A sub-group of the REB members designated by the REB Chair or designee or by the REB
- A designated REB member or members with sufficient knowledge and experience regarding the research and the regulations
- In deciding the procedures to be followed, the REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it
- Where the information or modifications are straightforward, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone
- Where the additional information/modification is technical (e.g., statistical clarifications), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s), If the Researcher's response is deemed complete and satisfactory, approval can be issued
- If the investigator's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the researcher
- The reviewers may decide upon reviewing the investigator's response that the decision should be deferred and that the application and the researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below)
- The approval date is defined as the date when all of the conditions for approval have been met and the final approval is granted by the full board or the REB Chair or his/her designee
- The expiry date of the REB approval is calculated from this date as mentioned above

3) Deferral (defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):

- The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met
- The REB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting
- The research and the investigator's response materials shall be reviewed at a Full Board meeting
- Upon consideration of the research along with the response from the investigator, at the Full Board meeting, the REB should issue its final decision (approved, approved with modifications, deferral or rejection)
- Investigator's responses must be received and reviewed at a Full Board meeting. The approval letter is not issued until all the conditions for approval have been met
- The approval date is defined as the date when all of the conditions for approval have been met and the final approval is granted by the full board
- The expiry date of the REB approval is calculated from this date as mentioned above

4) Rejection:

- The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination,
- Rejection cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to reject the research, a final decision must be made by the REB at a Full Board

meeting,
- The REB Chair or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the investigator
- If the research is rejected, the reasons for disapproval shall be communicated to the investigator and the investigator given an opportunity to respond in person or in writing

5) Delegated Reviews (see also SOP # 010):

- When the research qualifies for delegated review, the reviewer(s) has the authority to approve the application, to require modifications to any aspect of the application, or to request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting
- When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date as mentioned above; however, the approval letter is not issued until all of the conditions for approval have been met
- If the research cannot be approved through the delegated review mechanism, it must be reviewed at a Full Board meeting

6) Reconsideration and Appeal of REB Decisions:

- An investigator may appeal the decision of the REB, if the disagreement between the investigator and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the investigator shall have the right to be heard
- The investigator must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons, and a final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process
- Appeals are conducted in accordance with the established organizational policy. The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the investigator (and his/her affiliated organization)
- The appeal committee shall have the authority to review negative decisions made by the REB and in so doing it may approve, reject or request modifications to the research proposal. Its decision shall be final and shall be communicated to the investigator and the REB in writing

7) Documenting REB Decisions:

- The REB meetings minutes will satisfy the applicable requirements
- The REB shall notify the investigator in writing of its decision to approve or reject the proposed research, or of modifications/clarifications required to secure approval of the research;
- If the REB defers its decision, the letter to the investigator should include the issues of concern and what further information is required
- The final approval letter should include standard conditions of approval to which the investigator must adhere
- When the decision to approve a submission is recorded on behalf of the Full Board, or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification or correspondence to the investigator may be issued by the REB Office Personnel.

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. The REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility

for considering any further information prior to issuing approval is clearly agreed.

References:

1) N2 CAREB REB SOPs v1 *SOP 402.001* (September 2014) https://oicronca.box.com/s/95k7ydj574579ajvbe06

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: (short name: TCPS 2) http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library http://www.hhs.gov/ohrp/policy/index.html

6) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)