Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Submission of a new research ethics application for REB review
REB SOP # 009

Issued by: Research Ethics Board Office
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Purpose:
The purpose of this SOP is to describe the requirements and procedures for submitting a new research ethics application for initial Research Ethics Board (REB) review (full board or delegated review).

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 your ethics application to Ontario Shores' REB.

2) It is the duty and responsibility of Principal Investigator (PI) to provide all the relevant documentation, materials and information to adequately assess whether the research meets the criteria for REB approval.

3) The REB is supported by institutional procedures (see REB Terms of Reference) that assure that REB Members have adequate time for assessment of proposed research and participate in REB meetings.

4) For full board review, please submit 1 original and 11 paper copies (unless indicated otherwise as shown below) plus an electronic version of the application. For delegated review, submit one paper copy plus an electronic version of the application.

5) For non-clinical trial studies, the type of initial review provided by the REB will be decided by the Chair of Ontario Shores' REB. All clinical trial submissions by default will only go to full board review unless decided otherwise by the Chair of Ontario Shores' REB.

Procedure:
1) Completed application forms for REB review should be directed to the
Chair, Ontario Shores' REB
Room # 7-2043, 700 Gordon St. Whitby ON L1N 5S9
(Phone: 905-430-4055 x 6996; E-mail: REBsubmissions@ontarioshores.ca)

2) Applications will not be considered until all relevant information for the review is complete. A complete research ethics application should include the following:

- Application cover letter*****
- Approved research intake process form*****
- General checklist for the submission of new studies
- Toronto Academic Health Sciences Network (TAHSN) application form with all the required signatures
- Research protocol
- Informed consent checklists

- Consent form(s)
- Supplemental materials (e.g., questionnaires, letters of information/invitation, flyers/posters/advertisements, a copy of all assessment tools (both standard and non-standard) etc.)
- TCPS 2 Core tutorial certificate of each member of the research team***** (one time submission only. This requirement is a must for all studies)
- McMaster Chart Review tutorial certificate for each member of the research team***** (one time submission only. This requirement is a must for chart review studies)
- Curriculum Vitae of PI, Co-investigator(s), Study Co-Ordinator(s) and other research personnel***** (Must be annually updated every July)
- Allocated budget and any other relevant correspondence
- Most recent investigators brochure (for clinical trials only)******
- No Objection Letter from Health Canada (for clinical trials only)*****
- In addition, other supplemental material may need to be provided for the decision making process by the REB. Such supplemental material may include pre-clinical information from animal studies depending on the phase of the clinical trial, and any correspondence from other sources that might be pertinent to the review or the details from any other scientific or ethical reviews that have been carried out by other review committees or boards******. The primary cause of delay in ethics approval is incomplete information.

3) Upon receipt of a submission, the REB co-ordinator will date stamp the application, create a new project file folder and assign a unique REB file number.

4) The assigned REB number is used for all communication regarding the specific project.

5) The REB co-ordinator will screen the application for completeness and clarity. If a submission is incomplete, the REB co-ordinator will follow-up with the investigator to request the required information for inclusion with the submission

5) Complete applications are assessed for review pathway in consultation with the Chair - full REB review or delegated review using the risk matrix described in REB-SOP-XXX.

6) The Research Ethics Office staff notifies the research team of the review pathway. If full REB review is required the Principal Investigator or his/her representative may be asked to present the project at the next REB meeting and provide any required clarifications.

7) The review packages are prepared and distributed to the REB members for the full board meeting and/or delegated review by the REB office.

8) Original signed submission materials are retained in the REB office.

9) In general, the investigator will receive an initial response from the REB within 2 weeks (10 working days) of the full review REB meeting date.

10) Studies accepted for delegated review will receive an initial response from the REB within one week (5 working days) from the date of completion of review.

*****One copy only required
******Four copies are required

Responsibility:
Principal Investigator(s)
Research Assistant(s)

Research Planning Strategist
REB Chair, REB members & REB office

References:

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

4) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.108, 46.115
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108; 21 CFR 312, 812
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