Ontario Shores
Centre for Mental Health Sciences

Research Ethics Board
Terms of Reference, Functions and Responsibilities

Executive Lead: VP Professional Practice, Human Resources, Research & CNE	**Effective Date**: November 2016 (Revision 1)
Committee Approved by:	**Next Review**: November 2018

Purpose

Ontario Shores Centre for Mental Health Sciences (Ontario Shores) has a special patient population with mental illnesses that requires special conditions when conducting research involving these vulnerable patients. The Ontario Shores Research Ethics Board (REB) is part of Ontario Shores' vision to "lead the international mental health care community in safety." The REB has the role to ensure the protection of human research participants through the highest quality scientific and ethical review and ongoing oversight of research.

Authority

Ontario Shores REB authority includes, but is not limited to, approving, rejecting, proposing modifications to, putting on hold, suspending or terminating research that is proposed or ongoing involving human participants that is conducted within, or by members of, the institution provided such proposed research project(s) has been approved for submission to the REB by (a) any one of the institution's responsible Medical Directors /Administrative Directors/ Head of the Departments or Programs together with (b) approval of VP (Research) for non-clinical trials or VP (MA) for clinical trials or their respective authorized representatives.

All research proposals involving human participants must be approved by the REB before the research may begin. Medical Directors or Administrative Directors and Chiefs are responsible for ensuring that all such research proposals are submitted for REB review. Clinical investigators are responsible for submitting applications to the REB for review, and for conducting any and all approved research in an ethically appropriate manner. The REB has the responsibility of monitoring ongoing projects and of monitoring for instances of unapproved research.

Accountability

In order for the REB to perform its scientific and ethical review functions properly, it must operate as and be regarded by others as an administratively independent body at arm's length from administrative, programmatic, and research structures within Ontario Shores.

The REB is accountable to the Ontario Shores Board of Directors (Board) and shall report directly to the Board or at the Board's discretion, indirectly, through a Board committee designated by the Board. The REB Chair shall submit reports to the Board or its designated committee. The Board can reject a project that the REB approves (i.e. retain the authority to deny the implementation of REB-approved research projects at the institution for reasons other than research ethics, such reasons may be administrative, programmatic, philosophical, or resource-based in nature). However, neither the Board of Directors, Medical Advisory Committee (MAC), nor other administrative entities at Ontario Shores can make the REB approve a project. In addition, they cannot override a decision of the REB to reject a Research project.

The REB's actions shall be in accordance with the following:

- Freedom of Information and Protection of Privacy Act (FIPPA), ON
- Health Care Consent Act
- International Conference on Harmonization (ICH) of Good Clinical Practice (GCP)
- Mental Health Act
- Ontario Human Rights Code
- Part C, Division 5 of the Food and Drug Regulations of Health Canada
- Personal Health Information Protection Act (PHIPA) 2004, ON
- Personal Information Protection and Electronic Documents Act (PIPEDA)
- Public Hospitals Act
- Regulated Health Professions Act
- Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS-2 (2014))
- U.S. Code of Federal Regulations (CFR) Title 21 Parts 50 and 56, and CFR Title 45 Part 46
- U.S. Office of Human Research Protections (OHRP)
- Other applicable provincial or federal Statutes and Regulations
- All applicable Ontario Shores' policies and procedures, protocols and guidelines

Membership

As a mental health specific REB, the membership will be multidisciplinary including men and women with a majority of whom are Canadian citizens or permanent residents of Canada. The REB must consist of at least five (5) voting members of whom (Article 6.4, TCPS – 2 (2014)):

(a) At least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
(b) At least one member is knowledgeable in ethics;
(c) At least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
(d) At least one community member who has no affiliation with the institution.

In addition, membership may include: one member knowledgeable in privacy issues (PHIPA Regulation 329/04 and FIPPA), scientific and non-scientific backgrounds represented, expertise in psychiatry (physicians), psychiatric nurses with clinical and/or research experience, psychology, pharmacy, epidemiology and biostatistics.

The REB Chair, at his/her discretion and in consultation with the REB and the President and Chief Executive Officer (CEO), may nominate additional members to the REB. Individuals with specialties beyond the membership will be invited when the need arises to assist in the review of studies but they will not be voting members.

Selection and Terms of Office

The Chair of the REB is appointed annually by the Board of Directors. The Chair of the REB shall, in consultation with the institution's CEO or designate, appoint the other members of the REB. The members specified terms will overlap with the purpose of preserving experience and continuity of the function of the Board. The members of the REB shall be expected to provide the institution with three (3) months' notice of their intention to resign.

The Chair of the REB shall report administratively through the CEO, and his/her remuneration as well as all research contracts shall require sign off by the CEO.

Meetings

1. The REB meets monthly excluding August. It may also meet at the discretion of the Chair.
2. Appropriate expertise will be in attendance at the meetings to ensure an adequate review by the REB.
3. To support the ongoing review process, members who do not attend 70% of the REB meetings will be subject to a review of their REB membership status by the Chair.
4. All proceedings and decisions of the REB are recorded in detail.
5. Decisions, responses, and recommendations will be relayed in a timely manner to investigators. The REB office cannot promise a definite timeline but will make every effort to communicate decisions, responses and recommendations within two weeks following the REB meeting.
6. Revisions following protocol review are handled as follows:
    a. Very minor revisions are reviewed by the Chair
    b. Minor revisions are reviewed by the Chair and primary reviewer
    c. Major revisions are returned to the full Board for review.

Quorum

A quorum of the REB exists when 50% of voting membership plus one voting member in attendance and the representation requirements set forth in articles 6.4 and 6.9 of the Tri-Council Policy Statement are met.

Functions and Responsibilities

1. The REB is, among other things, responsible for reviewing and monitoring research involving human participants, in order to ensure that ethical principles govern this research. The REB is guided by the following ethical principles which are reflected in the Tri-Council Policy Statement (TCPS – 2 (2014)):

- Respect for Human Dignity
- Respect for Free and Informed Consent
- Respect for Vulnerable Persons
- Respect for Privacy and Confidentiality
- Respect for Justice and Inclusiveness
- Balancing Harms and Benefits
- Minimizing Harm
- Maximizing Benefit

The REB is also to review research projects with reference to the following:

- Scientific merit;
- Human research participant protection;
- Research Integrity;
- Ontario Human Rights Code requirements; and
- Legal Consideration.

2. To approve or decline research projects.

3. To monitor the ethical conduct of human research through:

    - Reviewing required periodic reports (must be at least annually);
    - Reviewing final reports at study close;
    - Providing on-site audit and observation of on-going projects proportionate to risk; and
    - Requiring researchers to report for review significant changes or unanticipated adverse events that rise in the course of the research.

4. To encourage education in research ethics through:

    - Requiring that all members of the research team successfully complete the TCPS-2 course on human research;
    - Ensuring that all members of the REB are provided with an understanding of the ethical principles involved in research ethics review;
    - Ensuring that all members of the REB are familiar with relevant policies and guidelines governing the conduct of human research; and
    - Providing on-going educational programs for members of the research community.

Confidentiality

The REB requires that all research projects comply with relevant federal and provincial privacy legislation and adhere to confidentiality and security requirements outlined in Ontario Shores' policies and procedures.

Conflict of Interest

REB members will disclose actual, perceived or potential conflicts of interest at the beginning of a meeting and will not participate (i.e. will not be present during the deliberation) in the review process of a study in which they have a conflict of interest. However, they may be asked to be a resource for information if the REB makes the request.

Review

Research activities that require REB review include:

- the administration of drugs;
- taking of blood/tissue samples;
- use of a novel or unproven technique;
- studies of psychotherapy and counseling modalities
- interviews, questionnaires, surveys;
- focus groups;
- use of non-public records (e.g. patient files);
- observations of behaviour; and
- secondary analysis of data derived from human research participants

Although all research involving human research participants requires REB review and approval, the following, as a general rule, are not subject to REB review and approval.

- quality assurance studies; and
- performance reviews or testing that proceeds within normal educational requirements

Any questions about whether a proposed research activity is governed by or exempt from REB review should be directed to the REB.

As the need arises, a subcommittee of the REB can be struck to consider evaluation studies which would not normally fall within the purview of the REB.

There are two types of review available: Full REB Review and Delegated Review.
The risks determine the level of review. If the research poses more than minimal risk (see TCPS-2 (2014), Article 6.12) then a full REB review is required.

1. *Full Board Review* – Most studies are submitted for full REB review at a convened REB meeting which will be face-to-face. A primary and secondary reviewer system is used in that each new project is given a detailed scientific and ethical review by an appointed member(s) of the REB with particular expertise in the study area. In addition to the standard documents provided to each REB member (i.e. protocol form, consent documents, non-standard instruments and advertisements) the primary and secondary reviewer are also provided with a full industry protocol or study protocol and the grant application as appropriate.

2. *Delegated Review* (TCPS 2 (2014), Article 6.12) - As a general rule, all research studies undergo full REB review. Some studies may receive delegated review, at the discretion of the Chair or his/her designee. The institution may decide that categories of research that are confidently expected to involve minimal risk may be approved by the Chair or [by] another designated [voting] member or by a subcommittee of the REB.

   Minimal risk is defined (TCPS 2 (2014), Chapter 2B. [p21]) as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk.

   Examples of such categories of delegated REB review might include the following:

- Research protocols that involve no more than minimal risk;
- Amendments to already approved (non-Health Canada) protocols where there is no increase in risks of human research participants
- Annual renewals of approved projects in which there has been little or no change in the ongoing research;
- Research involving review of patient records by hospital personnel;
- Chart reviews, where individual identifiers will not be maintained as part of research data;
- Adverse events reported in the course of an on-going approved study;
- Studies already approved by other established REB;
- Studies involving secondary analysis; and
- Affirmations that conditions laid down by the REB as a condition of approval have been met.

An institution that decides to authorize delegated REB review must require that such approvals be reported in appropriate ways to the full REB, permitting the REB to maintain surveillance over the decisions made on its behalf. Principles of accountability require that, regardless of the review strategy, the REB continue to be responsible for the ethics of all research involving human research participants that are carried out within the institution.
Every application for REB review must contain the Human Subjects Research Application Form, and whichever of the following materials are relevant to the study:

- budget
- study protocol/proposal
- consent and assent forms, fact or information sheets, phone consent scripts (letters and other communications to be provided to human research participants)
- investigator Brochure, if drug study
- all recruitment materials (e.g., flyers and advertisements, letters to participants)
- grants and Contracts
- questionnaires, interview scripts, phone scripts, etc.
- focus group guides
- documentation of approvals from any other reviewing bodies
- documentation of training in research ethics (i.e. Tri-Council Policy Statement - 2 On-line Tutorial)
- investigators' curriculum vitae; and
- any other tool that will be used in the conduct of the study.

The REB may request such further information and materials as it deems necessary in order for it to evaluate an application.

Applications for full board review must be submitted two weeks prior to the REB monthly meeting date at which the researcher wishes his/her application to be reviewed and submission should be received by the end of business day. Applications are added to the agenda on a first come, first–serve basis. If the agenda is full, the REB may defer consideration of an application until the next scheduled meeting.

The REB's minutes will be completed by the REB office and they will clearly reflect and document the relevant discussions and decisions reached by the REB, any dissents from the decisions reached by the REB, and the reasons underlying its decisions, and any dissents thereto, as well as other aspects of the meeting and the REB's deliberations. Once the REB has reached a decision, the REB will, in a letter signed by the REB Chair (or designee), promptly notify the applicant of its decision and the reasons underlying its decision. For the purposes of assisting internal and external audits or research monitoring, and to facilitate reconsideration or

appeals, the minutes must be accessible to authorized representatives of the institution, researchers and funding agencies (TCPS 2 (2014), Article, 6.17).

REB Determinations

Decisions:
Decisions of the REB are made, where possible, by consensus. If a consensus is not reached, a vote will be taken. In the event of a disagreement with the project, the study will be referred back to the investigator with comments and/or recommendations for revision. Investigators maybe invited to a meeting with the REB to respond to questions about their projects. They will not, however, be present during the decision-making process. Researchers will be advised of the outcome of the review in writing.

Studies may receive the following:

1. *Approval* – In the case of an approval with no changes, the research may proceed once the principal investigator receives written documentation of REB approval. Unless otherwise indicated by the REB, the approval period for research without changes is one year from the date of the approval letter (the date of the approval letter may be the date of the REB Board meeting when the study was reviewed).
2. *Conditional Approval* – The REB may determine that a study may be approved with stipulated minor changes or clarifications. Minor changes include, but are not limited to changes that do not involve potential for increased risk or decreased benefit to human research participants. Such changes must be clearly delineated at the meeting during which the REB made its decision, so that subsequent review of the application will require simple verification of concurrence and compliance. The Chair or a voting member designated by the Chair must ensure that the principal investigator makes the appropriate changes to the project. Research may proceed once the required changes have been made and either the Chair or the designated reviewer has approved the project. Unless, otherwise indicated, the approval period for conditionally approved research is one year from the date of the final approval letter (the approval date is the date of the REB Board meeting when the study was reviewed and approved).
3. *Request for Resubmission* – The submission is incomplete, major revisions are needed or there may be serious concerns with the study plan. The REB may request the researcher to rework his or her application and resubmit it.
4. *Suspension or Termination of Study* – The REB Chair or the REB itself may suspend a study at any time if it is determined that the study requires further review or evaluation. This may be due to an adverse event, non-compliance or other risks to human research participants. If a project is suspended, research (including all contact with research participants not required to ensure participant safety) must immediately cease. Though the Chair may suspend a study, pending REB review, only the convened REB may terminate a study. If a study is suspended or terminated, the Chair (in the instance of a suspension) or the REB (in the instance of a termination) shall provide the principal investigator written notification that includes a statement of reasons for the decision.

Reporting

Written reports will be provided to the Board of Directors on a yearly basis and as necessary, and reports regarding REB activities are communicated to the MAC through the PIC and/or the REB Chair.

Appeals and Request for Reconsideration

The investigator may ask the REB to reconsider any decision or any action it has made regarding a research project or research activity. An investigator may appeal any decision the REB makes concerning a proposed or ongoing research project or activity.

Review Procedures for Ongoing Research

Unless otherwise indicated, the approval period for all research projects is one year (from the REB meeting date that the study was reviewed and approved). If there is uncertainty on the probability of the harms, then the REB can request 4 month or 6 month reports, or reporting on any unexpected events. Research that remains ongoing one year subsequent to the study's initial period expires prior to a renewal of its approval by the REB. If a study lapses, all research-related activities must halt, except where and insofar as doing so would jeopardize the welfare of human participants. If the principal investigator fails to submit materials for continuing review/renewal within one month of the expiration date, then the lapsed study will be classified as inactive.

An Annual Renewal/Final Report Form must be submitted with the applicable renewal information completed. This form should be provided to the REB no later than one month prior to the anniversary of the study approval date, with due regard for next date on which the REB is scheduled to meet. The application for renewal/continuing review must include a progress report in which the principal investigator provides sufficient information for the REB to determine whether the research ought to be continued / renewed.

Researchers must adhere to the approved protocol and use the approved consent documents.

Completion of Study

Study closure refers to the completion of recruitment and all follow-up components of a study. In some cases, specific external reporting requirements may require annual renewal even after a study is closed. An Annual Renewal/Final Report Form must be submitted with the applicable information completed.

Researchers who leave Ontario Shores are required to inform the REB of the status of any on-going research. If a study is to be closed or transferred to another facility, the REB must be informed and any advertisements must be discontinued.

Modifications of Approved Protocols

A modification is a deviation from, an amendment of, or a change to a research project. Prior REB review and approval is required before investigators may modify research protocols, except when necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the trial (e.g. change of monitor, address, and telephone number). Proposed changes to a previously approved project must be submitted as an amendment to that project, along with the reasons therefore and any and all supporting and relevant documentation. Proposed changes to a previously approved project may, depending on the Chair's assessment of the associated risk, receive delegated or full review.

Reporting Requirements

Investigators must promptly report to the REB the following:

- Deviations, from, or changes to, the protocol that serve to eliminate immediate hazards to the trials participants.
- Changes that increase the risk to participants and/or significantly affect the conduct of the trial.
- Any new information that may adversely affect the safety of the participants or the conduct of the trial.
- All serious adverse events (at a minimum all serious, unexpected events must be reported).

An adverse event is an unexpected or normally avoidable event that negatively affects, or would reasonably be expected to have the potential for negatively affecting, the patient's health and/or overall well-being, and which event occurred in the course of the patient's illness or underlying condition. If an Ontario Shores participant (on-site) experiences an adverse event or if the principal investigator or local study lead become aware of any new information that may adversely affect the safety of the participants or the conduct of the trial the principal investigator or local study lead must notify the REB within 48 hours (or within two working days) and in accordance with Good Clinical Practice regulations. If an external (off-site) participant experiences an adverse event the principal investigator must notify the REB within two weeks (or 10 working days).

Any and all such reports must contain the following information:

- REB study number
- title of protocol
- name of principal investigator
- participant identifier (study number/reference of participant)
- date and location of the event
- description of the event (nature of injury or other adverse occurrence, assessment of severity, and assessment of event's relationship to the study)
- handling of/response to the event
- any proposed changes in the protocol or the consent form as a result of the event
- to whom else the event has been reported; and
- signature of the principal investigator.

The REB may ask the principal investigator to provide further information.

Monitoring

The REB conducts continuing review of research covered by this policy, at intervals that are in a manner that is appropriate to the degree of risk. The REB does this in order for it both to protect human participants and to maintain the scientific and ethical integrity of the research that is covered by this policy. Monitoring may include but is not limited to the following:

- reviewing periodic reports
- reviewing final report at the close of a study
- providing on-site and/or observation of ongoing research projects
- a third-party observing the consent process
- reviewing the consent forms
- reviewing documents (e.g. patient charts)
- reviewing records pertaining to the production and maintenance of data
- identifying unapproved activities (e.g. unauthorized research)

Records

Any and all records and documents pertaining to the REB (i.e. its membership, qualifications of members, its processes, its business, and its deliberations) shall be retained for at least 7 years. The REB may, at its discretion, decide to retain certain records and document for 25 years. The REB may also determine which records and documents that it is not required to retain and which to discard.

The REB expects researchers to adhere to Health Canada's requirements for the retention of clinical trial records which must be stored for 25 years. [Please note: With respect to clinical trials, Health Canada's Food and Drug Regulations, Division 5 places the responsibility on the sponsors of clinical trials to retain records for 25 years and this can include sponsors delegating the responsibility to others to retain the records (i.e. Qualified Investigators) for the purposes of possible Health Canada inspection. (Section 6.2, Guidance for Records Related to Clinical Trials" Guide 0068 - Interpretation of section C.05.012 of the *Food and Drug Regulations* - Division 5 "*Drugs for clinical trials involving human subjects)*.]

The REB also expects researchers to adhere to the Public Hospitals Act requiring medical records containing personal health information regarding in-patients or out-patients to be retained for a period of 10 years past the 18th birthday of a minor, or 10 years after the last visit/admission of a patient 18 years or older.

References:

Tri-Council Policy Statement - 2 (2014): Ethical Conduct for Research Involving Humans

St. Joseph's Health Centre's Research Ethics Board Standard Operating Procedures, version December 2015

Centre for Addiction and Mental Health's REB Terms of Reference, revised version 3 July 2016

Section 6.2, Guidance for Records Related to Clinical Trials" Guide 0068 - Interpretation of section C.05.012 of the *Food and Drug Regulations* - Division 5 "*Drugs for clinical trials involving human subjects)*.]

Reviewed By:

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