Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Suspension or Termination of REB Approval
REB SOP # 016

Issued by: Research Ethics Board Office
Date of Issue:
Revised: YYYY/MM/DD

Purpose:
This standard operating procedure (SOP) describes the procedures associated with the suspension or termination of the Research Ethics Board's (REB) approval of research (including the suspension or termination of approval).

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

Description:
Suspensions of terminations represent actions taken by the REB to temporarily or permanently withdraw approval for research. As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Investigator is not conducting the research in compliance with applicable regulations and guidelines. The REB also has the authority to suspend new enrollment while additional information is requested. A decision to suspend or to terminate the REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place. The REB has the authority to suspend or to terminate the REB's approval of the research. The REB Chair or designee has the authority to suspend ethics approval. Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board.

Procedure:

1) Administrative Hold:
This is a voluntary action by an investigator to temporarily or permanently stop some or all research activities as a modification to approved research. Examples when this would be appropriate include the following: unanticipated problem, investigator going on a sabbatical leave or leave of absence. Although the investigator may discuss this action beforehand with the REB chair, Director of Research, or Vice President for Research, the hold must be initiated voluntarily by the investigator in writing to the REB. During administrative hold, the research remains subject to continuing review and requirements for reporting non-compliance and unanticipated problems involving risks to subjects or others. Administrative holds are not considered suspensions or terminations, and do not meet reporting requirements to regulatory authorities.

2) Suspension or Termination of Research by the Sponsor:

- The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.)

- The Investigator must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action
- Reports of suspensions or terminations of the research by the sponsor will be forwarded to the REB Chair or designee for review
- If the REB Chair or designee decides to suspend REB approval of the research, he/she must notify the REB at its next Full Board meeting
- If REB approval is suspended, a subsequent Full Board review must be conducted and the REB suspension must be lifted prior to resumption of the research, following the sponsor's lifting of a suspension

3) Suspension or Termination of Research by the Institution

- Institution may suspend or terminate a study or trial by an investigator for philosophical or administrative (e.g. resource limitation) reasons or due to findings of a research misconduct by the investigator. Research misconduct means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. A study or a trial may also be suspended or terminated by the institution under the circumstances, when an investigator is asked to leave the institution
- Institutional authorities (Director or Vice-President of Research) must notify the REB Chair or designee on the suspension or termination of the research and provide reasons thereof
- If the REB Chair or designee decides to suspend REB approval of the research, he/she must notify the REB at its next Full Board meeting
- If REB approval is suspended, a subsequent Full Board review must be conducted for lifting the REB suspension, following the institutional lifting of a suspension prior to resumption of the research
- Terminations of REB approval must be approved by the full board and the study must come to a full halt. Re-activation of a terminated study is not possible

4) Suspension or Termination of Research by an Investigator:

- Investigator may suspend or terminate a research for valid reasons such as lack of resources or lack of time to responsibly conduct the research or investigator voluntarily leaving the institution to seek other academic/administrative appointments at other institutions
- Investigator must notify the REB Chair or designee on the suspension or termination of the research and provide reasons thereof
- Same protocol is followed thereafter as in # 3

5) Suspension or Termination of REB Approval

a) If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with the REB-approved protocol or REB requirements
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events or DSMB reports)
- Falsification of research records or data
- Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications)
- Repeated or deliberate failure to properly obtain or document consent from research participants
- Repeated or deliberate failure to limit administration of the investigational drug or device to those

research participants under the Investigator's supervision • Repeated or deliberate failure to comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies
- Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB

b) The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, he/she must notify the REB at its next Full Board meeting

c) The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;

d) Prior to suspending or terminating REB approval, the REB must consider:

• Risks to current participants
• Actions to protect the safety, rights and well-being of currently enrolled participants
• The appropriate care and monitoring of research participants
• Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal
• Whether participants should be informed of the termination or suspension
• Whether adverse events or outcomes should be reported to the REB
• Identification of a time frame in which the corrective measures are to be implemented

e) The REB Chair or designee will notify the Investigator of any suspensions or terminations of REB approval, and the reasons for the decision

f) Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events

g) If the research is suspended or terminated, the REB Chair or designee will issue a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB

h) If REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the REB's satisfaction

4) Reporting Suspensions or Terminations:

The REB Chair or designee will report any suspension or termination of REB approval to the appropriate Ontario Shore's Official(s) and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting to the organization.

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.

The Researcher is responsible for notifying the REB and if required, Ontario Shore's officials of any suspensions or terminations of the research by the Sponsor and for providing a detailed explanation for the action.

The REB Chair or designee is not authorized to terminate REB approval; however, the REB Chair or

designee is authorized to suspend REB approval, which must be reported to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.

The REB Chair or designee shall notify the Researcher, and Ontario Shore's Official(s), of any suspension or termination of REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the organization.

References:

1) N2 CAREB REB SOPs v1 *SOP 407.001* (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)