Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Amendments Review
REB SOP # 013

Issued by: Research Ethics Board Office
Date of Issue: 2015-06-15
Revised: YYYY/MM/DD

Purpose:
The purpose of this standard operating policy and procedure (SOP) is to describe the process for submission and review of amendments to Research Ethics Board (REB) approved research.

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

Description:
In addition to the formally scheduled continuing ethics review, the REB must receive and review all new information and changes (amendments) generated throughout the course of the research. The REBs has adopted a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the care in assessing the research.

Proportionate review reserves the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research. Changes to an existing protocol may constitute a new research study and application, as opposed to an amendment, when there are significant changes to:

- the Research Question
- the Recruitment strategy or eligibility criteria
- the Risk to participants

Procedure:

- The investigator is responsible for submitting to the REB any changes to the approved research in the form of an amendment. Changes to the approved research include modifications including modifications to the research, to the consent form, to the Investigator Brochure (IB) or product monograph (PM), changes in participant materials (e.g., wallet cards, diary cards, recruitment materials), a change in the Investigator etc.

- When the amendment includes a change to the consent form, the Investigator must indicate his/her recommendation for the provision of the new information to current and/or past research participants

- The Investigator must indicate the type of review being requested (i.e., Full Board, delegated review or acknowledgement for a minor correction). Supporting correspondence documentation and/or background information may be appended to the amendment submission

- The REB Chair or designee reviews the amendment to determine the appropriate level of REB review required (i.e., Full Board or delegated review)

- The REB Chair or designee also may use delegated review procedures for review of amendments when the conditions are met

- If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting. Amendments that may be classified as more than minimal risk may include:

- Addition of genetic testing, new genetic tests, or tissue banking where genetic testing may or will be performed
- Addition of an open label extension phase following a randomized trial
- Emergency amendments that arise because of participant safety and may include, but are not limited to: a) A change in drug dosing/duration of exposure b) A change in recruitment that may affect confidentiality or the perception of coercion c) A change in experimental procedure or research population

- For amendments requiring Full Board review, the responsible REB Office Personnel assigns the amendment to the next available Full Board meeting. For amendments that meet the criteria for delegated review, the responsible REB Office Personnel will forward the amendment to the designated reviewer in consultation with the REB Chair

- When an amendment involves a revised consent, the REB will consider the recommendations of the investigator in determining if, how and when the new information should be provided to the research participants and whether re-consent is required

- The REB must find that the criteria for approval are still met in order to approve the amendment

- The amended research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants. If changes are made to eliminate immediate hazards, the investigator must notify the REB Chair immediately. The REB Chair will notify the REB membership of the modifications at the next convened REB meeting

- REB review activities related to any amendments will be documented, filed and retained by the REB office as per REB operational procedures (Refer to REB-SOP- Document Management).

- Research Ethics Board notice of approval or changes required to obtain continuing approval will be distributed to Principal Investigator in a timely manner by the REB office

Responsibility:
This SOP applies to the REB Chair, all REB members, REB staff, Principal Investigator and research teams

References:

1) N2 CAREB REB SOPs v1 *SOP 404.001* (September 2014) https://oicronca.box.com/s/95k7ydj574579ajvbe06

2) St. Joseph's Care Group Research Ethics Board Terms of Reference *Amendment Application and Review REB-SOP-V-05.01* (May 2012)

3) 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/

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

5) 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

6) 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

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