Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Continuing/Annual Review
REB SOP # 014

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Purpose:
This standard operating procedure (SOP) describes the procedures for the continuing/annual review of research that is overseen by the Research Ethics Board (REB), and the criteria for continued REB approval.

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

Description:
REBs must establish procedures for conducting the continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

Procedure:

1) **Continuing Review by the Full Board:**

- The Researcher is required to submit an application for continuing review of research at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;
- At a minimum, the REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB;
- The REB may determine that the research requires continuing review more frequently than once per year by considering the following:
    - The nature of any risks posed by the research
    - The degree of uncertainty regarding the risks involved
    - The vulnerability of the participant population
    - The projected rate of enrolment and estimated research closure date
    - Whether the research involves novel interventions
    - The REB believes that more frequent review is required

- Continuing review applications are due by the deadline for the applicable REB meeting (i.e., the expiry date must be on or after the REB meeting date and prior to the date of the subsequent REB meeting), regardless of the type of review they may undergo;
- To assist the Researchers in submitting on time, two courtesy reminder(s) are generated at 60 and 30 days prior to the expiry date by the REB office personnel and sent to the Principal Investigator
- The responsible REB Office Personnel reviews the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable
- The REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:
    - Based on the results of a previous audit or inspection (internal or external)

    - Suspected non-compliance
    - Studies involving vulnerable populations
    - Studies involving a potentially high risk to participants
    - Suspected or reported protocol deviations
    - Participant or Research Staff complaints
    - Any other situation that the REB deems appropriate
- In consultation with the Chair of the REB, the responsible REB Office Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review
- A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda
- For research that meets the criteria for Full Board review, the REB will discuss the research at a Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

2) Continuing Review by Delegated Review Procedure:

- When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;
- Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met
- The responsible REB Office Personnel reviews the continuing review application for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;
- The responsible REB Office Personnel will forward the application to the appropriate REB reviewer;
- The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;
- Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

3) REB Determinations:

To grant a continuation of the approval of the research the REB must determine that:

- There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved
- There is no new conflict of interest or new information that has emerged that might adversely affect the safety or the well-being of research participants
- Risks to research participants are minimized and reasonable in relation to the anticipated benefits
- Selection of research participants is equitable
- Informed consent processes continue to be appropriate and documented
- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data
- Any complaints from research participants have been followed-up appropriately

- The REB may also make additional determinations, including:
    - Request changes to the informed consent form(s)
    - Request changes for the continuing review interval (based on risks)
    - Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period)
    - Require modifications to the research

- Suspend or terminate REB approval

4) Continuing Review Applications not Received by the Expiry Date:

- If an application for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Principal Investigator. When suspended, the Researcher must suspend all research activities as specified by the REB. The responsible REB Office Personnel will follow-up with the investigator to ensure that the application for continuing review is submitted as soon as possible
- In the event of a lapse in approval, the investigator is responsible for notifying the REB if there is a need to continue research-related medical treatment of current research participants for their safety and well-being. The investigator should provide as much detail as possible about the proposed continued activities. The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the investigator
- The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses
- If the REB approval lapses and the Researcher wants to continue with the research, the REB will complete the review of the research as soon as possible and the investigator may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented.

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

References:

1) N2 CAREB REB SOPs v1 *SOP 405.001* (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)