Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Research Completion
REB SOP # 017

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Purpose:
This standard operating procedure (SOP) describes the procedures for the closure of research with the Research Ethics Board (REB) after the participant enrolment and data collection is over and the study has been completed.

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

Description:
The Completion of research is a change in activity that must be reported to the REB. Although research participants will no longer be at risk under the research, a final report allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

Procedure:

- The Investigator must submit a final study closure report to the REB when there is no further participant involvement at the site, all data collection is complete, and the sponsor closeout activities, if applicable, have been complete
- The responsible REB Office Personnel will review the final study closure application and any attached conference or a journal publication report and request any outstanding information, clarification or documentation from the Investigator, if needed
- The REB Chair or designee will review the submission and issue a letter of Acknowledgement to the Investigator. The REB file on the research project will change from “Active” to “Closed” status as of the date of receipt of the closure report
- Once a research project is “Closed” with the REB, no further submissions for that research will be permitted; however, if required, the Investigator still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB
- If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB and the conditions of this request will be determined at the time of the review

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met. The REB Chair or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

References:

1) N2 CAREB REB SOPs v1 *SOP 406.001* (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)