Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: REB Communications
REB SOP # 019

Issued by: Research Ethics Board Office
Date of Issue: 2016-03-02
Revised: YYYY/MM/DD

Purpose:
This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with the 1) Investigator and his/her research team and 2) research participants.

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

Description:
In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between the REB and the Investigator and research participants. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies and procedures.

Procedure:
1) Communication with research participants:

- Research participants should be able to voice their concerns, questions and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the REB or in the REB office
- Research participants are encouraged to contact (by telephone or in writing) the REB office with questions and concerns, using the contact information provided in the informed consent document(s). If requested, the identity of the participant will not be recorded or shared
- The REB Office Personnel must document all communication with the research participant
- The REB Office Personnel will communicate participant concerns to the REB Chair or designee
- The REB Chair or designee works to resolve participant issues which may include a follow-up with the Investigator or the Investigator's supervisor or other organizational representative, and with appropriate federal agencies, as applicable
- The REB Chair or designee documents all communication with the research participant and a de-identified record of this communication is maintained securely and in the relevant research file

2) Communication with the Investigator:

All Investigators participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

Feedback from Investigators should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the REB office procedures.

In order to facilitate clear and accurate communication with Investigators and research staff, the REB will follow standardized notification and documentation procedures.

2.1 Notification of REB Decisions:

- The REB will notify the Investigator and/or his/her research staff of the REB's decision within a time frame specified by the REB, following the review (i.e., from the REB meeting or delegated review date) of new research, modifications, or amendments to currently approved research, applications for continuing review or reportable events

- The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

- If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Chair or designee will notify the Investigator of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow

- The REB Chair or designee will review the draft REB review letter, make revisions as necessary, and will indicate his/her approval

- The REB review letter will be issued to the Investigator(s)

- The Investigator will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB

- Upon receipt of the Investigator response to the REB review letter, the REB will follow-up with the Investigator and/or his/her staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewers

- Once all of the REB conditions are satisfied, the REB will issue an approval letter

2.2 Investigator Appeal of REB Decision:

- An Investigator may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB

- Appeals are conducted in accordance with established organizational policy at Ontario Shores'

- Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

Responsibility:
All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

References:

1) N2 CAREB REB SOPs v1 *SOP 106.001* (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)