



Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: Non-Compliance
REB SOP # 022

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Purpose:

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance

Scope:

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

Description:

Reports of non-compliance may come from any source including the REB members, Investigators, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Investigator or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.

Procedure:

1) Reports of Non-compliance:

- Reports of non-compliance in human participant research may come from many sources including, but not limited to Investigator (as a self-report), a sponsor representative, a quality assurance or compliance office, a research participant, a member of the research team, or a person not directly involved with the research
- Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance
- Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance inspections, sponsor audits or inspections, or regulatory agency audits or inspections

2) Evaluating Allegations of Non-compliance:

- When an allegation of non-compliance is referred to the REB, the REB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the REB Chair or designee
- The REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor
- The REB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegations

- The REB Chair or designee will obtain as much information as possible from the individual reporting the incident
- The REB Chair or designee will obtain as much information as possible, or verification from other sources by one or more of the following means:
 - Contacting the Investigator or member of the investigative team directly
 - Consulting with other relevant organizational personnel
 - Collecting relevant documentation
 - Reviewing any written materials
 - Interviewing knowledgeable sources
- If the REB Chair or designee determines that there is evidence of non-compliance, he/she will then assess whether the non-compliance was intentional, serious and/or repeated
- If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required

3) Managing Non-compliance:

- The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;
- If the REB Chair or designee determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance and took appropriate corrective actions, no further action may be required
- If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Investigator, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the REB at a Full Board meeting
- If it appears that an Investigator was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the REB, and will inform the appropriate Ontario Shores' Official
- The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions
- Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB may consider one or more of the following actions:
 - Request modification of the protocol
 - Request modification of the informed consent document
 - Require that additional information be provided to past participants
 - Require that current participants be notified
 - Require that current participants re-consent to participation
 - Modify the continuing review schedule
 - Require onsite observation of the consent process
 - Suspend the new enrollment of participants
 - Suspend REB approval of the research
 - Suspend Investigator involvement in the research

- Terminate REB approval of the research
- Require the Investigator and/or staff to complete a training program
- Notify organizational entities (e.g., legal counsel, risk management)
- Ensure that all other regulatory reporting requirements are met, as required
- Any other action deemed appropriate by the REB.

4) REB Response to Reports of Non-compliance:

- The REB Chair or designee will notify the Investigator in writing of the results of the REB review of incidents of non-compliance and any remedial actions required
- The REB Chair or designee will report any serious or continuing non-compliance to the Investigator as well as to the Ontario Shores' Official(s), and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to appropriate Ontario Shores' Officials
- The REB may submit an allegation of research misconduct to the Ontario Shores' Officials as appropriate
- The REB will request a time-sensitive response in writing from the Investigator, including the corrective action plan
- The Investigator's response may be reviewed using a delegated REB review procedure or the review may be referred to the REB, for a decision from the Full Board
- The REB Chair or designee will follow-up to assess any corrective measures implemented by the Investigator

5) Documenting Non-compliance:

- The REB Chair or designee will document the findings of reports of non-compliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the REB's decision and actions taken, and the Investigator's response
- For those incidents of non-compliance referred to the Full Board, the REB Office Personnel will document the following in the REB meeting minutes: a description of the incident and findings, verification of the non-compliance, the REB's decision, the remedial action required by the REB, the Investigator's response and actions implemented and plans for further follow-up

Responsibility:

All REB members, REB Office Personnel and Investigators are responsible for ensuring that the requirements of this SOP are met. Investigators are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of approval of the REB. The REB Office Personnel and the REB members are responsible for acting on information or reports of non-compliance received from any source. The REB Chair or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions. The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Investigator and to the appropriate Ontario Shores' Official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting (as applicable) to Ontario Shores' Officials.

References:

- 1) N2 CAREB REB SOPs v1 *SOP 903.001* (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)