



SOP Title	Non-compliance
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard Operating Procedure (SOP) describes The University of Western Ontario (UWO) Health Sciences Research Ethics Board (HSREB) and Office of Human Research Ethics (OHRE's) processes for responding to reports of non-compliance and the actions that the REB/OHRE may take as a result of its review of reports of serious and/or continuing non-compliance.

2. GENERAL POLICY STATEMENT

Reports of non-compliance may come from any source including the HSREB members, Investigators, research participants, institutional personnel, the media, anonymous sources, 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 an Investigator or any member of the research team. It is, therefore, the duty of the REB/OHRE to be receptive to these reports and act on all allegations of non-compliance.

3. RESPONSIBILITY

This SOP applies to Investigators, all HSREB members including the Chair, Vice-Chair(s), OHRE staff, and the Director, Research Ethics and Compliance.

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 HSREB.

The OHRE staff and HSREB members are responsible for acting on information or reports of non-compliance received from any source.

The HSREB Chair(s) or designee are responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the HSREB is responsible for determining the relevant corrective actions.

The HSREB Chair or designee is responsible for reporting any incidents of serious or continuing non-compliance to the Investigator and to the appropriate Organizational Official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The HSREB may delegate regulatory authority reporting (as applicable) to the organization.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Reports of Non-compliance

- 5.1.1 Reports of non-compliance in human research may come from many sources, including but not limited to, an Investigator (as a self-report), a Sponsor representative, a quality assurance or compliance office, a research participant, a departmental head, a member of the research team, or a person not directly involved with the research;
- 5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the OHRE will receive and document oral reports of non-compliance;
- 5.1.3 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.

5.2 Evaluating Allegations of Non-compliance

- 5.2.1 When an allegation of non-compliance is referred to the HSREB, the OHRE office staff will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the HSREB Chair or designee;
- 5.2.2 The HSREB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;
- 5.2.3 The HSREB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegation;
- 5.2.4 The HSREB Chair or designee will obtain as much information as possible from the individual reporting the incident;
- 5.2.5 The HSREB 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 institutional personnel,
 - Collecting relevant documentation,
 - Interviewing knowledgeable sources;
- 5.2.6 If the HSREB Chair or designee determines that there is evidence of non-compliance, they will then assess whether the non-compliance was intentional, serious and/or repeated;
- 5.2.7 If the HSREB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

5.3 Managing Non-compliance

- 5.3.1 The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized by interrupting the study;
- 5.3.2 If the HSREB 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;

- 5.3.3 If the HSREB Chair or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize that non-compliance or take appropriate corrective actions, the HSREB 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 full HSREB Chair at a convened meeting;
- 5.3.4 If it appears that an Investigator was intentionally non-compliant, the HSREB Chair or designee will refer the matter to the next Full Board meeting of the HSREB, and if inform the Institutional Official;
- 5.3.5 The HSREB will review the information at the next convened Full Board meeting and determine the appropriate corrective actions;
- 5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the HSREB may consider one or more of the following actions:
- Request modification of the protocol,
 - Request modification of the informed consent document,
 - Request that additional information be provided to past participants,
 - Require that current participants be notified,
 - Require that current participants re-consent to participant,
 - Modify the continuing review schedule,
 - Require onsite observation of the consent process,
 - Suspend the new enrolment of participants,
 - Suspend HSREB approval of the research,
 - Suspend Investigator involvement in the research,
 - Terminate HSREB approval of the research,
 - Require the Investigator and/or staff to complete a training program,
 - Notify local institutional entities (e.g., legal counsel, privacy, risk management),
 - Ensure that all other regulatory reporting requirements are met, as required,
 - Any other action deemed appropriate by the HSREB.

5.4 HSREB Response to Reports of Non-compliance

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

5.5 Documenting Non-compliance

- 5.5.1 The HSREB 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 HSREB Chair decision and actions taken, and the Investigator response;
- 5.5.2 For those incidents of non-compliance referred to the Full Board, the OHRE office staff will document the following in the meeting minutes: a description of the incident and findings, verification of the non-compliance, the HSREB's decision, the remedial action required by the HSREB, the Investigator's response, and actions implemented and plans for further follow-up.

6. REFERENCES

- 6.1. Health Canada, Division 5 of the Food and Drug Act;
- 6.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
- 6.3. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP);
- 6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Parts 50 and 56;
- 6.5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
903.001	Original	05/29/2014
903.002	Minor administrative changes for clarification	07/29/2014
903.003	Administrative changes for correctness	08/05/2014
903.004	Minor administrative revisions for clarity	05/10/2016
903.005	Updated to be more consistent with N2 CAREB SOP	01/28/2022