



SOP Title	Noncompliance
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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) Office of Human Research Ethics (OHRE's) processes for responding to reports of noncompliance and the actions that the OHRE may take as a result of its review of reports of serious and/or continuing noncompliance.

2. GENERAL POLICY STATEMENT

Reports of noncompliance may come from any source including the Health Sciences Research Ethics Board (HSREB) members, Non Medical (NM) REB, 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 noncompliance on the part of an Investigator or any member of the research team. It is, therefore, the duty of the OHRE to be receptive to these reports and act on all allegations of noncompliance.

3. RESPONSIBILITY

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

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 OHRE.

The OHRE staff and HSREB/NMREB members are responsible for acting on information or reports of noncompliance received from any source.

The HSREB/NMREB Chair(s) are responsible for the initial review of allegations of noncompliance.

The local Institutional Officials are responsible for reporting any incidents of serious or continuing noncompliance to the regulatory authorities in accordance with applicable laws, or the terms and conditions of research agreements or contractual arrangements.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Reports of Noncompliance

- 5.1.1 Reports of noncompliance 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 officer, 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. The OHRE will receive and document oral reports of noncompliance; however, the weight of an oral report will be less than a written one;
- 5.1.3 Evidence of serious or repeated noncompliance may also arise from human protection related Quality Assurance inspections, sponsor audits, or regulatory agency audits or inspections.

5.2 Evaluating Allegations of Noncompliance

- 5.2.1 When an allegation of noncompliance is referred to the OHRE, 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 and/or NMREB Chair;
- 5.2.2 The HSREB Chair and/or NMREB Chair or designee manages all allegations of noncompliance and reports of noncompliance that are determined to be more than minor;
- 5.2.3 The HSREB Chair and/or NMREB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegation;
- 5.2.4 The HSREB Chair and/or NMREB Chair or designee will obtain as much information as possible from the individual reporting the incident;
- 5.2.5 The HSREB Chair and/or NMREB 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 and/or NMREB Chair or designee determines that there is evidence of noncompliance, he/she will then assess whether the noncompliance was intentional, serious and/or repeated;
- 5.2.7 If the HSREB Chair and/or NMREB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

5.3 Managing Noncompliance

- 5.3.1 The OHRE will attempt to resolve apparent instances of noncompliance 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 and/or NMREB Chair or designee determines that the noncompliance was not serious or repeated, and the research staff recognized the noncompliance and took appropriate corrective actions, no further action may be required;
- 5.3.3 If the HSREB Chair and/or NMREB Chair or designee determines that the noncompliance was not serious or repeated, but the research staff did not recognize that noncompliance or take appropriate corrective actions, the HSREB and/or NMREB 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 full HSREB Chair and/or NMREB at a convened meeting;

- 5.3.4 If it appears that an Investigator was intentionally noncompliant, the HSREB Chair and/or NMREB Chair or designee will refer the matter to the next HSREB Chair and/or NMREB meeting or to the local Institutional Official if immediate suspension of the research is required;
- 5.3.5 The OHRE will review the information at the next convened meeting and determine the appropriate corrective actions;
- 5.3.6 Corrective actions are based upon the nature and the degree of the noncompliance. In evaluating the noncompliance, the OHRE 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/NMREB approval of the research,
 - Suspend Investigator involvement in the research,
 - Terminate HSREB/NMREB 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 OHRE.

5.4 OHRE Response to Reports of Noncompliance

- 5.4.1 The HSREB Chair and/or NMREB Chair or designee will notify the Investigator in writing of the results of the OHRE review of incidents of noncompliance and any remedial actions required;
- 5.4.2 The OHRE will report to the University Secretariat and/or to the appropriate regulatory authorities;
- 5.4.3 The OHRE will request a time-sensitive response in writing from the Investigator, including a corrective action plan;
- 5.4.4 The Investigator response will be reviewed by the HSREB Chair and/or NMREB. Any required further follow up, review procedure or the review itself may be referred to a convened meeting, of the full HSREB and/or NMREB for a decision regarding future proceedings;
- 5.4.5 The HSREB Chair and/or NMREB Chair or designee will follow-up to assess any corrective measures implemented by the Investigator.

5.5 Documenting Noncompliance

- 5.5.1 The report will include the allegations, the information obtained during the initial assessment, whether allegations of noncompliance were verified, the HSREB Chair and/or NMREB decision and actions taken, and the Investigator response;
- 5.5.2 For those incidents of noncompliance referred to the full HSREB Chair and/or NMREB, the OHRE office staff will document the following in the meeting minutes: a description of the incident and findings, verification of the noncompliance, the Board's decision, the remedial

action required by the Board, 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 2010 (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