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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 Western University's Non-Medical Research Ethics Board (NMREB) and the Office of Human Research Ethics (OHRE) processes for responding to reports of non-compliance and the actions that the 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 NMREB 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 OHRE to be receptive to these reports and act on all allegations of non-compliance.

3. RESPONSIBILITY

NMREB members including the Chair, Vice-Chair, 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 from the NMREB.

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

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

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

The NMREB 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 NMREB 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 noncompliance is referred to the NMREB, the OHRE staff will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the NMREB Chair or designee;

5.2.2 The NMREB 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 NMREB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegation;

5.2.4 The NMREB Chair or designee will obtain as much information as possible from the individual reporting the incident;

5.2.5 The 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 NMREB 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;

5.2.7 If the 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 Non-compliance

5.3.1 The OHRE 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 NMREB Chair or designee determines that the noncompliance 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 NMREB 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 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 NMREB at a convened meeting;

5.3.4 If it appears that an Investigator was intentionally non-compliant, the NMREB Chair or designee will refer the matter to the next NMREB meeting or to the local Institutional Official if immediate suspension of the research is required;

5.3.5 The NMREB 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 NMREB 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 participate,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrolment of participants,
- Suspend NMREB approval of the research,
- Suspend Investigator involvement in the research,
- Terminate 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 NMREB Response to Reports of Non-compliance

5.4.1 The NMREB Chair or designee will notify the Investigator in writing of the results of the NMREB review of incidents of noncompliance and any remedial actions required;

5.4.2 The NMREB 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 NMREB may delegate regulatory authority reporting to the organization;

5.4.3 The NMREB may submit an allegation of research misconduct to the Institutional Official as appropriate;

5.4.4 The NMREB 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 NMREB review procedure or the review may be referred to the NMREB, for a decision from the full board;

5.4.6 The NMREB Chair or designee will follow-up to assess any corrective measures implemented by the Investigator.

5.5 Documenting Non-compliance

5.5.1 The NMREB 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 NMREB Chair decision and actions taken, and the Researcher's response;

5.5.2 For those incidents of non-compliance referred to the NMREB, the OHRE staff will document the following in the meeting minutes: a description of the incident and findings, verification of the non-compliance, 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. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
6.2. 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
N903.001	Original	06/16/2016
N903.002	Update to NMREB Chair & Administrative Changes	05/11/2018
N903.003	Correct SOP number, update NMREB Chair and administrative updates for clarity and removal of reference to HSREB	02/21/2025