TITLE	**903: Non-Compliance**
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	March 2022

1.0 PURPOSE

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

2.0 RESPONSIBILITIES

All HREB members, Research Ethics Office (REO) Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers 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 by the HREB.

REO Personnel and HREB members are responsible for acting on information or reports of non-compliance. The Ethics Director or designee is responsible for the initial review of allegations of non-compliance.

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

The HREB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate official(s) at the Researcher's organization, if applicable. The HREB has the authority to notify the sponsor and regulatory authorities (as applicable), as well as the persons outlined in Section 26 of the HREA Act.

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

Reports of non-compliance may come from any source including HREB monitoring, HREB members, Researchers, research participants, the research team, the media or the public. The rights and welfare of research participants could be at risk if there was non-compliance on the part of a Researcher or any member of the research team. It is the duty of the HREB to be receptive to these reports and to act on all credible allegations of non-compliance.

4.1 Reports of Non-compliance

4.1.1 Persons reporting non-compliance are encouraged to identify the basis for their report via email or in writing. However, the REO will receive and document verbal reports of non-compliance.

4.1.2 Evidence of non-compliance may also arise from monitoring inspections, sponsor audits or inspections, and regulatory agency audits or inspections.

4.2 Evaluating Allegations of Non-compliance

4.2.1 When an allegation of non-compliance is referred to the HREB, the REO Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the HREB Chair and the Ethics Director.

4.2.2 The Ethics Director or designee will conduct an initial review of all allegations to determine the veracity of the allegations.

4.2.3 The Ethics Director or designee will obtain as much information as possible from the individual reporting the incident.

4.2.4 The Ethics Director or designee will collect as much information as possible by one or more of the following means and provide the information to the HREB:

- Contact the Researcher or member of the investigative team directly,
- Consult with other relevant personnel,
- Collect relevant documentation,
- Review any written materials,
- Interview knowledgeable sources.

4.2.5 If the HREB determines that there is evidence of non-compliance, they will then assess whether the non-compliance was intentional, serious and/or repeated.

4.2.6 If the HREB determines that there is insufficient evidence to support the allegations, no further action will be required.

4.3 Managing Non-compliance

4.3.1 The HREB 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 an interruption.

4.3.2 If the HREB 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.

4.3.3 If the HREB 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 HREB or designee will discuss the matter directly with the Researcher and/or recommend corrective action.

4.3.4 If it appears that the non-compliance was intentional or serious, the HREB Chair or designee may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the HREB. Examples of serious non-compliance include, but are not limited to:

- failure to submit the study for continuing review,
- a failure to respond to a request for information from the HREB before proceeding with the protocol,
- changes made to the approved protocol without first obtaining HREB approval,
- a failure to obtain consent from research participants,
- a failure to use approved documentation during the consent process,
- a failure to appropriately include or exclude participants.

4.3.5 The HREB will review the information at the next Full Board meeting and determine the appropriate corrective action. The HREB or designee will inform the applicable persons outlined in section 2.0.

4.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the HREB 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 HREB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate HREB approval of the research,
- Require the Researcher and/or staff to complete a training program,
- Notify organizational entities, if applicable (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Notify the persons as per Section 26 of the HREA Act,
- Any other action deemed appropriate by the HREB.

4.4 HREB Response to Reports of Non-compliance

4.4.1 The HREB or designee will notify the Researcher in a letter of the results of the HREB review of incidents of non-compliance and any remedial actions required.

4.4.2 The HREB or designee will report any serious or continuing non-compliance to the Researcher as well as to the applicable persons outlined in section 2.0, as appropriate.

4.4.3 The HREB will submit an allegation of research misconduct to the applicable persons outlined in section 2.0, as appropriate.

4.4.4 The HREB will request a time-sensitive response in writing from the Researcher, including the corrective action plan.

4.4.5 The Researcher's response will be reviewed by the HREB, or by using a delegated HREB review procedure, as determined by the HREB.

4.4.6 The HREB or designee will follow-up to assess any corrective measures implemented by the Researcher.

4.5 Documenting Non-compliance

4.5.1 The HREB or designee will document the findings of reports of non-compliance. The report will including the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the HREB's decision and actions taken, and the Researcher's response. A copy of the report will be kept in the HREB Monitoring file.

4.5.2 The HREB or designee will document the findings of incidents of non-compliance. The report will include the following: a description of the incident and findings, verification of the non-compliance, the HREB's decision, the remedial action required by the HREB, the Researcher's response and actions implemented and plans for further follow-up. If the incident of non-compliance is reviewed at a Full Board meeting, it will be documented in the HREB meeting minutes. A copy of the report will be kept in the study file and in the HREB Monitoring file.

5.0 REFERENCES

Health Research Ethics Authority Act: An Act to Establish A Health Research Ethics Authority For The Province (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6: Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations, Part 46 (45 CFR 46): Electronic Code of Federal Regulations (eCFR)

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21CFR56: CFR - Code of Federal Regulations Title 21(fda.gov) CFR - Code of Federal Regulations Title 21 (fda.gov)