Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.903**
Title	Non-Compliance
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1. Purpose

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) process for investigating potential incidents of non-compliance and the actions that the REB may take as a result of determining serious and/or continuing non-compliance. Non-compliance is defined as a failure to follow applicable guidelines and regulations governing human participant research and/or failure to follow the protocol approved by the Research Ethics Board (REB), or stipulations imposed by the REB as a condition of approval.

2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. Scope

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

4. Responsibilities

4.1. All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

4.2. Researchers are required to comply with all of the applicable policies, guidelines and other requirements governing the conduct of human research, as well as with the required conditions of approval of the REB.

4.3. The REB Office Personnel and the REB members are responsible for acting on information of potential incidents of non-compliance received from any source.

4.4. The REB Chair or designee is responsible for the initial investigation of potential incidents of non-compliance.

4.5. If intentional, serious, or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions, as pertains to the ethical review of the research.

4.6. The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Organizational Official(s).

4.7. The REB may direct the report to the Organizational Official as an allegation of breach of responsible conduct of research.

5. **Procedures and/or Specific Policies**

Information of potential incidents of non-compliance may come from any source including REB members, Researchers, 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 Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to information about potential incidents of non-compliance, to investigate quickly and to act on all credible allegations of non-compliance.

5.1. Reports of Non-compliance

5.1.1. Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance;

5.2 Evaluating Allegations of Non-compliance

5.2.1 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;

5.2.2 The REB 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 REB Chair or designee will conduct an initial review of all allegations to determine whether further investigation is necessary and may involve other Organizational personnel as required to make this determination;

5.2.4 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 Researcher,
- Consulting with other relevant Organizational personnel,
- Collecting relevant documentation,
- Reviewing any written materials,
- Interviewing knowledgeable sources;

5.2.5 If the REB 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;

5.2.6 If the REB 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 research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;

5.3.2 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;

5.3.3 If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research team did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance visit, and/or refer the matter to the REB at a Full Board meeting;

5.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately, as per SOP 407, and refer the matter to the next Full Board meeting of the REB, and will inform the Organizational Official responsible for receiving allegations of breaches of responsible conduct of research;

5.3.5 The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions that fall within its mandate;

5.3.6 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 documents,
- 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 recruitment of participants,
- Suspend REB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate REB approval of the research,
- Require the Researcher and/or staff to complete a training program,
- Notify Organizational personnel (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Other actions, as deemed appropriate by the REB

5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Chair or designee will notify the Researcher in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The REB Chair or designee will report any serious or continuing non-compliance to the Researcher as well as to the appropriate Organizational Official(s);

5.4.3 The REB may submit an allegation of breach of responsible conduct of research to the Organization Official as appropriate;

5.4.4 The REB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

5.4.5 The Researcher'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;

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

5.5 Documenting Non-compliance

5.5.1 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 (if applicable), and the Researcher's response;

5.5.2 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 Researcher's response and actions implemented and plans for further follow-up.

5.5.3 The REB Chair or designee will document cases where the non-compliance was referred to the Organizational Official responsible for allegations of breaches of responsible conduct of research and will follow-up with the official to ensure that they have received information on outcomes of an inquiry or investigation that could be relevant to the REB's decision-making on the Research.

6. References

See References listed (if applicable)
Also see MSVU Policy - REB.POL.003 – Research Ethics Compliance Policy

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.903	Original	September 2021