SOP Title	**NMREB Ongoing Review**
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Approvals

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

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for the ongoing review activities that occur after the initial NMREB approval of a research proposal and prior to the scheduled continuing review.

2. GENERAL POLICY STATEMENT

It may be that the real risk/benefit ratio can be evaluated only after research has begun; therefore, in addition to the formally scheduled continuing review, the NMREB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such review may include:

2.1.1. Revisions to the previously approved research,

2.1.2. Protocol deviations,

2.1.3. Reports of any privacy breaches,

2.1.4. Summary reports of any audits and inspections,

2.1.5. Revisions to the approved research proposal may not be initiated without prior NMREB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If revisions are made to eliminate immediate hazards, the Investigator must notify the NMREB immediately.

3. RESPONSIBILITY

This SOP is applicable to the Office of Human Research Ethics (OHRE), NMREB Chair, Vice-Chair(s), NMREB members and the Investigator.

The Investigator is responsible for reporting to the NMREB any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants, including reportable events that meet the reporting criteria as per this SOP.
The Investigator is responsible for reporting to the NMREB any information about the conduct of the research that could affect the rights, safety and well-being of research participants, including information about any serious or continuing non-compliance

When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for an unanticipated problem involving risks to participants or others) the NMREB is responsible for reporting to the Investigator and the Organizational Official(s) and has the authority to notify the sponsor

and/or the appropriate regulatory authorities of any events that meet the reporting criteria. The NMREB may delegate regulatory authority reporting (as applicable) to the organization.

The NMREB Chair or designee is responsible for reviewing all reportable events submitted to the NMREB as well as any proposed amendments to the research, and for determining the type of review (i.e., delegated or Full Board) or action required.

The NMREB members are responsible for reviewing any new information, reportable events or proposed amendments that are assigned to them or that are assigned to a Full Board meeting, and for recommending the appropriate course of action.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

It may be that the real risk/benefit ratio can be evaluated only after the research has begun; therefore, in addition to the formally scheduled continuing review, the NMREB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such information may include:

- Modifications or changes to the previously approved research,
- Reports of unanticipated problems involving risks to participants or others,
- Reports of any serious or continuing non-compliance,
- Reports of any changes significantly affecting the conduct of the research or increasing the risk to research participants,
- Deviations to the previously approved research,
- Reports of any privacy breaches,
- Summary reports of any audits and inspections,
- Any other new information that may affect adversely the safety of the research participants or the conduct of the research,

Modifications to the approved research may not be initiated without prior NMREB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the Investigator must notify the NMREB immediately

5.1. Amendments to the Approved Research

5.1.1. Investigator is responsible for submitting to the NMREB any changes to the approved research in the form of an amendment. Changes to the approved research include modifications including (for example) modifications to the research, to the consent form, changes in participant materials (e.g., recruitment materials), a change in the Investigator etc.;

5.1.2. When the amendment includes a change to the consent form, the Investigator must indicate his/her recommendation for the provision of the new information to current and/or past research participants;

5.1.3. Supporting correspondence documentation and/or background information may be appended to the amendment submission;

5.1.4. The NMREB Chair or designee reviews the amendment to determine the appropriate level of NMREB review required (i.e., Full Board or delegated review);

5.1.5. The NMREB Chair or designee also may use delegated review procedures for review of amendments when the conditions are met:

5.1.6. If the proposed change represents more than minimal risk, it must be reviewed by the NMREB at a Full Board meeting. Amendments that may be classified as more than minimal risk may include:

1. A change in recruitment that may affect confidentiality or the perception of coercion,
2. A change in experimental procedure or research population

5.2. **Reportable Events**

5.2.1. Deviations to Previously Approved Research: The Researcher must report to the NMREB any deviations that meet the following reporting criteria:

- Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity,
- Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented),
- Deviations must be reported within a time frame specified by the NMREB;

5.2.2. Privacy Breaches: The Researcher must report to the NMREB any unauthorized collection, use, or disclosure of personal information (PI) including, but not limited to:

- The collection, use and disclosure of PI that is not in compliance with the jurisdictional legislation or its regulation,
- Circumstances where PI is stolen, lost or subject to unauthorized use or disclosure or where records of PI are subjected to unauthorized copying, modifications or disposal,
- In the Researcher context, any unauthorized collection, use or disclosure of PI that was not authorized under the research and approved in the plan that was submitted to the NMREB,

The breach must be reported to the NMREB and, if applicable, to the appropriate Organizational Official as soon as the Researcher becomes aware of the breach;

5.2.3. Audit or Inspection Findings: The Researcher must report to the NMREB a summary of any relevant audit or inspection findings following an audit or an inspection;

5.2.4. Research Participant Complaint: The Researcher must report to the NMREB, and to the organization if required by local procedures, a complaint from a participant when the participant reports concerns about their rights as a research participant or about ethical issues related to the research.

5.3. **Review of Reportable Events by the NMREB**

5.3.1. The responsible NMREB Office Personnel will screen the reportable event submission for completeness;

5.3.2. Privacy breaches are reviewed by the NMREB Chair or designee, and any recommendations including remedial action are determined in consultation with the organization's privacy office. The privacy breach report is forwarded to the NMREB Chair or designee for review and final acknowledgement;

5.3.3. The NMREB Office Personnel may route the submission back to the Researcher to request clarifications, missing documents or additional information;

5.3.4. The NMREB Office Personnel will forward the submission to the designated NMREB reviewer(s);

5.3.5. The assigned NMREB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

5.3.6. The assigned reviewer(s) may request further information from the Researcher;

5.3.7. When reviewing a reportable event, the NMREB should: If the event does not raise concerns and does not appear to involve risks to research participants or others, the NMREB Chair or designee acknowledges the report, and no further action is required;

- Assess the appropriateness of any proposed corrective or preventative measures by the Researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the Researcher,
- Consider whether the affected research still satisfies the requirements for NMREB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

5.3.8. If the NMREB Chair or designee determines that the event meets the criteria for an unanticipated problem, and if immediate action is required to protect the safety of research participants, he/she may suspend ethics approval of the research pending review by the Full Board, providing the justification for such action is documented;

5.3.9. If the event raises concerns or involves risk to research participants such that NMREB action may be required, the item is added to the agenda of the next Full Board meeting;

5.3.10. For reportable events reviewed at a Full Board meeting, the NMREB determines whether further action is required. Possible actions that could be taken by the NMREB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,

- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants' willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Observing the research or the consent process,
- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- If the NMREB determines that the event does not raise concerns about risks to research participants, the NMREB may decide that no further action needs to be taken;

5.3.11. When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for an unanticipated problem involving risks to participants or others) the NMREB chair or designee is responsible for reporting to the Researcher and the Organizational Official(s) and has the authority to notify the sponsor and the appropriate regulatory authorities (as applicable). The NMREB may delegate regulatory authority reporting (as applicable) to the organization.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Chapter 1 Section C; Chapter 2 Section B;

6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;

6.3. OHRP Guidance on Continuing Review;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N405.001	Original	07/07/2016
N405.002	Administrative revisions	05/11/2018