SOP Title	**NMREB Communications – Investigator and Investigator Staff**
Number.Version	N601.003
Effective Date	03/03/2025

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance	Erika Basile	Mar 3, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board	Isha DeCoito	Mar 4, 2025

1. PURPOSE

This standard operating procedure (SOP) describes the Non-Medical Research Ethics Board (NMREB) communications with the Investigator and his/her research team.

2. GENERAL POLICY STATEMENT

In the interest of enhancing human research participant protection, it is important for the NMREB to foster collaboration and open communication between and among the NMREB, Investigators and research staff. This applies not only to communication related to a specific research study, but also communication related to ethical issues as well as NMREB processes, policies and procedures.

All Investigators participating in NMREB approved research shall be informed, in writing, of all determinations made by the NMREB related to the research reviewed.

Feedback from Investigators should also be encouraged and considered as opportunities for NMREB and Office of Human Research Ethics (OHRE) procedure processes improvements.

3. RESPONSIBILITY

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

The NMREB Chair or designee is responsible for overseeing all communications with Investigators conducted on behalf of the NMREB and for the content of all review and approval letters issued on behalf of the NMREB.

The OHRE staff is responsible for drafting correspondence on behalf of the NMREB following a convened meeting or delegated review procedure. The OHRE staff is responsible for distributing the NMREB correspondence to appropriate parties and for day-to-day operational communication with the Investigator and Investigator staff.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Notification of NMREB Decisions

5.1.1. The Ethics Officer (EO) will notify the participating Investigators in writing of the NMREB's decision within three business days of the NMREB meeting for new studies;

5.1.2. The EO drafts the Recommendation Letter summarizing the NMREB determinations, and any concerns or requests for clarification;

5.1.3. The NMREB Chair or Vice-Chair(s) reviews the meeting minutes which are then drafted into the Recommendation Letter, requests revisions as necessary, and signs off on the minutes;

5.1.4. The EO sends the NMREB Recommendation Letter to the Investigator(s);

5.1.5. Upon receipt of the Investigator response to the NMREB Recommendation Letter, the EO will follow-up with the Investigator or his/her staff to request any additional clarifications as needed or as requested by the NMREB Chair, Vice-Chair(s) or NMREB reviewers;

5.1.6. Once all of the NMREB conditions are satisfied, the EO will notify the Investigator in writing of the final approval and the period of approval. The Investigator will be asked to use the unique NMREB number assigned in any subsequent correspondence with the NMREB;

5.1.7. The NMREB Chair, Vice-Chair(s), or designee reviews and signs the approval letter;

5.1.8. The OHRE staff sends the NMREB approval letter to the Investigator.

5.2. Investigator Appeal of NMREB Decision

5.2.1. An Investigator may appeal an NMREB determination not to approve a study or the revisions to the study requested by the NMREB;

5.2.2. Appeals are conducted in accordance with the established process for The University of Western Ontario as per MAPP 7.14 (http://www.uwo.ca/univsec/pdf/policies_procedures/section7/mapp714.pdf);

5.2.3. As per the appeals process, only a fully convened NMREB may lift restriction or re-review a previously disapproved submission. Delegated review procedures may not be used.

5.3. Other Communication with the Investigator or Research Staff

5.3.1. The OHRE staff will respond to queries in a timely and professional manner to encourage communication with the Investigator and research staff.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2) Article 6.18;

6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;
6.3. The University of Western Ontario. MAPP 7.14 Policy and Procedures for Research Involving Human Participants. June 17, 2021.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N601.001	Original	07/08/2016
N601.002	Update to NMREB Chair	05/11/2018
N601.003	Update to NMREB Chair	03/03/2025