

SOP Title	NMREB Communications – Study Participants
Number.Version	N602.003
Effective Date	03/03/2025

Approvals

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

1. PURPOSE

This Standard Operating Procedure (SOP) describes the Non-Medical Research Ethics Board (NMREB) communications with study participants involved in research overseen by the NMREB.

2. GENERAL POLICY STATEMENT

In the interests of enhancing human research participant protection and harmonization of policies and procedure, it is important for the NMREB to foster collaboration and open communication.

Research participants should be able to confidentially voice their concerns or questions, or request information regarding their participation, potential participation in a research project or rights as a research participant to an informed individual on the NMREB or in the Office of Human Research Ethics (OHRE).

3. RESPONSIBILITY

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

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Communication with Research Participants

5.1.1. Research participants are encouraged to contact (by telephone, email or in writing) the OHRE with questions and concerns using the contact information provided in the informed consent document. If requested, the identity of the participant will not be recorded or shared;

5.1.2. OHRE staff relay communications promptly to the NMREB Chair or Vice-Chair(s) when the participant shares concerns or problems encountered with a research project;

- 5.1.3. The NMREB Chair, Vice-Chair(s) or designee works to resolve participant issues, including follow-up with the Investigator or the Investigator’s supervisor or institutional official and appropriate federal agencies, as indicated;
- 5.1.4. The NMREB Chair, Vice-Chair(s) or designee documents communication with the research participant and keeps a record on file at the OHRE.

6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) Chapter 1 Section B;
- 6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N602.001	Original	07/08/2016
N602.002	Update to NMREB Chair	05/11/2018
N602.003	Update to NMREB Chair and minor changes to 5.1.1 for added clarity.	03/03/2025