



| | |
|-----------------------|--|
| SOP Title | HSREB Communications – Study Participants |
| Number.Version | 602.004 |
| Effective Date | January 27, 2022 |

Approvals

| Name and Title of Signatories | Signature | Date mm/dd/yyyy |
|--|---|----------------------------|
| Erika Basile Director, Research Ethics and Compliance |  | 26 Jan 2022 |
| Dr. Philip Jones Chair, Health Sciences Research Ethics Board |  | 27 Jan 2022 |

1. PURPOSE

This standard operating procedure (SOP) describes the Health Sciences Research Ethics Board (HSREB) communications with study participants involved in research overseen by the HSREB.

2. GENERAL POLICY STATEMENT

In the interests of enhancing human research participant protection and harmonization of policies and procedure, it is important for the HSREB to foster collaborative 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 HSREB or in the Office of Human Research Ethics (OHRE).

3. RESPONSIBILITY

This SOP applies to the REB Chair, Vice-Chair(s), REB 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 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 HSREB Chair or Vice-Chair(s) when the participant shares concerns or problems encountered with a research project;

- 5.1.3. The HSREB 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 HSREB 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;
- 6.3. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115;

7. SOP HISTORY

| SOP Number.Version | Key Changes | Effective Date mm/dd/yyyy |
|--------------------|--|------------------------------|
| 602.001 | Original | 01/21/2014 |
| 602.002 | Minor administrative corrections | 05/29/2014 |
| 602.003 | Minor administrative corrections for clarity | 05/10/2016 |
| 602.004 | Minor administrative corrections | 01/27/2022 |