SOP Title	HSREB Communications – Study Participants
Number.Version	602.003
Version Date	05/10/2016

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board	Joseph Gilbert	05/11/2016

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 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 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 (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 2010 (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/yyy
602.001	Original	01/21/2014
602.002	Minor administrative corrections	05/29/2014
602.003	Minor administrative corrections for clarity	05/10/2016