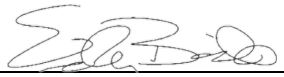
SOP Title	**HSREB Communications – Other Entities**
Number.Version	603.004
Effective Date	January 27, 2022

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 various parties, apart from the Investigator, involved in research overseen by the HSREB.

2. GENERAL POLICY STATEMENT

In the interest of enhancing human research participant protection and the harmonization of policies and procedures, it is important for the HSREB to foster collaborative and open communication with the local HSREB and its various institutional representatives and departments.

The HSREB is required by federal regulations to ensure that specific reports and actions are communicated to entities that may have an interest in the status of the research being conducted, including institutional officials and regulatory authorities.

3. RESPONSIBILITY

This SOP applies to all HSREB members including the Chair and Vice-Chair(s), and to all Office of Human Research Ethics (OHRE) staff.

The Investigator is responsible for informing the HSREB of study related correspondence to and from the regulatory agencies (e.g., Health Canada, FDA, and OHRP), including notification regarding any planned inspections or audits.

The OHRE staff are responsible for notifying the HSREB Chair or Vice-Chair(s) of any communication to or about the HSREB from regulatory agencies (e.g., Health Canada, FDA, and OHRP).

The HSREB Chair or Vice-Chair(s) is responsible for requesting that the Investigator communicate any reportable events to the HSREB, the Sponsor, and Institutional Official(s) as appropriate. The HSREB Chair or Vice-Chair(s) may choose to notify the Institutional Official directly.

The Institutional Official is responsible for communicating required reportable events to the regulatory authorities in accordance with applicable laws, or the terms and conditions of research agreements or contractual arrangements.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Communication with Institutional Contacts

5.1.1. The OHRE staff will provide to the designated institutional representative(s), access to and notification of all HSREB approvals for all initial and continuing approvals (as applicable);

5.1.2. The Investigator must communicate any reportable events occurring during the conduct of the study to the HSREB, the sponsor and the appropriate Institutional Official. The HSREB Chair or Vice-Chair(s) may choose to notify the Institutional Official directly;

5.2. Communication with Institutional Departments

5.2.1. If during its review the HSREB has concerns with the Investigator's application (e.g., conflicts of interest), the HSREB may contact the applicable institutional contact (e.g., contract office);

5.2.2. Reciprocal communication is desirable between the HSREB, the contracts office, the research office, or other departments as applicable, on various matters related to or unrelated to the reviewed research.

5.3. Communication with External Bodies

5.3.1. The HSREB Chair or Vice-Chair(s) may communicate with the regulatory agencies (e.g., Health Canada) to discuss research projects when appropriate, to seek guidance as needed, or to report the termination or suspension of the HSREB approval of a research study;

5.3.2. The HSREB Chair, Vice-Chair(s) or designee is the point of contact for a Health Canada Inspection or an FDA or OHRP Audit. The HSREB Chair or Vice-Chair(s) notifies the HSREB members, the applicable Investigators and the OHRE staff of any planned inspections or audits.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
6.2. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 56.109, 56.115;
6.3. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.115.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
603.001	Original	01/21/2014
603.002	Minor administrative corrections	05/29/2014
603.003	Minor administrative corrections for clarity	05/10/2016
603.004	Minor administrative corrections	01/27/2022