



SOP Title	HSREB Communications – Investigator and Investigator Staff
Number.Version	601.004
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 the Investigator and their research team.

2. GENERAL POLICY STATEMENT

In the interest of enhancing human research participant protection, it is important for the HSREB to foster collaborative and open communication between and among the HSREB, 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 HSREB processes, policies, and procedures.

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

Feedback from Investigators should also be encouraged and considered as opportunities for the HSREB and the Office of Human Research Ethics (OHRE) to improve their procedures.

3. RESPONSIBILITY

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

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

The OHRE staff is responsible for drafting correspondence on behalf of the HSREB following a convened meeting or delegated review procedure. The OHRE staff is responsible for distributing the HSREB 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 REB Decisions

- 5.1.1. The Ethics Officer (EO) will notify the participating Investigators in writing of the HSREB's decision within three business days of the HSREB meeting for new studies;
- 5.1.2. The EO drafts the Recommendation Letter summarizing the HSREB determinations, and any concerns or requests for clarification;
- 5.1.3. The HSREB Chair or Vice-Chair(s) reviews the drafted HSREB Recommendation Letter for Full Board studies, requests revisions as necessary, and signs the letter;
- 5.1.4. The EO sends the HSREB Recommendation Letter to the Investigator(s);
- 5.1.5. Upon receipt of the Investigator response to the HSREB Recommendation Letter, the EO will follow-up with the Investigator or their to request any additional clarifications as needed or as requested by the HSREB Chair, Vice-Chair(s), or HSREB reviewers;
- 5.1.6. Once all of the HSREB 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 HSREB number assigned in any subsequent correspondence with the HSREB;
- 5.1.7. The HSREB Chair, Vice-Chair(s), or designee reviews and signs the approval letter;
- 5.1.8. The OHRE staff sends the HSREB approval letter to the Investigator.

5.2. Investigator Appeal of REB Decision

- 5.2.1. An Investigator may appeal an HSREB determination not to approve a study or the revisions to the study requested by the HSREB;
- 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 HSREB 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 (TCPS2) 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. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115;
- 6.4. The University of Western Ontario. MAPP 7.14 Research Involving Human Participants. June 17, 2021.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
601.001	Original	01/21/2014
601.002	Minor administrative corrections	05/29/2014
601.003	Minor administrative corrections for clarity	05/10/2016
601.004	Minor administrative corrections	01/27/2022