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| <b>SOP Title</b>      | <b>HSREB Communications – Investigator and Investigator Staff</b> |
| <b>Number.Version</b> | 601.003   |
| <b>Version Date</b>   | 05/10/2016  |

### Approvals

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

### 1. PURPOSE

This standard operating procedure (SOP) describes the Health Sciences Research Ethics Board (HSREB) communications with the Investigator and his/her research team.

### 2. GENERAL POLICY STATEMENT

In the interest of enhancing human research participant protection, it is important for the HSREB to foster collaboration 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 HSREB and Office of Human Research Ethics (OHRE) procedure processes improvements.

### 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, 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 his/her staff 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](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 2010 (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 Policy and Procedures for Ethical Review of Research Involving Human Participants. June 30, 2009.

**7. SOP HISTORY**

| <b>SOP Number.Version</b> | <b>Key Changes</b>                           | <b>Effective Date<br/>mm/dd/yyyy</b> |
|---------------------------|--|--------------------------------------|
| 601.001                   | Original                                     | 01/21/2014                           |
| 601.002                   | Minor administrative corrections             | 05/29/2014                           |
| 601.003                   | Minor administrative corrections for clarity | 05/10/2016                           |

