
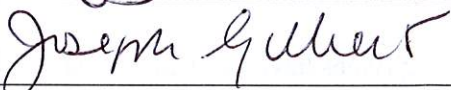


SOP Title	Study Completion
Number.Version	407.002
Version Date	05/10/2016

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		05/11/2016

1. PURPOSE

This standard operating procedure (SOP) describes the procedures for the closure of a research study with the Western University Health Sciences Research Ethics Board (HSREB).

2. GENERAL POLICY STATEMENT

The completion of a research study is a change in activity that must be reported to the HSREB. Although research participants will no longer be at risk under the study, a final report allows the HSREB to close its files.

3. RESPONSIBILITY

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

The OHRE staff is responsible for verifying that all study completion documents are submitted through the online system. Reports are filed appropriately by the ORE staff.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Determining When a Research Study Can be Closed

An End of Study (EOS) report form is submitted when there is no further participant involvement and all data collection, clarification and transfer is complete (including access to the participants' medical record). Submission of this report indicates that these activities have ceased, the study does not require continuing ethics approval, and the HSREB study file can be closed.

- 5.1.1. For single centre research, a study may be closed with the HSREB when there is no further participant involvement and all data collection, clarification and transfer is complete (including access to the participants' medical record);

5.1.2. For multi-centre research, a study may be closed with the HSREB when contact with the local research participants and data collection have ceased and the sponsor has conducted their study closeout procedures.

5.2. Study Completion Reports

5.2.1. When a study is ready to be closed, the Investigator should submit an EOS report form to the HSREB;

5.2.2. The OHRE staff will perform an administrative review of the EOS report form and the files and request any outstanding information, clarification or documentation from the Investigator if needed;

5.2.3. Once all outstanding issues have been addressed, the responsible OHRE staff will issue the letter of acknowledgment to the Investigator. The study state will be changed to “Closed”;

5.2.4. If the sponsor requests additional data following the closure of the study, a request for approval shall be made to the ORE and the conditions of this request will be determined at the time of the review.

6. REFERENCES

- 6.1. The International Conference on Harmonization Good Clinical Practices, Section 4.13;
- 6.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.14;
- 6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109;
- 6.4. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109;
- 6.5. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
407.001	Original	05/29/2014
407.002	Minor administrative corrections for clarity	05/10/2016