



<b>SOP Title</b>	<b>Study Completion</b>
<b>Number.Version</b>	N407.002
<b>Effective Date</b>	05/11/2018

## Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Office of Human Research Ethics		2019-02-26
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### 1. PURPOSE

This standard operating procedure (SOP) describes the procedures for the closure of a research study with the Western University Non-Medical Research Ethics Board (NMREB).

### 2. GENERAL POLICY STATEMENT

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

### 3. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice-Chair(s), NMREB 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 OHRE staff.

### 4. DEFINITIONS

See glossary of terms

### 5. SPECIFIC POLICIES AND PROCEDURES.

#### 5.1. Determining When a Research Study Can be Closed

A Study Closure form is submitted when there is no further participant involvement and all data collection, analysis, clarification and transfer is complete. Submission of this report indicates that these activities have ceased, the study does not require continuing ethics approval, and the NMREB study file can be closed.

#### 5.2. Study Completion Reports

5.2.1. When a study is ready to be closed, the Investigator should submit a Study Closure form to the NMREB;

5.2.2. The OHRE staff will perform an administrative review of the Study Closure 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 OHRE and the conditions of this request will be determined at the time of the review.

## 6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.14;
- 6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109;

## 7. SOP HISTORY

<b>SOP Number.Version</b>	<b>Key Changes</b>	<b>Effective Date mm/dd/yyyy</b>
N407.001	Original	07/07/2016
N407.002	Administrative revisions	05/11/2018