UNIVERSITY OF ONTARIO INSTITUTE OF TECHNOLOGY

SOP Title	**200: REB Operations**
Number. Version	**REB SOP 209 Study Completion**
Version Date	**April 22, 2013**
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Approved By	**REB**
Revised and Approved	**January 18, 2017**

1.0 PURPOSE

This section describes the procedure for the closing of a research project and the required notification of the Research Ethics Board (REB).

2.0 GENERAL PROCEDURE STATEMENT

The completion of a study is a change in activity and must be reported to the REB. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies.

3.0 RESPONSIBILITY AND AUTHORITY

The Chair, Vice-Chair and the REB Administration are responsible for executing this SOP.

4.0 SPECIFIC PROCEDURES

4.1 Determining When a Study Protocol can be closed

Study Completion is required as applicable when:

a. Where no further participant contact is contemplated and all data collection procedures as per the approved protocol have been completed;
b. The acquisition of data that do not involve direct participant participation is complete (i.e., no new cases are being added to the study datatset); and/or
c. No additional tissue samples are being drawn from or deposited to the tissue bank or being acquired from another research group.

4.2 Study Closure Form should include:

a. The Principal Investigator's affirmation that participant data collection is completed;
b. Total number of research participants enrolled at UOIT (or local site);
c. The number of unexpected or unanticipated problems;
d. The final disposition/storage of all research-related study documents;
e. The final disposition of any electronic data; and,
f. Any other information relevant to the REB.

4.3 Clinical Trials Study Closure Form (if required):

The Notification of Study Closure Form should include:

a. The Principal Investigator's affirmation that participant data collection is completed;
b. Total number of research participants enrolled at UOIT (or the local site);
c. The number of unexpected unanticipated problems date of study monitor's final visit
d. The final disposition/storage of all research-related study documents;
e. The final disposition of any electronic data; and,
f. Any other information relevant to the REB.

5.0 Termination

Once the Study Completion has been received by the Research Ethics Coordinator and ratified by the REB at the next REB meeting, the Office of Research Services will notify the researcher that the study is closed. The only activity available to the Investigator from that point on is a "Request for Acknowledgement Termination" if needed. The study cannot be amended or reactivated.