

<b>SOP Title:</b>	<b>Study Completion</b>		
<b>SOP #:</b>	IV.09.001	<b>Original Issue Date:</b>	February 23, 2015
<b>Category:</b>	REB Review of Research	<b>Reviewed/Effective Date:</b>	October 1, 2019
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<b>Approved By:</b>	Dr. Elizabeth Stephenson		

### 1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the closure of research with the Research Ethics Board (REB).

### 2.0 POLICY STATEMENT

The Completion of research is a change in activity that must be reported to the REB. Although research participants will no longer be at risk under the research, a final report allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

### 3.0 DEFINITIONS

See Glossary of Terms

### 4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

### 5.0 PROCEDURES

#### 5.1 Determining when Research can be Closed

- 5.1.1 The Researcher may submit a research closure report to the REB when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed;
- 5.1.2 The responsible REO Personnel will review the research closure application and request any outstanding information, clarification or documentation from the Researcher, if needed;
- 5.1.3 The REB Chair or designee will review the submission and issue a letter of Acknowledgement to the Researcher. The research state will change to "Closed";

- 5.1.4 Once a research project is “Closed” with the REB, no further submissions for that research will be permitted.
- 5.1.5 If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB and the conditions of this request will be determined at the time of the review.
- 5.1.6 Studies that are funded or supported by the US Federal Government are considered open and subject to annual review requirements even where:
- (i) the research is permanently closed to the enrollment of new participants; and
  - (ii) all participants have completed all research-related interventions. Such studies may not be considered completed until all follow up of participants is final.

If the remaining activities are limited to data analysis, there is no further analysis of individually identifiable information.

## **6.0 REFERENCES**

See References