MUHC REB-SOP-408.001

Research Ethics Board
Standard Operating Procedure

Title	Research Completion
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Site Approvals

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Authored	CAE, Manager	2017-02-20
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Acknowledge of receipt	MUHC Board of Directors	

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1. PURPOSE

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

2. SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3. RESPONSIBILITIES

All REB members and REB Office 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.

4. DEFINITIONS

See Glossary of Terms.

5. PROCEDURE

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.

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, participants are no longer exposed to research risks, all data collection is complete, and the sponsor closeout activities, if applicable, have been completed;

5.1.2. The responsible REB Office 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 an 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; however, if required, the Researcher still may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB;

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. Access to medical records require patient consent or DPS approval.

6. REFERENCES

See References.

7. REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
MUHC-REB-SOP-408.001	2017-02-24	Original Version