REB-SOP 408.001
Research Ethics Board
Standard Operating Procedure

Title
Research Completion

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SOP-406.002

Effective Date
2017-02-24
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Site Approvals

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<td>Director, MUHC Centre for Applied Ethics MUHC REB Full Board Meeting</td>
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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 designated REB Office Personnel staff 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 PROCEDURES

The Completion of research is a change in activity that must be reported to the REB.\(^1\)

Although research participants will no longer be at risk under the research, this final report allows by the Researcher contains required information that will enable 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.\(^2\)

5.1 Determining when Research can be Closed with the REB

5.1.1 The Researcher may will submit a research closure report to the REB\(^3\) when there are no further participant involvement at the site, participants are no longer exposed to research risksunder REB jurisdiction, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed;

5.1.2 The responsible REB Office Personnel The Researcher will also submit a research closure report to the REB when the study is prematurely, but definitely, stopped;

5.1.3 The REB Chair or designee or a designated member of the REB Support Staff will review the research closure application and request any outstanding information, clarification or documentation from the Researcher, if needed;

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2 Modèle, sect. 13.2.

3 TDR, s. 9.7.
5.1.35.1.4 The REB Chair or designee or a designated member of the REB Support Staff will review the submission and issue an acknowledgment letter of Acknowledgement to the Researcher. The research status will change from “Approved” to “Closed”;

5.1.45.1.5 Once a research project is “Closed” with the REB, no further submissions for that research will be permitted; however, if required, the Researcher may still submit relevant documents for REB acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB;

5.1.55.1.6 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 patient records require the consent of the patient (or DPS approval/legal representative) or the authorization of the Director of Professional Services at the institution.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

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8 APPENDICES