Title	Research Completion
~~MUHC~~ SOP Code	~~MUHC~~ REB-SOP~~-~~ 408.001
N2/CAREB SOP CODE	SOP~~-~~ 406.002
Effective Date	~~2017-02-24~~2020-03-20

~~**Site Approvals**~~

Status	~~Name and~~ Title	Date
~~Authored~~Author of Harmonized Template	~~CAE, Manager~~SOPs, Institutional REBs	~~2017-02-20~~2019-04-01
Approved	~~Director, MUHC Centre for Applied Ethics~~MUHC REB Full Board Meeting	~~2017~~2020-02-~~20~~13
Acknowledge ~~of~~ receipt	MUHC Board of Directors	2020-03-20

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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, a~~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 ~~is~~are no further ~~participant involvement at the site,~~ participants ~~are no longer exposed to research risks~~under 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;

~~5.1.2~~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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1 Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 9.6; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, *Ministère de la Santé et des Services sociaux*, DGAERA, 2004, hereafter "*Modèle*", s. 13.2.

2 *Modèle*, sect. 13.2.

3 TDR, s. 9.7.

~~5.1.3~~5.1.4 The REB Chair or designee or a designated member of the REB Support Staff will review the submission and issue ~~an acknowledgement~~a letter of Acknowledgement to the Researcher. The research ~~state~~status will change from "*Approved*" to "*Closed*";

~~5.1.4~~5.1.5 Once a research project is "*Closed*" with the REB, no further submissions for that research will be permitted~~; however, if~~. If required, however, the Researcher may still ~~may~~ submit relevant documents for REB acknowledgement ~~and, if~~. If applicable, further investigation and/or action may be undertaken by the REB;

~~5.1.5~~5.1.6 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 patient~~ requires 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

SOP Code	Effective Date	Summary of Changes
~~MUHC~~ REB-SOP-408.001	~~2017-02-24~~2020-03-20	Original ~~Version~~version

8 APPENDICES