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| **Title** | Research Completion |
| **SOP Code** | REB-SOP 408.001 |
| **N2/CAREB SOP CODE** | SOP 406.002 |
| **Effective Date** | 2020-03-20 |

| Status | Name and Title | Date |
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| ***Author of Harmonized Template*** | SOPs, Institutional REBs | 2019-04-01 |
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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 staff are responsible for ensuring that the requirements of this SOP are met.

## 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]

This final report by the Researcher contains required information that will enable the REB to close its files.[2]

### 5.1 Determining when Research can be Closed with the REB

5.1.1 The Researcher will submit a research closure report to the REB[3] when there are no further participants under REB jurisdiction, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed;

5.1.2 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;

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

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

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. Access to patient records requires the consent of the patient (or legal representative) or the authorization of the Director of Professional Services at the institution.

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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.

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|---|---|---|
| REB-SOP 408.001 | 2020-03-20 | Original version |
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## 8 APPENDICES