Title	Standard Operating Procedures Maintenance
SOP Code	REB-SOP 108.001-1
N2/CAREB SOP CODE	SOP 108.002
Effective Date	2021-03-22

Status	Name and Title	Date
Author of Harmonized Template	SOPs, Institutional REBs	2019-04-01
Approved	MUHC REB Full Board Meeting	2021-02-11
Pending Approval	MUHC Board of Directors	2021-03-22

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1 PURPOSE

This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

2 SCOPE

This SOP pertains to Research Ethics Boards (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

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1 Development, Review, Revision and Approval of Policies & Procedures

5.1.1 The REB establishes written SOPs to be followed[1];

5.1.2 The qualified REB Support Staff will review the SOPs as needed. As a minimum, applicable SOPs will be reviewed when changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;

5.1.3 SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to REB or administrative practices;

5.1.4 The qualified REB Support Staff will make the necessary modifications to existing SOPs, or draft one or several new SOPs;

5.1.5 As SOPs are modified, new drafts and newly approved SOPs will be indicated by updating the presentation, status and revision history tables of the SOP as follows:

- **Draft/Under Review:**

[1] ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.3; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 1 and 3.

- "Effective Date" fields: The date will be replaced by the term "DRAFT" followed by the date of the latest iteration of the current revision process.

- "SOP Code" field: A major revision of all SOPs will warrant the update of the last three digits in the SOP Code whereas revisions taking place between major revisions of all SOPs will be indicated by adding a dash ("-") and a consecutive number at the end of the SOP Code.

- "Status" fields: The status with the MUHC REB and the MUHC Board of Directors will be updated by the adding of "(Under Review)" after the current status of the SOP.

- "Summary of changes" field: The history of revisions will be recorded in the "summary of changes" field of each SOP.

- **Approved by the MUHC REB:** Once the SOP content is approved by the MUHC REB at a full board meeting:

  - "Status" fields: The status with the MUHC REB will be updated to "Approved" and the status with the MUHC Board of Directors will be updated to "Pending approval."

  - "Date" field: The field corresponding to the MUHC REB approval will be updated accordingly;

  - "Effective date" fields: The MUHC REB approval date is considered the effective date of the modifications to the SOP and, consequently, both "Effective Date" fields found in the SOP will be updated with the date of the MUHC REB approval.

- **Approved by the MUHC Board of Directors :** Once the MUHC Board of Directors approves the revisions to the SOP,

  - "Status" field: The status with the Board of Directors will be updated to "Approved" and the approval date will be updated accordingly.

The changes to the SOPs will be implemented as of the "Effective Date".

A new "Approved" version of the SOP supersedes any previous versions.

5.2 Distribution and Communication

5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the 'Responsibilities' section of each SOP;

5.2.2 The SOPs will be available to Researchers and researcher sites, Sponsors and Regulatory Authorities as required;

5.2.3 Qualified REB Support Staff will inform and, if needed, train members of the REB and the REB Support Staff on any new or revised policy and/or relevant procedure, as applicable;

5.2.4 Each new REB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an REB member;

5.2.5 Each new REB Support Staff must review the applicable policies and procedures prior to undertaking his/her responsibilities with the REB office;

5.2.6 Evidence of training, if any, must be documented and updated.

5.3 Forms, Memos and Guidance Documents

5.3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOPs;

5.3.3 Memos and guidance documents will be made available to the Researchers and researcher sites as applicable;

5.3.4 The qualified REB Support Staff and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 108.001	2020-03-20	Original version
REB-SOP 108.001-1 5.1.5 revised 5.1.6 deleted	2021-02-11	Added Board of Director Approval of REB SOP Process by which the SOPs can be updated and implemented as of the effective date pending the MUHC Board of Directors approval.

8 APPENDICES