

<b>Title</b>	Standard Operating Procedures Maintenance
<b>SOP Code</b>	REB-SOP 108.001
<b>N2/CAREB SOP CODE</b>	SOP 108.002
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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<sup>1</sup>;
- 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 will be indicated by the addition of “DRAFT version date” instead of the previous “Final Version Date”. Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the “Final Version Date”. The history of revisions will be recorded in the ‘SOP History’ section of each SOP;

<sup>1</sup> 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.

5.1.6 SOP approval will be indicated by the word “Approved”, along with the date of approval and the signature of the highest echelon in research ethics as determined by organizational policy (e.g. Head of the REB office, REB Chair, etc.). A new final 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

## 8 APPENDICES