SOP 108.004

Title	**Standard Operating Procedures Maintenance by Network of Networks and CAREB**
SOP Code	108.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 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. The REB SOPs are prepared and distributed by N2.

2.0 SCOPE

The REB SOPs are made available to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

The N2/CAREB REB SOP Committee is responsible for developing and maintaining this set of SOPs to ensure that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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 SOP Committee will review the SOPs at least every 3 years. If re-versioning is not required a Memo will be posted with the documents to indicate that the review was conducted. Applicable SOPs will be reviewed sooner if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;

5.1.2 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;

5.1.3 The REB SOP Committee will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”;

5.1.4 The revised SOP(s) will be circulated to the REB SOP Committee for review. Comments will be incorporated into a new version with an updated version date;

5.1.5 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;

5.1.6 Signatures on the SOP as determined by University policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

5.2 Distribution and Communication

5.2.1 New or revised SOPs will be communicated and disseminated through posting on the N2 and the CAREB websites.;

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

5.2.3 Qualified Research Ethics staff will train members of the REB and Research Ethics 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 their responsibilities as an REB member;

5.2.5 Each new Research Ethics staff must review the applicable policies and procedures prior to undertaking their responsibilities with Research Ethics;

5.2.6 Evidence of training must be documented;

5.2.7 Research Ethics shall maintain all documentation of SOP training.

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 SOP;

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

5.3.4 The REB SOP Committee will evaluate the need for new or revised forms, memos or guidance documents.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP108.001	15-Sept-2014	Original version
SOP108.002	08-Mar-2016	No revisions needed
SOP108.003	08-Oct-2019	5.1.1: revision (sp) of word biennial
SOP 108.004	15-May-2023	Responsibility for the SOP revised to indicate the responsibility for the management of the SOPs is with the N2/CAREB REB SOP Committee