

Title	Standard Operating Procedures Maintenance by Network of Networks and CAREB
SOP Code	108.005
Effective Date	14-Apr-2026

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 written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with principles, policies, and regulations governing the ethics review and oversight of research involving humans; and support the training of new personnel. The Research Ethics Board (REB) SOPs are prepared and distributed by N2.

2.0 SCOPE

The REB SOPs are made available to REBs that review human Participant research in accordance with applicable regulations and policies.

3.0 RESPONSIBILITIES

The N2/CAREB REB SOP Committee is responsible for developing and maintaining this set of SOPs to ensure compliance with the requirements outlined in 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 outline the processes that must be followed and documented to ensure that the rights and welfare of human Participants 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 revisions are not required a memo will be posted alongside the documents to indicate that the review was conducted. Applicable SOPs will be reviewed sooner if changes to regulations, policies, 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 or revised 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 new SOPs. 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 ‘Revision History’ section of each SOP;
- 5.1.6 Signatures on the SOP, as determined by organizational 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 CAREB websites.;
- 5.2.2 The SOPs will be available to REBs, Researchers, researcher sites, Sponsors, and Regulatory Authorities as required;
- 5.2.3 Qualified REB Office Personnel will train members of the REB and the REB Office Personnel on any new or revised policies and/or any relevant procedures, 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 REB Office Personnel must review the applicable policies and procedures prior to undertaking their responsibilities in the REB office;
- 5.2.6 Evidence of training must be documented and retained in accordance with institutional record retention policies.
- 5.2.7 The REB office 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 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
SOP 108.005	14-Apr-2026	1.0, 2.0 and 5.1.1, replaced “guidelines” with “policies”. 1.0 replaced “outlines” with “describes”; deleted “applicable to” from “regulations applicable to governing...”; replaced ‘facilitate’ with ‘support’.

		<p>2.0: replaced “compliance” with “accordance”.</p> <p>3.0: minor wording revisions to match wording in 1.0 and 2.0.</p> <p>5.0: replaced ‘describe’ with ‘outlines’; deleted ‘of such research’ from the last sentence.</p> <p>5.1.1: replaced ‘reversioning’ with ‘revisions’.</p> <p>5.1.2: added ‘...or revised’ to ‘...new or revised...’.</p> <p>5.2: minor wording changes e.g. pluralization.</p> <p>5.2.4: replaced ‘his/her’ with ‘their’.</p> <p>5.2.6: added ‘...and retained in accordance with institutional record retention policies.’</p>