

	Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)	CGHMC RERB SOP Version No. 6 Date of Approval: 01 December 2019 Effective Date: 01 Jan 2020
	Chapter 6 Writing and Revising SOPs	

6.1 Writing SOPs
6.2 Revising SOPs

REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Date of revision was added as an item in sec 6.2.5.6
6	Sep 26, 2018	RERB Members	Flow charts were revised to ensure consistency in all chapters
6	Sep 26, 2018	RERB Members	Frequency of revision indicated
6	Sep 26, 2018	RERB Members	History of changes/ revisions included
7	July 18, 2022	SOP Team	Changed 2 years to 3 years

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6.1. Writing SOPs

6.1.1. Purpose

To define the process for writing SOPs used by the CGHMCRERB

6.1.2. Scope

This SOP provides instructions on how the CGHMCRERB Standard Operating Procedures are prepared, approved and distributed.

6.1.3. Responsibility

It is the responsibility of the RERB Chair to organize an SOP Team to formulate or revise the SOPs of the RERB. The Chair designates the members of the team, initiate approval processing of final version of SOPs, and submit the SOP to the DMER Director for final approval.

The SOP Team is an ad hoc committee composed of appointed RERB members with invited resource persons, as needed. The team is responsible for proposing and formulating new SOPs, and reviewing and revising existing SOPs when necessary. The team must follow existing procedures, format, and coding system of the hospital when drafting or editing any SOPs of the hospital, and consults the Secretariat and Chair about the need for new or revised versions of SOPs. The team submits SOP drafts to the Chair for approval processing.

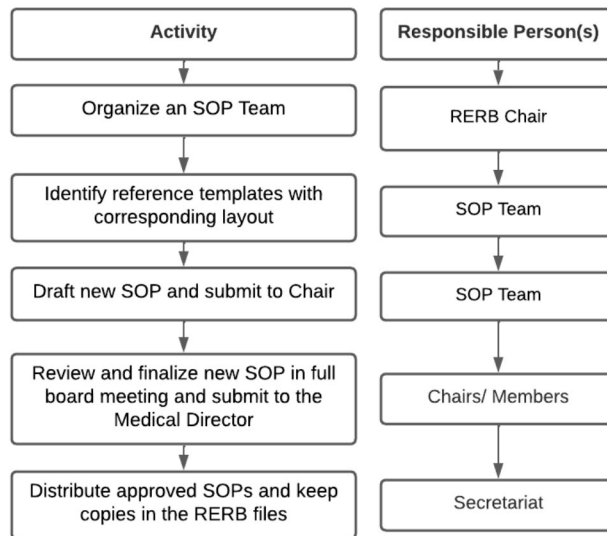
The Secretariat is responsible for coordinating the writing and revising of SOPs, maintains current SOPs with a complete SOP list, ensures that all RERB members have access to the SOPs and are working according to the current version of the SOPs.

CGHMCRERB members are responsible for reviewing and approving the drafts of new or revised SOPs in a full board meeting, keep a copy of complete SOPs, and perform their functions according to current SOPs.

The CGHMCM Medical Director is responsible for final approval of all SOP

6.1.4. Process flow/Steps for New SOP

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6.1.5. Detailed Instructions

6.1.5.1. Organize an SOP team

The Chair designates members to be part of the SOP team and invites resource person as needed.

The SOP Team receives an orientation from the Chair regarding duties and responsibilities.

The Chair may organize SOP team workshops to facilitate the drafting of SOPs.

6.1.5.2. Identify reference templates with corresponding layout

Identify reference templates with corresponding layout from SOPs of other Ethics Committees to guide the SOP team in drafting new SOPs.

An SOP is written according to the following format:

- Number and version
- Date of revision
- Title
- Objectives of the SOP
- Scope which includes description and purpose of the SOP
- A flowchart when necessary
- Detailed instructions

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- Standard forms and checklists to be used
- Glossary
- Reference

Assign an identifier to the SOP

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. For the CGHMCRERB SOPs, the following format is used: CGHMCRERBSOPWW/XX-YY-ZZZZ where WW corresponds to chapter-section in the manual where the SOP is found, XX corresponds to the version, YY pertains to number of revisions made, and ZZZZ is a four-digit number identifying the year SOP was drafted or revised.

Thus, the SOP on writing of SOPs is identified as SOP05-5.1/01-0-2012 meaning that this SOP can be seen in Chapter 5 section 5.1 (05-5.1), first version (05-5.1/01) and has no changes, (05-5.1/01-0) as of 2012 when it was drafted.

The layout of SOP uses a header with the following elements:

- Institutional seal or logo
- Name of institution
- SOP Title
- SOP Version
- Approval Date
- Effective Date

The SOP is introduced by a cover laid out as a typical SOP page with the following additional items included:

- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version; if not applicable, the date of previous issue is indicated by "N/A" (not applicable)
- Approval information such as approving authorities and offices

6.1.5.3. Draft the SOP and submit to Chair

The CGHMCRERB SOP shall contain details under the following main topics:

- Structure and Composition of the RERB—describes the composition of the RERB membership with specific review functions
- Initial Review Procedures—describe the types of review and initial review procedures

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- Monitoring procedures (Post-Approval Procedures) – describe how the RERB monitor implementation of approved protocols
 - Conduct of the meeting – describes the preparation of the agenda and minutes of the meeting and conduct of full board and special (emergency meeting).
 - Documentation and archiving – describe administrative procedures that support the review functions
 - Writing and revising SOPs – describes how to draft and revise SOPs
- The SOP Team submits completed draft to the Chair.

6.1.5.4. Review and finalize the new SOPs during full board meeting and submit to the Medical Director.

The Chair submits the draft to full board review where RERB members deliberate and finalize the draft

Upon full board approval, the Chair submits the approved draft to the Medical Director for final approval.

The CGHMC Medical Director approves the SOP by signing in the appropriate section in the cover page.

The approved SOPs will be implemented from the date of approval by the Medical Director

6.1.5.5. **File and distribute the SOP**

Once the SOP has been granted approval by the Medical Director, the secretariat submits a copy of the SOP to the Office of Quality Management Team (QMT). The QMT takes charge of assigning quality control number to the document and publishing the SOP through the Hospital website.

The Secretariat distributes the printed copy of the approved SOPs to the RERB members and staff; with an electronic copy published through the Hospital website.

The Secretariat retains one complete originally signed SOP copy in file.

6.2. Revising SOPs

6.2.1. Purpose

To describe the procedures for revising SOPs used by the CGHMCRERB.

6.2.2. Scope

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This SOP provides instructions on how to revise existing SOPs.

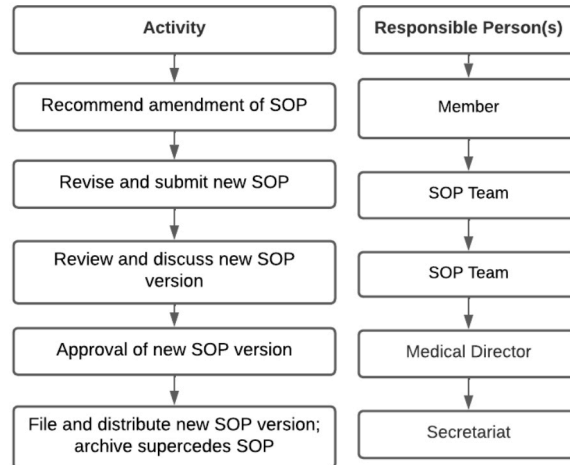
6.2.3. Responsibility

It is the responsibility of the RERB members to suggest revisions in the existing SOPs. The Chair shall designate a team to regularly review the SOPs at least every three (3) years for internal and external consistency, efficiency and applicability.

The Chair convenes a full board meeting to review and finalize revised SOPs and submit the final draft to the Medical Director for final approval.

The Secretariat is responsible for keeping all versions of SOPs and ensures that all RERB members have access to current versions of SOPs to guide them in the performance of their functions.

6.2.4. Process Flow/Steps



6.2.5. Detailed Instructions

6.2.5.1 As the RERB sees it fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier or version of an SOP is considered substantial). Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.

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6.2.5.2. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary.

6.2.5.3. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the RERB. A draft of the revised SOP will be discussed by the RERB members. The draft version will be reviewed by the Chair who will submit it to the DMER Director for approval.

6.2.5.4. Any member of the board may propose for the revision of the SOPs. Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.

6.2.5.5. The proposal is discussed and acted upon through full board review.

6.2.5.6. The SOP team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.

6.2.5.7. The Chair submits the draft to full board review where RERB members deliberate on the draft.

6.2.5.8. The Chair submits the approved draft to the Medical Director for final approval.

6.2.5.9. The CGHMC Medical Director approves the revised SOP by signing on the appropriate section of the cover page.

6.2.5.10. The approved revised SOP will be implemented from the date of approval by the Medical Director.

6.2.5.11 File and distribute the revised SOP

Upon approval of CGHMC DMER Director, a copy will be submitted to the Office of Quality Management Team. The QMT assigns a quality control number to the document and takes charge of publishing the SOP through the Hospital website.

The Secretariat distributes revised SOP to CGHMCRERB Members, updates the SOP manual.

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The Secretariat maintains an updated SOP manual in the hospital, but retains the original manual in the archives.

The Secretariat distributes the printed copy of the approved SOPs to the RERB members and staff; with an electronic copy published through the Hospital website.

The Secretariat retains one complete originally signed SOP Copy for filing.

6.2.5.12. Archive supersedes SOP

The Secretariat archives the superseded version of the SOP in the historical file maintained by the RERB

Superseded SOPs are clearly marked “superseded” with the year of archiving stamped in the cover page.