



Department of Health  
**Jose R. Reyes Memorial Medical Center**  
Rizal Avenue, Sta. Cruz, Manila



**INSTITUTIONAL REVIEW BOARD**

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# 5. Writing and Revising Standard Operating Procedures

## 5.1 Writing SOPs

## 5.2 Revising SOPs

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## 5.1. Writing SOPs

### 5.1.1. Purpose

To define the process for writing and revising SOPs used by Jose R. Reyes Memorial Medical Center Institutional Review Board (IRB).

### 5.1.2. Scope

This SOP provides instructions on how the Jose R. Reyes Memorial Medical Center IRB Standard Operation Procedures are prepared, approved and distributed.

### 5.1.3. Responsibility

It is the responsibility of the Chair of Jose R. Reyes Memorial Medical Center IRB to appoint an SOP Team to formulate or revise the SOPs of the Jose R. Reyes Memorial Medical Center IRB. The Chair designates the members of the team, initiate approval processing of final version of SOPs, and submit the SOP to the Jose R. Reyes Memorial Medical Center IRB Hospital Director for final approval.

The SOP Team is an ad hoc committee composed of appointed IRB members with invited resource persons. 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 SOP's 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 Jose R. Reyes Memorial Medical Center IRB members have access to the SOPs and are working according to the current version of the SOPs.

Jose R. Reyes Memorial Medical Center IRB 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 Jose R. Reyes Memorial Medical Center) Director is responsible for final approval of all SOPs.

## 5.1.4. Process Flow/Steps for New SOP

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Design the format, layout, identifier of SOP	SOP Team	7 days
2	Write a new SOP and submit to Chair	SOP Team	7-14 days
3	Review new SOP in full board meeting	IRB	1 day
4	Approve new SOP	Hospital Director	2days
5	File/distribute approved SOPs	Secretariat	1 day

## 5.1.5. Detailed Instructions

### 5.1.5.1. The Chair designates an SOP team

- 5.1.5.1.1. The Chair assigns members and non-members, as needed, to be part of the SOP Team.
- 5.1.5.1.2. The SOP Team receives an orientation from the Chair regarding duties and responsibilities.
- 5.1.5.1.3. The Chair can organize SOP Team workshops to facilitate the drafting of SOPs.

### 5.1.5.2. The design, format, and layout of an SOP is based on the following guidelines:

- 5.1.5.2.1. An SOP is written according to the following format:
  - 5.1.5.2.1.1. Number and version
  - 5.1.5.2.1.2. Title
  - 5.1.5.2.1.3. Objectives of the SOP
  - 5.1.5.2.1.4. Scope which includes description and purpose of the SOP
  - 5.1.5.2.1.5. A flowchart when necessary
  - 5.1.5.2.1.6. Detailed instructions
  - 5.1.5.2.1.7. Glossary
  - 5.1.5.2.1.8. References

### 5.1.5.2.2. 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 Jose R. Reyes Memorial Medical Center IRB SOPs, the following format is used: Jose R. Reyes Memorial Medical Center IRB SOP XX/YY-ZZZZ where XX is a two-digit number corresponding to the chapter/section in the manual where the SOP is found. The YY is a two-digit number identifying the version of the SOP and ZZZZ is a four-digit number identifying the year of SOP was drafted or revised.

Thus, the SOP on writing of SOPs is identified as SOP 05.1/01-0-2012 meaning that this SOP can be seen in Chapter 5 of the SOP manual (01), it is section 1 of Chapter 1 (01.1), it is the first version (01.1/01), and has no changes, (01.1/01-0) as of 2012 when it was drafted.

### 5.1.5.2.3. The layout of a typical SOP uses a header with the following elements:

- 5.1.5.2.3.1. Institutional seal or logo
- 5.1.5.2.3.2. Name of institution
- 5.1.5.2.3.3. SOP identifier
- 5.1.5.2.3.4. SOP title
- 5.1.5.2.3.5. Effective date
- 5.1.5.2.3.6. Page number

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

- 5.1.5.2.4.1. Summary content after the title
- 5.1.5.2.4.2. Institutional contact details (address, telephone numbers, facsimile number, email address)
- 5.1.5.2.4.3. Date of the previous version; if not applicable, the date of previous issue is indicated by "N/A" (not applicable)
- 5.1.5.2.4.4. Name of the authors/editors
- 5.1.5.2.4.5. Approval information such as approving authorities and offices

5.1.5.3. The SOP Team makes a draft of the SOP based on the design and format detailed above.

5.1.5.3.1. The SOP Team submits completed draft to the Chair.

5.1.5.3.2. The Chair submits the draft to full board review where ERC members deliberate on the draft.

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

5.1.5.3.4. The Jose R. Reyes Memorial Medical Center Director approves the SOP by signing in the appropriate section in the cover page.

5.1.5.3.5. The approved SOPs will be implemented from the date of approval by the Hospital Director.

**5.1.5.4. File and distribute the SOP.**

5.1.5.4.1. Upon approval of Jose R. Reyes Memorial Medical Center Director, the Secretariat distributes SOP to Jose R. Reyes Memorial Medical Center IRB members, and publishes the SOP through the Hospital website.

5.1.5.4.2. The Secretariat distributes the printed copy of the approved SOPs to the Jose R. Reyes Memorial Medical Center IRB members and staff; with an electronic copy published through the Hospital website.

5.1.5.4.3. The Secretariat retains one complete originally signed SOPs copy.

## 5.2. Revising SOPs

### 5.2.1. Process Flow/ Steps

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Propose to revise an SOP	IRB	1 day
2	Review and discuss an SOP revision in a full board meeting	IRB	1 day
3	Approve SOP revision	Chair/ Hospital Director	2 days
4	File/distribute SOP	Secretariat	1 day
5	Include revised SOP in SOPs manual that is currently used	Secretariat	1 day
6	Archive superseded SOP	Secretariat	1 day

### 5.2.2. Detailed Instructions

5.2.2.1. As the ERC sees 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 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.

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

5.2.2.3. 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 ERC. A draft of the revised SOP will be discussed by the ERC members. The draft version will be reviewed by the Chair who will submit it to the Hospital Director for approval.

5.2.2.3.1. 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.

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

5.2.2.3.3. 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.

5.2.2.4. The Chair submits the draft to full board review where ERC members deliberate on the draft.

5.2.2.4.1. The Chair submits the approved draft to the **Jose R. Reyes Memorial Medical Center** Director for final approval.

5.2.2.4.2. The **Jose R. Reyes Memorial Medical Center** Director approves the revised SOP by signing on the appropriate section of the cover page.

5.2.2.4.3. The approved revised SOP will be implemented from the date of approval by the Hospital Director.

### 5.2.3. File and distribute the revised SOP

5.2.3.1. Upon approval of Jose R. Reyes Memorial Medical Center Director, the Secretariat distributes revised SOP to Jose R. Reyes Memorial Medical Center IRB members, updates the SOPs manual, and publishes the SOP through the Hospital website.

5.2.3.2. The Secretariat maintains an updated SOP's manual in the Hospital, but retains the original manual in the archives.

5.2.3.3. The Secretariat distributes the printed copy of the approved SOPs to the Jose R. Reyes Memorial Medical Center IRB members and staff; with an electronic copy published through the Hospital website.

5.2.3.4. The Secretariat retains one complete originally signed SOPs copy.

### 5.2.4. Archive superseded SOP

5.2.4.1. The Secretariat archives the superseded version of the SOP in the historical file maintained by the Jose R. Reyes Memorial Medical Center IRB.

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