



Institutional Review Board – Standard Operating Procedure

<b>Chapter V : Writing and Revising Standard Operating Procedures (SOPs)</b>	Document Code: <b>IRB-SOP-1120-WRS-005-04</b>	
	Effective Date: April 15, 2021	Page: Page 1 of 9
Issued by: <b>Institutional Review Board</b>	Approved by:  <i>(original document signed)</i> <b>SATURNINO P. JAVIER, M.D</b> <b>(Medical Director)</b>	
<input type="checkbox"/> New	Supersedes: IRB-SOP-0813-WRS-005-03	Dated: April 01, 2021

- A. Writing Standard Operating Procedures**
- B. Revising Standard Operating Procedures**

Supersedes:	IRB-SOP-0813-WRS-005-03
Authored by:	MMC IRB SOP Team (adapted from DOH SOP)
Effective Date:	April 15, 2021
Approved by:	<i>(original document signed)</i> <b>D. DARWIN A. DASIG, M.D., Chair, MMC IRB</b>
Approval Date:	April 01, 2021

**\*REVIEW: This Standard Operating Procedure is reviewed every 3 years or earlier as indicated.**

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### 5.1 Purpose

To define the process for writing and revising Standard Operating Procedures (SOPs) used by the Makati Medical Center Institutional Review Board (MMC IRB).

### 5.2 Scope

This SOP provides instructions on how the MMC IRB SOPs are prepared, approved and distributed.

### 5.3 Responsibility

It is the responsibility of the Chair of MMC IRB to appoint an SOP Team to formulate or revise the SOPs of the MMC IRB. The Chair designates the members of the team, initiates approval processing of final version of SOPs, and submits the SOP to the Makati Medical Center Medical Director for final approval.

The SOP Team is an ad hoc committee composed of appointed MMC 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 consult 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, maintaining current SOPs with a complete SOP list, ensuring that all MMC IRB members have access to the SOPs and are working according to the current version of the SOPs.

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

The MMC Medical Director is responsible for the final approval of all SOPs.

### 5.4 Writing SOPs

#### 5.4.1 Process Flow/Steps for New SOP

NO.	ACTIVITY	RESPONSIBILITY
1	Design the format, layout, coding identifier of SOP 	SOP Team

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<b>2</b>	Write a new SOP and submit to Chair ↓	SOP Team
<b>3</b>	Review and approve new SOP draft in a full board meeting and submit to the Medical Director. ↓	IRB Members/ Chair
<b>4</b>	Approve and sign new SOP ↓	Medical Director
<b>5</b>	File/ distribute approved SOPs	Secretariat

**Detailed Instructions**

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

- A. Summary content after the title
- B. Institutional contact details (address, telephone numbers, facsimile number, email address)
- C. Date of the previous version; if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
- D. Name of the authors/editors
- E. Approval information such as approving authorities and offices

**SOP Document Code**

- Each SOP chapter is given a code and a title that is self-explanatory and is easily understood. For the Makati Medical Center IRB SOPs, the following format is used: IRB-SOP-MMYX-XXX-YYY-RR where MMYX is the month/year of implementation and/or circulation. XXX is a three-letter chapter code. YYY is the three-digit chapter number. RR reflects the revision number.

**SOP Header Layout:**

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

- A. Institutional seal or logo
- B. Name of institution
- C. SOP identifier
- D. SOP section
- E. SOP title

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- F. Effective date
- G. Page number

**SOP is divided into the following sections**

- A. SOP Revision Tracker
- B. Abbreviation Index
- C. Chapters 1 to 5
- D. Forms
- E. Appendices
- F. SOP Approval Sheet

**Format and layout of each SOP chapter is as follows:**

- A. Number and version
- B. Title
- C. Objectives of the SOP
- D. Scope which includes description and purpose of the SOP
- E. A flowchart when necessary
- F. Detailed instructions

**5.4.1.2 SOP Writing, Review and Approval**

SOP Team makes a draft of the SOP based on the design and format detailed above. SOP Team submits completed draft to the Chair.

- Completed draft is submitted to Member-Secretary, Vice-Chair and Chair for review.

**5.4.1.3** Chair submits the draft to full board review where IRB members deliberate on the draft.

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

**5.4.1.4** Makati Medical Center 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.

**5.4.1.5 Filing and Distribution of SOP.**

- A. Upon approval of Makati Medical Center Medical Director, the Secretariat distributes SOP to Makati Medical Center IRB members, and publishes the

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SOP through the MMC IRB Official website (<https://irb.makatimed.net.ph/manuals-of-sop/>).

- B. The Secretariat retains one copy of the complete originally signed SOPs.

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### 5.5 Revising Standard Operating Procedures (SOPs)

**SOP is reviewed and revised at least every three years or as necessary when MMC IRB sees fit.**

- A. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial).
- B. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary.
- C. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.
- D. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.

#### 5.5.1 Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Propose to revise an SOP	IRB Member
	↓	
2	Review, discuss and approve the SOP draft revision in a full board meeting.	IRB Members
	↓	
3	Approve and sign the SOP revision	IRB Chair and Medical Director
	↓	
4	File/ distribute the revised SOP	Secretariat
	↓	
5	Include the revised SOP in the SOPs manual that is currently used	Secretariat
	↓	
6	Archive the superseded SOP	Secretariat

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**Detailed Instructions**

**5.5.1.1 Revision Proposal**

- A. 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 MMC IRB.
- B. Any member of the board may propose for the revision of the SOPs.
- C. Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.
- D. The proposal is discussed and acted upon through full board review.
- E. The draft version will be reviewed by the Chair who will submit it to the Medical Director for approval.

**5.5.1.2 Approval and Effectivity**

- A. The Makati Medical Center Medical Director and Chair of the IRB approve the revised SOP by signing on the appropriate section of the cover page.
- B. The approved revised SOP will be effective 14 days upon the approval and signing of the Medical Director.

**5.5.1.3 Revision Tracking and Coding**

- A. SOP revision number in chronological order as well as date of the revision is reflected on the SOP document code, example IRB-SOP-**0813**-WRS-005-**01**.
- B. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the SOP Revision Tracker on the SOP cover, located in front of the SOP manual.

**5.5.1.5 Distribution of Revised SOP**

- A. Upon approval of Makati Medical Center Medical Director, the Secretariat distributes the printed revised SOP to Makati Medical Center IRB members, updates the electronic SOP manual, and publishes the SOP through the Hospital website.
- B. Secretariat collects the old SOP manuals in exchange of the revised manual.
- C. The Secretariat distributes the latest version of the SOP to the PHREB within 30 days upon approval. This is in line with PHREB Resolution No.

**Revising Standard Operating Procedures** Oct. 2020.

**5.5.1.6 Archive superseded SOP**

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- A. Secretariat maintains the originally signed updated SOP manual in the MMC IRB office and retains one copy of the originally signed outdated versions.
- B. Superseded SOPs are clearly marked “superseded” with the year of archiving stamped in the cover page.
- C. The Secretariat archives the superseded version of the SOP in the historical file maintained by the Makati Medical Center IRB.
- D. Outdated SOPs are considered a permanent file.



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**MMC IRB SOP Version 5  
Document History (Chapter 5)**

Author	Chapter	Version	Date	Summary of Changes
Darwin A. Dasig, M.D.	5	3	November 17, 2020	<ul style="list-style-type: none"> <li>Updated the version to Version 6</li> <li>Added PHREB Resolution No. 20-003, dated 15 Oct. 2020. On Section 5.1.5.5, Letter C</li> </ul>
Hazel Faye R. Docuyanán, RPh, MS	5	2	April 01, 2021	<ul style="list-style-type: none"> <li>Revised effectivity date of revised SOP to 14 calendar days upon approval and signing of the Medical Director as per the hospital policy on Management of Information (MOI).</li> <li>Revised SOP will be published on the MMC IRB website (<a href="https://irb.makatimed.net.ph/manuals-of-sop/">https://irb.makatimed.net.ph/manuals-of-sop/</a>)</li> </ul>