

**Departmental General Operating Procedures**

<b>Chapter V. Writing and Revising Standard Operating Procedures (SOPs)</b>		Document Code: IRB-GOP-WRS-005	Rev. Code : 09
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<b>Approved by:</b>  (original document signed) Dr. Saturnino P. Javier <b>Division Head</b> Date Signed: December 16, 2025		(original document signed) Dr. Carolyn A. Butler <b>Physician Head</b> Date Signed: December 18, 2025	

**I. Objective**

- 1.1.** To establish the process for writing and revising Standard Operating Procedures (SOPs) utilized by the Makati Medical Center Institutional Review Board (MMC IRB).

**II. Scope:**

- 2.1.** This SOP outlines the procedures for preparing, approving, and distributing MMC IRB SOPs.

**III. Definition of Terms:**

- 3.1. Standard Operating Procedure (SOP)** – A set of written instructions that detail the step-by-step processes to be followed in order to carry out specific tasks or operations consistently and efficiently within an organization.
- 3.2. Sop document Code** – A unique identifier assigned to an SOP document, typically following a standardized format that helps in organizing, locating, and referencing SOPs within a document control system.
- 3.3. Draft** – A preliminary version of a document that is under development and has not yet been finalized, approved, or issued for official use.
- 3.4. Revision** – An updated version of a document that reflects changes, corrections, or improvements made to the original or previous version. Each revision is typically tracked with a version number or date.
- 3.5. Tracking** – The process of monitoring and recording changes, updates, or the status of a document (such as an SOP) to ensure accurate version control and traceability.
- 3.6. Coding** – The process of assigning standardized codes or identifiers to documents (e.g., SOPs) to categorize, manage, and retrieve them efficiently within a system.

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- 3.7. Superseded** – Refers to a document that has been replaced by a newer version. A superseded SOP is no longer in effect and should not be used.
- 3.8. Effectivity Date** – The date on which a document (e.g., an SOP) becomes officially active and enforceable for use within the organization.
- 3.9. SOP Manual** – A comprehensive collection or compilation of all SOPs relevant to a particular department, process, or organization, often organized for easy access and reference.
- 3.10. Outdated SOP** – An SOP that is no longer current or valid due to process changes, updates, or replacement by a revised version. It should not be used unless revalidated.

#### IV. Responsibility:

- 4.1.** The Chair of the MMC Institutional Review Board (IRB) is responsible for appointing a Standard Operating Procedure (SOP) Team tasked with formulating or revising the SOPs of the MMC IRB. The Chair designates the team members, initiates the approval process for the final version of the SOPs, and submits the SOPs to the Medical Director of Makati Medical Center for final approval.
- 4.2.** The SOP Team is an ad hoc committee made up of appointed MMC IRB members, along with invited resource persons. This team is responsible for proposing and developing new SOPs, as well as reviewing and revising existing SOPs as needed. When drafting or editing any SOPs, the team must adhere to the hospital's established procedures, format, and coding system.
- 4.3.** They should also consult with the Secretariat and the Chair to determine if new or revised SOPs are necessary. Once the drafts are completed, the team submits them to the Chair for approval processing. The Secretariat coordinates the writing and revising of SOPs, maintains an up-to-date list of all current SOPs, and ensures that all MMC IRB members have access to the SOPs while working with the latest versions.
- 4.4.** MMC IRB members are responsible for reviewing and approving drafts of new or revised SOPs during full board meetings. They must keep copies of all complete SOPs and perform their duties according to the current SOPs. Finally, the Medical Director of MMC is responsible for the final approval of all SOPs.

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### V. Writing Standard Operating Procedures

#### 5.1. Guidelines:

No.	ACTIVITY	RESPONSIBILITY
1	Design the format, layout, coding identifier of SOP	SOP Team
2	Write a new SOP and submit to Chair	SOP Team
3	Review and approve new SOP draft in a full board meeting and submit to the Medical Director.	IRB Members/ Chair
4	Approve and sign new SOP	Medical Director
5	File/ distribute approved SOPs	Secretariat

#### 5.1.1. The Standard Operating Procedure (SOP) is introduced with a conventional format, which includes the following essential elements:

- 5.1.1.1. Title of the document
- 5.1.1.2. Institutional contact information, including address, telephone numbers, and email address
- 5.1.1.3. Date of the previous version; if there is no previous version, please indicate "N/A" (Not Applicable)
- 5.1.1.4. Names of the authors and editors responsible for this document
- 5.1.1.5. Approval information, detailing the approving authorities and applicable offices

#### 5.1.2. SOP Document Code

- 5.1.2.1. 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-GOP-XXX-YYY-RR where XXX is a three-letter chapter code. YYY is the three-digit chapter number. RR reflects the revision number.

#### 5.1.3. SOP Header Layout:

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

- 5.1.3.1.1. Institutional seal or logo
- 5.1.3.1.2. Name of institution
- 5.1.3.1.3. SOP identifier
- 5.1.3.1.4. SOP section
- 5.1.3.1.5. SOP title
- 5.1.3.1.6. Effective date
- 5.1.3.1.7. Page number

### 5.1.4. SOP is divided into the following sections:

- 5.1.4.1. SOP Revision Tracker
- 5.1.4.2. Abbreviation Index
- 5.1.4.3. Chapters 1 to 6
- 5.1.4.4. IRB Forms
- 5.1.4.5. Appendices/Attachments
- 5.1.4.6. SOP Approval Sheet

### 5.1.5. Format and layout of each SOP chapter is as follows:

- 5.1.5.1. Number and version
- 5.1.5.2. Title
- 5.1.5.3. Objectives of the SOP
- 5.1.5.4. Scope which includes description and purpose of the SOP
- 5.1.5.5. A flowchart when necessary
- 5.1.5.6. Detailed instructions

### 5.1.6. SOP Writing, Review and Approval

- 5.1.6.1. SOP Team makes a draft of the SOP based on the design and format detailed above. SOP Team submits completed draft to the Chair.
- 5.1.6.2. Completed draft is submitted to Member-Secretary, Vice-Chair and Chair for review.
- 5.1.6.3. The chair presents the draft for full board review, where IRB members discuss it with the help of IRB Secretariats.

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**5.1.6.4.** The IRB members will require a quorum of favorable votes to recommend the SOP.

**5.1.6.4.1.** If the decision is to defer, the member secretary will manage the discussion along with the IRB Chair. The members will collaborate to reach a favorable vote.

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

**5.1.6.6.** The IRB secretariat will ensure that comprehensive minutes of the meeting are documented.

**5.1.6.7.** Makati Medical Center Director approves the SOP by signing in the appropriate section in the cover page.

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

**5.1.7. Filing and Distribution of SOP**

**5.1.7.1.** Upon approval from the Medical Director of Makati Medical Center, the Secretariat distributes the Standard Operating Procedures (SOPs) to the members of the Makati Medical Center Institutional Review Board (IRB) via electronic copies.

**5.1.7.2.** The SOPs are also published on the official MMC IRB website (<https://irb.makatimed.net.ph/manuals-of-sop/>)

**5.1.7.3.** Additionally, the Secretariat keeps one signed copy of the complete SOPs for their records.

**5.1.8. Revising Standard Operating Procedures (SOPs)**

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

**5.1.8.1.1.** A revision should be substantial (correction of grammatical errors is not considered substantial);

**5.1.8.1.2.** A change in the identifier of an SOP is considered substantial).

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

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**5.1.8.1.4.** Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.

**5.1.8.1.5.** Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.

**5.1.9. Process Flow**

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

**5.1.10. Revision Proposal**

**5.1.10.1.** 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.

**5.1.10.2.** Any member of the board may propose for the revision of the SOPs.

**5.1.10.3.** Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.

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

**5.1.10.5.** The draft version will be reviewed by the Chair who will submit it to the Medical Director for approval.

**5.1.11. Approval and Effectivity**

**5.1.11.1.** 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.

**5.1.11.2.** The approved revised SOP will be effective 14 days upon the approval and signing of the Medical Director.

**5.1.12. Revision Tracking and Coding**

**5.1.12.1.** SOP revision number in chronological order as well as date of the revision is reflected on the SOP document code, example IRB-GOP-WRS-005- 01.

**5.1.12.2.** 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.

**5.1.13. Distribution of Revised SOP**

**5.1.13.1.** 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.

**5.1.13.2.** Secretariat collects the old SOP manuals in exchange of the revised manual.

**5.1.13.3.** The Secretariat distributes the latest version of the SOP in both printed and electronic formats within 30 days of approval by the Medical Director.

**5.1.13.4.**

**5.1.14. Archive superseded SOP**

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

**Review:** A GOP is reviewed every three years or as deemed necessary.

**Signatories:**

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