



MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

# **Standard Operating Procedure (SOP) Manual**

Approval Date:

**June 15, 2021**

Effective Date:

**June 28, 2021**

**ABBREVIATION INDEX**

\*Abbreviations of terms utilized throughout the Standard Operating Procedure Manual

ABBREVIATION	DEFINITION
<b>ADR</b>	Adverse Drug Reaction
<b>CIOMS</b>	Council for International Organizations of Medical Sciences
<b>CRF</b>	Case Report Form
<b>CRO</b>	Contract Research Organization or Clinical Research Organization
<b>CTA</b>	Clinical Trial Agreement
<b>CV</b>	Curriculum Vitae
<b>D/M/Y</b>	Date/Month/Year
<b>DOH</b>	Department of Health
<b>DSMB</b>	Data and Safety Monitoring Board
<b>DSMC</b>	Data and Safety Monitoring Committee
<b>FDA</b>	Food and Drug Administration
<b>GCP</b>	Good Clinical Practice
<b>IB</b>	Investigator's Brochure
<b>ICF</b>	Informed Consent Form
<b>ICH-GCP</b>	International Conference on the Harmonization of Good Clinical Practice
<b>IDE</b>	Investigational Device Exemption
<b>IRB</b>	Institutional Review Board
<b>MMC</b>	Makati Medical Center
<b>MMC IRB</b>	Makati Medical Center Institutional Review Board
<b>NSR</b>	Non Significant Risk
<b>OIC</b>	Officer-in-Charge
<b>PHREB</b>	Philippine Health Research Ethics Board
<b>PI</b>	Principal Investigator
<b>RM</b>	Research Monitor
<b>RSER</b>	Resubmission Expedited
<b>RSFR</b>	Resubmission Full Board
<b>SAE</b>	Serious Adverse Event
<b>SOP</b>	Standard Operating Procedure
<b>SR</b>	Significant Risk
<b>SUSAR</b>	Suspected, Unexpected Serious Adverse Reaction
<b>TOR</b>	Terms of Reference
<b>WHO</b>	World Health Organization

## **VISION**

We are the nation's most trusted, caring and internationally-recognized healthcare institution with top-notch service, expertise and technology.

## **MISSION**

To provide the highest quality healthcare experience for all stakeholders through:

1. Competent, compassionate, collegial and ethical medical professionals and allied hospital personnel.
2. Superior service deliver, enhanced by technological and digital innovations and supported by research.
3. Sustained training/educational programs and other capacity-building initiatives; ethics-based and responsive to evolving health challenges and global standards.
4. Community responsive, collaborative and socially empowering healthcare programs.

## **VALUES**

**Service Excellence** – providing competent, appropriate, safe & responsive health care services that result to: positive outcome, highest level of satisfaction of patient & colleagues.

### Behavioral Statements:

- Delivers healthcare service on time.
- Defines objectives, identifies measures & implements strategies to deliver exceptional results.
- Follow-through & fulfills commitments made.
- Meets or exceeds the stakeholder's needs & expectations consistent with MMC policies.
- Constantly seeks innovative ways to improve the quality of service.

**Integrity** – Demonstrating sound moral and ethical principles at work; never compromising the name & ethical standards of the hospital.

### Behavioral Value Statements:

- Continues to do the right thing even when no one is looking or watching.
- Communicates openly, honestly and truthfully with others.
- Takes accountability for own actions & decisions at all times.

**Professionalism** – Upholding the code of conduct of the Hospital & ethical standards of one's profession; consistently demonstrating competence in the performance of one's duties.

Behavioral Value Statements:

- Respects diversity (gender, ethnicity, religion, cultural & economic status).
- Inspires trust by delivering results at the highest level of professionalism.
- Learns rapidly and adapts quickly to changing situations,
- Willingly accepts additional responsibilities in the face of challenging situations.
- Strictly adheres to and complies with established policies, procedures, and standards.

**Compassion** – showing genuine concern and empathy through words and actions that lead to enhanced well-being of patients & colleagues.

Behavioral Statements:

- Always asks the patient about his/her condition and responds accordingly with kindness and encouragement.
- Acknowledges the patient's emotional state in the process of treatment.
- Goes the extra mile for the good of others and the organization.

**Teamwork** – collaborating harmoniously & respectfully with the team towards a common goal.

Behavioral Statements:

- Encourages and values the ideas, expertise and contributions, including constructive criticism of all team members.
- Shares knowledge and expertise with team members.
- Holds team accountable for upholding MMC values.
- Provides the needed support and resources to achieve goals and objectives.
- Builds and maintains synergy with co-workers across the organization.

## INTRODUCTION

The Makati Medical Center Institutional review Board (MMC-IRB) is an independent body created by the Makati Medical Center under the Medical Director. Its responsibility is to ensure the protection rights, safety and well-being of human subjects involved in health-related research and to provide public assurance of that protection. In its effort to protect the study participants, the IRB constructed the Standard Operating Procedures (SOP) to guide its members, staff, and investigators who are planning to conduct a study protocol.

The Makati Medical Center Institutional Review Board (MMC-IRB) - Standard Operating Procedures (SOP) Manual consists of the different processes practiced by IRB to accomplish its activities. The SOP is developed by the members and staff of MMC-IRB, using standard references such as Ethical Considerations, WHO Operational Guidelines, ICH-GCP, National Ethics Guidelines for Health Research, and FDA Policies.

The MMC-IRB SOP begins with the vision, mission and quality policy. The chapters are presented comprehensively for easy reference.

The IRB office is located at the 7th Floor Keyland Building, Tower 3, Makati Medical Center. Currently, it is composed of thirteen active members who are lay members and physicians with different medical expertise and age groups. Its organizational structure is also illustrated and defined in this SOP.

## HISTORY

In 1987, the Makati Medical Center Institutional Review Board (MMC IRB) was formed in partnership with the Tropical Disease Foundation (TDF). In 2005, the MMC IRB and TDF separated into two district entities when TDF moved its operations to a new building. The MMC IRB became an independent committee under the Medical Education & Research Division of the Makati Medical Center (MMC). The Medical Education & Research Division was mandated by the MMC to serve as the executive/advisory body of the MMC IRB. In 2006, Dr. Saturnino P. Javier was appointed as Chair. In April 16, 2012, the MMC IRB was granted a certificate of registration by the Philippine Health Ethics Board (PHREB).

In 2013, the MMC IRB underwent several changes, such as establishing the MMC IRB as an independent office under the Medical Director, separate from the Medical Education and Research Division; development of a manual of Standard Operating Procedures; construction of a web portal that facilitates access and communication; provision of facilities, such as office space, secured storage for protocols, reference materials, computerized database and archiving documents; and addition of personnel to handle various aspects of implementation of clinical trials. It also provided Good Clinical Practice training for the residents, fellows and consultants and hospital staff.

As it moves forward, the MMC IRB stays abreast with new developments in the field of technical and ethical research review. Simultaneously, the MMC IRB is promoting participation of more doctors and research staff in workshops and conferences to further uplift the quality of research in the institution.