MAKATI MEDICAL CENTER

INTER-OFFICE MEMO
Institutional Review Board

IRB-GM-2020-02-00

Date: October 29, 2020

To: **All Concerned**

From: **D. DARWIN A. DASIG, M.D.**
Chair, MMC - IRB

Noted by: **SATURNINO P. JAVIER, M.D.**
Medical Director

SUBJECT: Makati Medical Center Institutional Review Board: Description and Purpose, Independence, Structure and Policy on Research Ethics Review

Pursuant to the accreditation policy of 2020 by the Philippine Health Research Ethics Board (PHREB), the Makati Medical Center - Institutional Review Board (MMC-IRB) hereby releases this administrative issuance for the following:

Description and Purpose of the Committee

MMC IRB is an independent body created by the Makati Medical Center under the Office of the Medical Director. It safeguards the rights and welfare of human participants in the conduct of research (including stem cell researches) at Makati Medical Center and other autonomous organizations associated with MMC, as evidenced by a Memorandum of Agreement, in accordance with the provisions of the Helsinki Declaration, International Ethical Guidelines for Biomedical Research, WHO Operational Guidelines, ICH-GCP, National Ethics Guidelines for Health Research, and FDA Policies involving human subjects.

MMC IRB requires all researches involving human participants to be reviewed and approved by the Board prior to the actual conduct of the study/trial.

Independence

In June 01, 2013, the MMC-IRB became an independent committee under the Office of the Medical Director. In line with this, the MMC-IRB has undergone several changes to fulfill its role in the organization, such as the establishment of its own Standard Operating Procedures, development of a web portal containing important information about its processes and to facilitate communication, provision of an office space dedicated to its operations mainly in receving and securing storage for protocols and reference materials, utilization of computerized database and archiving of documents; and the addition of secretariat staff equipped to handle various aspects of implementation of clinical trials.

Leadership and Administrative Support

The Medical Director supports and ensures sufficient financial and administrative support for MMC IRB operations. One of the provisions include an administrative budget agreed upon by the MMC Board through the Office of the Medical Director.

Structure and Constitution

The Medical Director appoints the MMC IRB Chair and Member - Secretary to facilitate the discharge of functions of the MMC IRB along the line of authority indicated by the following chart:

	BUDGET FOR 2019	PROPOSED BUDGET FOR 2020	VARIANCE
Executive	0	0	0
Manager/Specialist	0	0	0
Staff	4	4	0
Total	4	4	0

Note:

— · — Clinical Research Center coordinates with IRB for review of clinical researches/studies

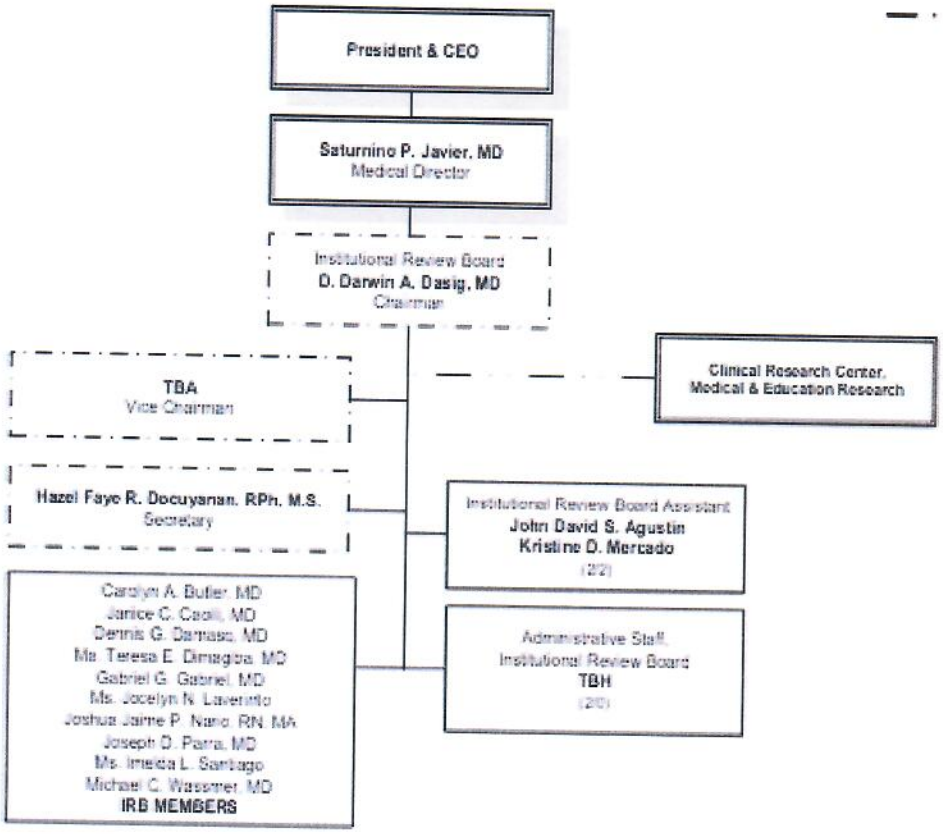

Figure 1 - Makati Medical Center - Institutional Review Board's Table of Organization

MMC -IRB is established by the authority of the MMC Medical Director and exercises its mandate through the following structure:

- MMC Medical Director, as the appointing officer.
- MMC IRB Chair, as the recommending officer.
- Institutional Review Board, as the implementing office
    - Chair
    - Vice-Chair
    - Member-Secretary is the head of the Secretariat and is a voting member of the IRB
    - Members
    - IRB Secretariat

Functions:

1. Safeguards the rights and welfare of human subjects by ensuring adherence to the approved policy on informed consent.
2. Promotes research integrity by identifying and resolving conflicts of interest.
3. Provides independent, competent and timely ethical review of research with human participants. Responsible for acting in the full interest of potential research participants and affected communities with consideration of local value systems, taking into account the interests and needs of the researchers and having due regard for the requirements of relevant regulatory agencies and applicable laws;
4. Evaluates the conduct of research in accordance with the provisions of the Helsinki Declaration, and the Guidelines on the Conduct of Biomedical Research, National Ethics Committee and FDA;
5. Provides timely, comprehensive and independent ethical / technical reviews based in local laws and regulations, standards of professional conduct and practice with sensitivity to cultural differences and community values;
6. Ensures adherence to the confidentiality rule and policy on informed consent;
7. Identifies and resolves conflicts in the conduct of research;
8. Monitors the progress of research study/trial and ensures continuing review and prompt reporting of post approval monitoring parameters such as adverse drug reactions and other adverse events, protocol deviations, and amendments ;
9. Ensures proper documentation and reporting of completed or terminated projects; and
10. Coordinates with the Clinical Research Center for review of clinical researches/trials.

MMC IRB Subcommittees:

Adverse Events Subcommittee (AES)

- The Makati Medical Center Institutional Review Board (MMC IRB) Adverse Event Subcommittee (AES) reviews all adverse events in protocols approved by Makati Medical Center Institutional Review Board.
- The Adverse Event Subcommittee Chair consists of one (1) Subcommittee Chair and two (2) members, as appointed by the MMC IRB Chair. The IRB Member-Secretary is assigned as the Adverse Event Subcommittee Chair.
- A member of the AES should have a strong background on pharmacology/ clinical pharmacy.

Subcommittee PAnels for Investigator-Initiated REsearch ProtocolS (SPARES)

- These are six teams to be formed by the regular members of MMC-IRB. A senior member is paired with a junior member. The former acts as the chair while the latter is the vice-chair of the subcommittee.
- Each group is assigned to review for two months. Thus, each SPARE will review for two months of the year.
- The composition of the teams is determined by the Chair.
- The other members of the subcommittees are the independent resource consultants who are Good Clinical Practice (GCP)-certified. Research coordinators from the different departments may also be invited when necessary. Each subcommittee consists of 3-4 members. All independent resource consultants are invited and their conforme are sought.
- The Chair of SPARES has the option to recommend to the IRB Chair to invite other members to sit as temporary members if the SPARES chair believes their expertise is required to review a protocol.

Policy on Research Ethics Review

It is the responsibility of the MMC-IRB to ensure the protection of the rights, safety and well-being of human subjects involved in health-related research, (including stem cell researches), and to provide public assurance of that protection, in accordance with the applicable national/international regulations.

The MMC IRB requires all researches involving human participants to be reviewed and approved by the Board prior to the actual conduct of the study/trial. The Board reviews and monitors health researches that involve:

- Makati Medical Center patients (including employees, trainees, and hospital staff), done within the hospital premises by its staff and non-affiliated organizations
- Protocols done by Makati Medical Center active and associate active staff, house staff in areas outside the hospital premises.
- Protocols done by investigators not affiliated to Makati Medical Center in sites outside MMC.

Submissions are accepted on the 3rd and 4th weeks of the month. All protocols, which are determined to undergo a full board review, are scheduled for review and deliberation on the next scheduled meeting.

Turnaround time from protocol submission to communication of MMC IRB decision is four (4) weeks.