

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) 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.