Chapter I: Institutional Review Board (IRB) Composition and Ethical Framework	Document Code: **IRB-SOP-1120-CEF-001-06**	
	Effective Date: November 23, 2020	Page: Page 1 of 28
Issued by: **Institutional Review Board (IRB)**	Approved by: *(Original document signed)* **SATURNINO P. JAVIER, M.D. (Medical Director)**	
☐ New	Supersedes: IRB-SOP-0916-CEF-001-05	Dated: November 17, 2020

1.1 Ethical Framework and Constitution of the Institutional Review Board
1.2 Appointment of Institutional Review Board Members
1.3 Selection of Independent Consultants
1.4 IRB Secretariat
1.5 Training of Institutional Review Board Members and IRB Secretariat
1.6 Incentives for Institutional Review Board Members and Consultants

Supersedes:	IRB-SOP-0916-CEF-001-05
Authored by:	MMC SOP Team (adapted from DOH SOP)
Effective Date:	November 23, 2020
Approved by:	**D. DARWIN A. DASIG, M.D., Chair, MMC IRB**
Approval Date:	November 18, 2020

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

1.1 Ethical Framework and Constitution of the Makati Medical Center Institutional Review Board (MMC IRB)

1.1.1 Purpose

To describe the composition and structure of the Makati Medical Center Institutional Review Board (MMC IRB) in compliance with the national and international guidelines in ethical research.

1.1.2 Specific Objectives

To describe the following MMCIRB procedures and define the Terms of Reference (TOR) for the MMC IRB related to the:

A. Constitution of the IRB
B. Confidentiality/Conflict of Interest Agreement with MMCIRB members, IRB Secretariat and consultants
C. Training of Personnel and MMCIRB Members
D. Selection of Independent Consultants
E. Incentives for MMCIRB Members and Consultants

1.1.3 Scope

The Makati Medical Center Institutional Review Board (MMC IRB) is an independent body created by the Makati Medical Center (MMC) under the Medical Director. Its responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in health-related research and to provide public assurance of that protection. In accordance with the applicable national/international regulations, the MMC IRB has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval such as to require progress reports from the investigators and oversee the conduct of the study, suspend or terminate approval or place restrictions on a study.

The MMC IRB reviews and monitors health researches that involve:

A. Makati Medical Center patients (including employees, trainees, and hospital staff), done within the hospital premises by its staff and non-affiliated organizations

B. Protocols done by Makati Medical Center active and associate active staff, house staff in areas outside the hospital premises.
C. Protocols done by investigators not affiliated to Makati Medical Center in sites outside MMC.

The MMC IRB reviews researches involving human subjects and generally charges a review fee for researches with funding from sources other than MMC.

This Standard Operating Procedure (SOP) provides the Terms of Reference (TOR) that describe the framework for the constitution of the MMC IRB, the responsibilities and activities of its officers, members, staff and consultants.

1.1.4 Responsibilities

It is the responsibility of the Medical Director to:

A. Constitute and establish the MMC IRB.
B. Appoint the MMC IRB Officers, Members, and Independent Consultants;
C. Provide the Terms of Reference for these appointments in accordance with prevailing hospital policies, guidelines, and regulations.

It is the responsibility of the MMC IRB Officers, Members, and Staff to study, comprehend, comply with, and respect the procedures and guidelines set by the MMC IRB as approved by the appropriate hospital officials.

1.1.5 Ethical basis

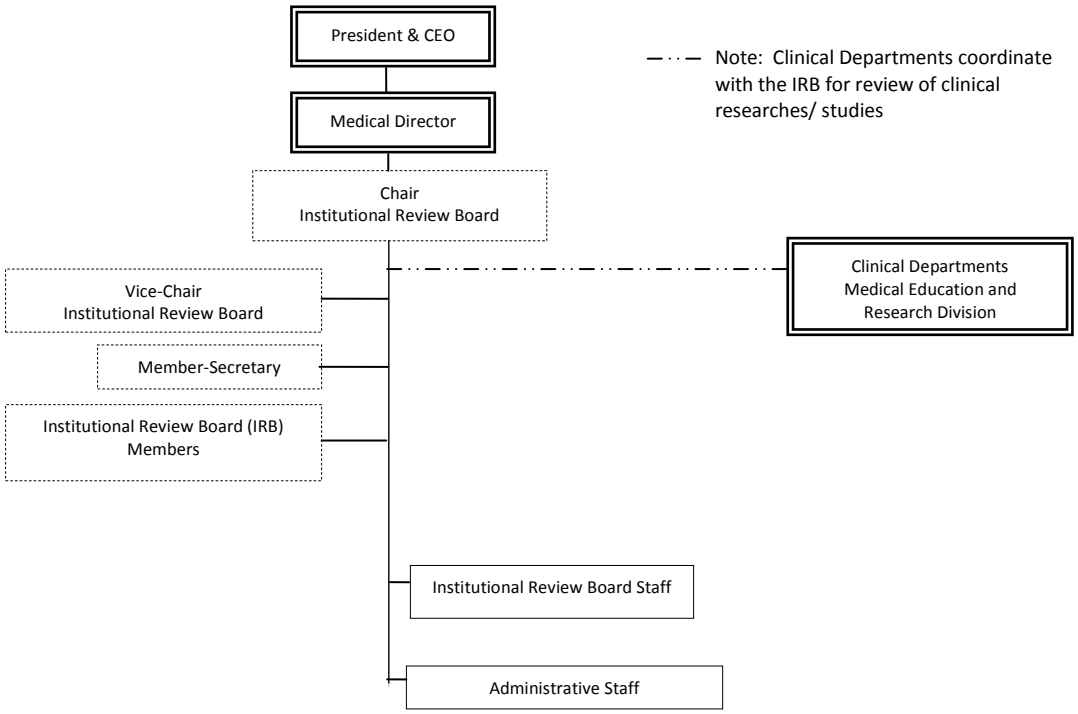
A. MMC IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents:
   1) Declaration of Helsinki (2013 and subsequent revisions)
   2) Council for International Organizations of Medical Sciences (CIOMS) 2002 and 2009
B. MMC IRB adheres to the national and international ethical standards and functions in accordance with the national laws, regulations, and guidelines.
C. MMC IRB provides its own standard operating procedures based on:
   1) Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO)

2) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)
3) International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
4) National Ethical Guidelines for Health Research (2011) by the Philippine Health Research Ethics Board (PHREB)
5) Philippine Food and Drug Authority regulations and other relevant laws and regulations

D. MMC IRB recognizes that the protocols it approves may also be approved by the national and/or local ethics committees prior to their implementation in specific localities.
E. In evaluating protocols and ethical issues, MMC IRB is cognizant of the diversity of laws, cultures and practices governing health research in various countries around the world.
F. It attempts to inform itself, whenever possible, of the regulations and requirements of the sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of the various localities where a proposed Makati Medical Center research is being considered.
G. MMC IRB takes the initiative to be informed, as appropriate, by the national/local ethics committees and researchers of the impact of the research that it has approved.

1.1.6 Constitution - Organizational Structure

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:



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

A. MMC Medical Director, as the appointing officer.
B. MMC IRB Chair, as the recommending officer.
C. Institutional Review Board, as the implementing office
    1) Chair
    2) Vice-Chair
    3) Member-Secretary is the head of the Secretariat and is a voting member of the IRB.
    4) Members
    5) IRB Secretariat

The MMC IRB collaborates and coordinates with the research committees of the different Clinical Departments of the institution with the support of the IRB Secretariat. The research committee reviews the technical aspect of the research protocols submitted by the residents and fellows. The research committee

head or research adviser endorses the protocols to MMC IRB for ethical review and approval. The IRB Secretariat reviews the completeness of the submission.

For other protocols, MMC IRB reviews both the technical and ethical aspects.

Only the Medical Director has the authority to dissolve the MMC IRB after due process. At any point in time, should the MMC IRB cease to exist, any subcommittee is automatically dissolved.

1.1.7 Determination of Quorum

A. MMC IRB adheres to the quorum requirements as defined in international and national guidelines for IRBs that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist is present during its board meeting.
B. Fifty percent (50%) of the total number of MMC IRB members plus one member is present.
C. A lay member and a non-affiliated member must be present.

1.1.8 Decision-making

1.1.8.1 After the review and discussion of every protocol or report, the MMC IRB gives the summary of main points for revision and/or final set of recommendations and decision.

1.1.8.2 Decision is made through voting of the board. A decision by voting requires all members to consider the decision at least acceptable and no member considers the decision unacceptable.

1.1.8.3 IRB members will vote on the approval of the particular proposal. At least 50% plus one or majority of the members present is needed for approval. Record of voting is shown (i.e., for, against or abstention).

1.1.8.4. Decision points are:

<u>Initial Review/Resubmission/ Amendment</u>

A. Approved –MMC IRB approves the research to initiate.
B. For Minor Modification –research that requires minor modifications and undergoes expedited review.
C. For Major Modification –research that requires major modification and undergoes full board review.

D. Disapproved –MMC IRB does not give the approval to initiate the research. Further review of the paper is terminated.
E. Pending Decision

SAE

A. Request an amendment to the:
   1) Protocol
   2) Consent form
B. Request for further Information
C. Suspension of:
   1) Enrollment of new research participants until further review of the IRB.
   2) All trial-related procedures (except those intended for safety and well-being of the participant) until further review by the IRB.
D. Termination of the study
E. Take note and continue monitoring
F. Site visit

Site Visit Report

A. Continue study and post-approval monitoring
B. Amend the protocol
C. Amend the Informed Consent Form
D. Stop recruitment
E. Terminate the study
F. Blacklist the Principal Investigator/ Sponsor
G. Recommend other corrective measures (specify)
H. Others (specify)

Protocol Deviation

A. Continue Study and monitor compliance
B. Request for further information
C. For site visit
D. Amend protocol
E. Amend Informed Consent Form
F. Suspend the study
G. Terminate approval of current study

Progress Report

A. Uphold approval with no further action
B. Approval pending:
   1) Request additional information

2) Recommend modification

C. Recommend suspension of:
   1) Enrollment of new subjects
   2) Research procedures in currently enrolled subjects
   3) The entire study

D. Termination of approval for the entire study

E. Others (specify)

Notification

A. Acknowledged
B. Request for further information
C. Recommend further action
D. Others (specify)

Final Report

E. Acknowledged
F. Request for further information
G. Recommend further action
H. Others (specify)

Early Study Termination

A. Acknowledged
B. Request additional information
C. Request meeting with the Principal Investigator
D. Other (specify)

1.1.8.5 Appeal of MMC IRB Decisions:

A. The sponsor or Principal Investigator of a disapproved protocol may appeal its decision by a letter of intent addressed to the IRB Chair. The letter of intent should stipulate the reasons for reconsideration.
B. Submission contains the changes required by the MMC IRB.
C. The revised protocol and the letter of intent are presented to the full board for deliberation.
D. The Full board decides whether to approve or disapprove the appeal.
E. The decision of the board is final. No further appeal is accepted.

1.1.9 Conflict of Interest and Confidentiality Agreement

A. The Confidentiality and Conflict of Interest agreement **(Form 1.3)** protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work.

B. The agreement covers all applications, meeting deliberations, information on research participants and related matters.
C. IRB Secretariat provides a copy of the Conflict of Interest and Confidentiality agreement form **(Forms 1.1 to 1.3)** to each member of the Makati Medical Center IRB together with the appointment letter.
D. All MMC IRB Members, Independent Consultants/ Guest Reviewers and IRB Secretariat sign the Confidentiality and Conflict of Interest agreement **(Form 1.3)** at the start of term.
E. It is the responsibility of all IRB members to carefully read, understand, accept and sign the agreement contained in the Confidentiality/ Conflict of Interest form before beginning their ethical review functions.
F. Signed Confidentiality and Conflict of Interest agreement **(Form1.3)** is completely filled out and dated.
G. Refusal to sign such agreement **(Form 1.3)**, may be a ground for his/her disqualification to serve in the MMC IRB.
H. All MMC IRB members and consultants should disclose any conflict of interest prior to the review and/or discussion of items in the agenda.
I. MMC IRB shall decide on how to manage specific conflicts of interest of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions of the Confidentiality and Conflict of Interest Agreements **(Form 1.3)**.
J. Any MMC IRB member who discloses a conflict of interest may remain for the presentation of the research protocol as a resource person but should refrain from exerting undue influence on the decision of the other IRB members. He/ she must leave before the Board conducts its deliberation and decision process on the protocol. He/she is not counted in the quorum for the protocol being discussed.
K. If the chair has conflict of interest, he/she must surrender the duties to the Vice-Chair or other designated member for the portion of the meeting in which he has conflict of interest. Such abstention will be recorded in the minutes of the meeting.
L. No selection of IRB members for the review of a protocol by the investigator is allowed.
M. Newly appointed members obtain two copies of the Agreement Form – one copy for the member and another for the MMC IRB member file.

1.2 Appointment of MMC IRB Members

1.2.1 Purpose

To describe the appointment procedures of the members of the Makati Medical Center Institutional Review Board (MMC IRB) and to identify the roles and responsibilities of the IRB officers and members.

1.2.2 Scope

While the MMC IRB remains under the authority of the Medical Director, it has to maintain its independence and develop its competence related to decision making as defined in the international and national guidelines. The membership Standard Operating Procedures (SOPs) covers the nomination and appointment procedures of IRB members, officers and independent consultants.

1.2.3 Responsibility

It is the responsibility of the Makati Medical Center (MMC) Medical Director to formally appoint the members and officers and consultants of the IRB after due consultation with the current members of the IRB.

1.2.4 Process Flow/Steps

NO	ACTIVITY	RESPONSIBILITY
1	Ask the MMC IRB members to nominate potential new members. ⬇	Chair/ IRB Secretariat
2	Submit names of potential members to the Chair. ⬇	Member/ IRB Secretariat
3	Recommend and submit a list of potential members to the Medical Director ⬇	Chair/ IRB Secretariat
4	Appoint new MMC IRB members. ⬇	Medical Director
5	Receive appointment letter **(Form 1.1)** and sign Confidentiality and Conflict of Interest Agreements **(Form 1.3)** and submit updated Curriculum Vitae **(Form 1.2).**	New Members

	⬇	
6	Files documents	IRB Secretariat

Detailed Instructions

1.2.4.1 Nominations and Appointment
Chair/ IRB Secretariat asks the IRB members to nominate potential new members.

1.2.4.2 Current MMC IRB members nominate candidates for new members to the Chair/ IRB Secretariat.

1.2.4.3 Chair discusses the qualifications of the nominees and submits the list to the Medical Director.

1.2.4.4 Medical Director selects from the list of nominees for MMC IRB members and consultants and issues an appointment letter.

1.2.4.5 New member receives the appointment letter **(Form 1.1)**, signs the Confidentiality and Conflict of Interest Agreements **(Form 1.3)** and submits updated curriculum vitae **(Form 1.2)**.

1.2.4.6 IRB Secretariat files the documents

1.2.5 Requirements for membership

A. MMC IRB is composed of at least 9 members.
B. Membership is multidisciplinary and multi-sectoral.
C. Membership includes persons whose primary concerns are in medical science, at least one member who is a pediatrician, at least one member who is in a non-medical / non-scientific area and at least one member who is non-affiliated.
D. Members have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by the Makati Medical Center (MMC) staff and non affiliated organizations.
E. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the MMC IRB should include a person who will represent the interest and concerns of the community.
F. MMC IRB aims for gender balance in its membership with equal representation of men and women members in order to promote gender sensitivity in its review procedures.
G. Older and younger generations are both represented.

H. Independent consultants are invited whenever necessary to provide expert opinion related to protocols under review.

1.2.6 Qualifications

A. Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to volunteer their time and effort to perform their functions in the MMC IRB.
B. Members have prior training in Good Clinical Practice (GCP), research methodology, research Ethics, standard operating procedures (SOP) training, or should be willing to undergo such training during their membership.
C. Members disclose in writing any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
D. Members submit their curriculum vitae **(Form 1.2)**, properly signed and dated and update them at least once every two years.
E. Members are required to sign a Confidentiality and Conflict of Interest agreement **(Form 1.3)** at the start of their term.

1.2.7 Conditions of Appointment of Members

All prospective MMC IRB members shall be willing to:

A. Make public his/her full name, profession, and affiliation as an MMC IRB member,
B. Disclose all financial accountability, reimbursement for work and expenses, related to their work in the MMC IRB that shall record and publicly disclose its financial records upon request.
C. Sign the Confidentiality and Conflict of Interest Agreements **(Form 1.3)** regarding meeting deliberations, applications, information on research participants, and related matters.

1.2.8 Appointment and Terms of Office

A. The appointing authority shall indicate in the appointment letter**(Form 1.1)** the MMC IRB's functions, terms of office, scope of work, conditions of appointment, system of replacement or recall, and compensation, if any.
B. Initial appointment of members is for one (1) year and reappointment is for a period of two (2) years.

C. Appointments may be renewed on the recommendation of the MMC IRB Chair upon the approval of the Medical Director.
D. MMC IRB adopts some mechanism for rotation of its membership roster, to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, the development and maintenance of expertise.
E. MMC IRB Chair likewise has a fixed term of four (4) years to ensure continuity of policy structures in place.
F. MMC IRB Vice-Chair is appointed for three (3) years.
G. MMC IRB Member-Secretary is appointed initially for one (1) year and reappointment is for two (2) years.
H. Medical Director of the Makati Medical Center is responsible for appointing MMC IRB members and consultants upon the recommendation of the MMC IRB Chair.

1.2.9 Types of IRB Members:

A. Medical/Scientific members are Physicians
B. Non-Medical/Non-Scientific members include non-physicians, lay, paramedical, nurse, and pharmacist.
C. Special/Alternative Members

1.2.10 Roles and Responsibilities

MMC IRB Officers

The following officers through the exercise of their respective responsibilities contribute to efficient MMC IRB operation:

Chair	A. Presides over the MMC IRB meetings and is accountable to the Medical Director B. Prepares an annual report summarizing MMC IRB activities and decision outcomes to the Medical Director. C. Ensures sufficient financial and administrative support for MMC IRB operations; submits an annual operating budget agreed upon by the Board to the Office of the Medical Director. D. Represents the MMC IRB interests within the hospital administration. E. Represents the MMC IRB within and beyond the hospital jurisdiction. F. Decides which protocols are expedited or for full board deliberation and recommendation. G. Ensures overall MMC IRB compliance with good clinical practice.
Vice-Chair	A. Presides over meetings in the absence of the Chair B. Performs other duties as designated by the Chair
Member-Secretary	A. Supervises the IRB Secretariat B. Recommends to the chair the type of review of the protocol - for expedited or for full board review. C. Assigns primary reviewers and guest reviewers when appropriate for approval by the Chair D. Ensures good MMC IRB documentation and archiving E. Consolidates and presents to the board post approval reports and submissions for deliberation and resolution (i.e.

amendment, serious adverse event reports, protocol deviations, communication, etc.)

Regular MMC IRB Members

A. Participate in MMC IRB meetings.
B. Maintain confidentiality of the documents and deliberations during MMC IRB meetings.
C. Declare any conflict of interest.
D. Review, discuss and consider research proposals submitted for evaluation.
    1) Medical members of the MMC IRB are the members with scientific expertise who ensure the scientific soundness of the research being reviewed.
    2) Non-medical members are the individuals representing the lay and have no primary background on health research. The primary role of the non-medical members is to assume the perspective of the study participants. Non-affiliate member may either be medical or non medical. This member is not associated with the institution or other organizations involved with the research reviewed. The role is depending on the individual's background, ensure scientific soundness and/or to review the informed consent form from the study participant's point of view.
E. Assess serious adverse event reports and recommend appropriate action.
F. Review progress reports and post approval monitoring reports of ongoing studies as appropriate.
G. Evaluate final reports.
H. Participate in continuing education activities in health research and ethics.

Alternate MMC IRB Members

A. Can attend at least 4 IRB Meetings per year or as needed based on his/her expertise.
B. Ensure scientific soundness and/or to review the informed consent (if applicable).
C. Maintain confidentiality of the documents and deliberations during MMC IRB meetings.
D. Assess serious adverse event reports and recommend appropriate action.
E. Review progress reports and post approval monitoring reports of ongoing studies as appropriate.

Adverse Events Subcommittee (AES)

A. 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.
B. 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.
C. A member of the AES should have a strong background on pharmacology/ clinical pharmacy.

Subcommittee PAnels for Investigator-Initiated REsearch ProtocolS (SPARES)

A. These are six subcommittees 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.
B. Each group is assigned to review for two months. Thus, each SPARE will review for two months of the year.
C. The composition of the subcommittees is determined by the Chair.
D. 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.
E. 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.

1.2.11 Resignation, Disqualification, and Replacement of Members

A. Members may resign their positions by submitting a letter of resignation to the Chair and endorsing to the Medical Director.
B. Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members, such as:
   1) Refusal to sign the Confidentiality and Conflict of Interest Agreement **(Form 1.3)**.
   2) Failure to comply with the Confidentiality and Conflict of Interest Agreement.
   3) Failure to attend three (3) consecutive regular monthly meetings without filing a leave of absence.

4) Non-compliance of duties and responsibilities stated in the Makati Medical Center Institutional Review Board (MMC IRB) Standard Operating Procedures (SOPs).

C. Members that have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.

D. The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

1.3 Selection of Independent Consultants

1.3.1 Purpose

To describe the procedures for the appointment of Makati Medical Center Institutional Review Board (MMC IRB) consultants.

1.3.2 Scope

This Standard Operating Procedure (SOP) describes the procedures for engaging the services of a professional/expert as a consultant to the MMCIRB. If the Chair of the MMC IRB determines that a study involves procedure(s) that are not within the area of competence or expertise of the MMC IRB members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the MMC IRB.

1.3.3 Responsibility

Any IRB member may nominate independent consultants to be endorsed by the Chair for appointment by Medical Director.

1.3.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Request for independent consultants. ⬇	Chair/ IRB Secretariat
2	Submit name of the potential consultants to the Chair. ⬇	Members/ IRB Secretariat
3	Selects and recommends list of consultants to the Medical Director. ⬇	Chair
4	Appoints new MMC IRB Consultant(s). ⬇	Medical Director
5	Receives appointment letter and sign Confidentiality and Conflict of Interest Agreements **(Form 1.3)** and submit updated Curriculum Vitaes (CV) **(Form 1.2)** ⬇	New members/ Officer/ Consultants
6	Files documents.	IRB Secretariat

Chapter I : IRB Composition and Ethical Framework	Document Code: IRB-SOP-1120-CEF-001-06	
Section 1.3 Selection of Independent Consultants	Effective Date: November 18, 2020	Page: Page 19 of 28

Detailed Instructions

1.3.4.1 Selection of Independent Consultants

1.3.4.1.1 The Chair/ IRB Secretariat request for independent consultant(s).

1.3.4.1.2 MMC IRB member/ IRB Secretariat nominates the independent consultants to help review research where the MMC IRB lacks expertise.

A. MMC IRB Secretariat compiles a list of independent consultants.
B. MMC IRB Chair/ Member-Secretary conduct a qualification review of the prospective consultants.

1.3.4.1.3 The Chair finalizes a list based on expertise and willingness to be available and submits to the Medical Director.

1.3.4.1.4. The Medical Director appoints independent consultants to help the MMC IRB in protocol review.

1.3.4.1.5 Consultant signs agreements and provides

A. Curriculum vitae **(Form 1.2)**
B. Signed Terms of Reference**(Form 1.1A)**
C. Signed Confidentiality and Conflict of interest Agreement **(Form 1.3)**
D. Photocopy of updated/ current good clinical practice certificate.

1.3.4.1.6 IRB Secretariat files all documents in the respective MMC IRB Independent Consultant folder in alphabetical order.

1.3.4.2 Independent Consultant Responsibilities

A. Evaluates study protocol
B. Completes assessment form **(Form 2.7B** and **2.8).**This report becomes a permanent part of the study file.

C. Independent consultant may attend the MMC IRB meeting, present his/her assessment, and participate in the discussion but without the right to vote. He/ she will not be counted in the quorum.
D. Recommends protocol revisions as necessary or approval to the IRB for deliberation and discussion.

1.3.4.3 Termination of services

A. Consultant's services may be terminated by either the consultant or by the MMC IRB.
B. Upon termination of the consultant's services, the IRB Secretariat ensures that all the necessary documentation is filed accordingly.

1.4 IRB Secretariat

1.4.1 Purpose

To describe the composition and identify the functions of the IRB Secretariat.

1.4.2. Scope

The MMC IRB secretariat is composed of the Member-Secretary, and the IRB Secretariat staff who are employees of the Makati Medical Center. The MMC IRB has an office and adequate support staff for carrying out its responsibilities.

1.4.3 Responsibility

It is the responsibility of the IRB Secretariat to provide the technical and administrative support to the MMC IRB.

1.4.4 Qualifications

A. Degree holder of BS Nursing, or other Health Science courses, preferably with background in Good Clinical Practice.
B. Computer literate
C. Efficient skills in archiving and organizing.
D. Signs the Conflict of Interest and Confidentiality Agreement
E. Updated curriculum vitae

1.4.5 Functions of the IRB Secretariat

A. Organizes an effective and efficient tracking procedure for each proposal received.
B. Prepares, maintains and distributes the study files
C. Organizes the MMC IRB meetings regularly.
D. Prepares and ensures the maintenance of meeting agenda and minutes.
E. Maintains good MMC IRB documentation and archiving procedures.
F. Manages MMC IRB database
G. Ensures organized documentations and files.
H. Keeps file of curriculum vitae of MMC IRB members and staff and ensures updating every 2 years.
I. Keeps a file of independent or expert consultant.
J. Communicates with the MMC IRB members and investigators.
K. Prepares the training plan, for MMC IRB members and staff and keeps files of the training certificates and record.
L. Ensures the attendance to external training at least once a year.

M. Organizes the preparation, review, revision and distribution of SOPs and guidelines and ensures the training of the MMC IRB members, and IRB Secretariat and on the SOP.
N. Provides the necessary administrative support for MMC IRB-related activities to the Chair of the MMC IRB.
O. Supports the MMC IRB-related activities.
P. Provides updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the MMC IRB members.
Q. Maintains a library of relevant resource materials and references.
R. Coordinates with the research committees for the MMC IRB to ensure complete protocol requirements.
S. Prepares a template of the annual operating budget of the IRB that will address all operational and training needs of staff and members. This will be submitted to the Chair for deliberation by the Board.

1.5 Training of MMC IRB Members and IRB Secretariat

1.5.1 Purpose

To describe Makati Medical Center Institutional Review Board (MMC IRB) procedures in ensuring initial and continuing training of the MMC IRB members, and the IRB Secretariat.

1.5.2 Scope

The Makati Medical Center recognizes the importance of training and continuing professional development. This Standard Operating Procedure (SOP) describes the training requirements of MMC IRB members and staff from initial training to continuing education to maintain and update MMC IRB competence in the review of different types of protocols.

1.5.3 Responsibility

MMC IRB officers ensure that training is provided to all new members.

It is the responsibility of the MMC IRB officers, members and IRB Secretariat to have themselves educated and trained regularly.

The IRB Secretariat programs a training plan and keeps track of the training needs of all members, and the IRB Secretariat.

1.5.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Provide initial training for new MMC IRB members and staff. ⬇	Chair/ IRB Secretariat
2	Keep track of training needs of MMC IRB members and staff and plan for continuing education. ⬇	Member/ IRB Secretariat
3	Watch out for training opportunities. ⬇	Member/ IRB Secretariat
4	Signify intention to attend training program/ workshop/ seminars	Member/ IRB Secretariat / IRB Chair
5	Attend in-house and external training ⬇	Member/ IRB Secretariat

6	Keep training records **(Form 1.4)** of the MMC IRB members and staff.	IRB Secretariat

Detailed instructions

1.5.4.1 Initial training of MMC IRB Members

- Initial research ethics training consists of basic training in research ethics principles, Good Clinical Practice (GCP), and in-house mentoring in MMC IRB standard operating procedures.

1.5.4.2 Continuing education of MMC IRB members and IRB Secretariat

In order to ensure continuing education of MMC IRB members and secretariat:

- Reminds individual MMC IRB members based on the training need and validity of the Good Clinical Practice Certificate.

1.5.4.3 Monitors training opportunities and informs MMC IRB officers about training courses, workshops, conferences, etc. that are periodically announced on websites, bulletin boards and various media channels.

A. Provides with external training opportunities at least once a year.
B. Ensures sufficient budgetary support for training activities.
C. Facilitates the attendance of MMC IRB members and IRB Secretariat whenever specific training activities are scheduled.

1.5.4.4 Signify intention to attend training program/ workshops/ seminars

A. Any MMC IRB member may file a written request to the Chair to attend training, with supporting documents (registration forms and programs) at least (1) month prior to the training date.
B. The MMC IRB chair recommends the participation of the member and endorses the request to the Medical Director.

1.5.4.5 Topics for training

MMC IRB members should maintain competence by ensuring that they have updated knowledge of the following:

A. Good Clinical Practice (GCP)updated/ renewed every 3 years
B. Declaration of Helsinki
C. Council for International Organizations of Medical Sciences (CIOMS)
D. Ethical Guidelines

E. Relevant laws and regulations
F. Relevant developments in science, health and safety, etc.
G. International meetings and conferences
H. MMC IRB Standard Operating Procedures

1.5.4.6 Safe-Keeping of training records

A. Attendance sheets of in-house training with relevant information about the topic, duration, date and venue are prepared and filed accordingly.
B. Training records of IRB members and IRB Secretariat are kept in the membership and IRB Secretariat files **(Form 1.4)**.
C. Curriculum Vitae **(Form 1.2)** of individual member/ IRB Secretariat are updated to reflect attendance of training activities.*Photocopy of certificates is filed when possible.

1.6 Incentives for the Makati Medical Center Institutional Review Board (MMC IRB) Members and Consultants

1.6.1 Purpose

To describe procedures to facilitate granting of honorarium to MMC IRB members and consultants.

1.6.2 Scope

This Standard Operating Procedure (SOP) describes how MMC IRB members and consultants are given honorarium for their work in the MMC IRB.

1.6.3 Responsibility

It is the responsibility of the MMC IRB members under the leadership of the Chair to explore the possibility of providing honorarium to all MMC IRB members.

1.6.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Explore administrative mechanisms and precedents to provide honorarium for MMC IRB work. ⬇	Chair/ Member/ IRB Secretariat
2	Discuss feasibility options and prepare a recommendation ⬇	Chair/ Member
3	Endorses MMC IRB recommendation to the Medical Director ⬇	Chair
4	Approves the honorarium ⬇	Medical Director
5	Dispenses the honorarium ⬇	IRB Secretariat
6	Acknowledge the honorarium	Member/ Consultant

Chapter I : IRB Composition and Ethical Framework	Document Code: IRB-SOP-1120-CEF-001-06	
Section 1.6 Incentives for the MMCIRB Members and Consultants	Effective Date: November 18, 2020	Page: Page 27 of 28

Detailed instructions

1.6.4.1 Chair/ Member-Secretary explore possible financial and administrative mechanisms and precedents to be able to provide honorarium for MMC IRB work.

1.6.4.2 Chair includes the topic in the MMC IRB meeting agenda for discussion among MMC IRB members. MMC IRB may suggest other schemes, endorse or modify the recommendation.

1.6.4.3 Chair makes a recommendation for honorarium or its adjustment to the Medical Director as reflected in the budget.

1.6.4.4 Medical Director may approve or disapprove the recommendation.

1.6.4.5 MMC IRB members are informed of the decision and IRB Secretariat dispenses honorarium.

MMC IRB SOP Version 5
Document History (Chapter 1)

Author	Chapter	Version	Date	Summary of Changes
Darwin A. Dasig, M.D.	1	6	November 17, 2020	• Updated the version number to Version 6