

Date (MMM/DD/YYYY)

<NAME OF APPOINTEE>

Designation

Dear <Name of Appointee>

I have the honor to appoint you as a Member of the Makati Medical Center Institutional Review Board (MMC IRB) for a period of _____ year(s), effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Participate in the IRB meetings;
- Review, discuss and consider research proposals submitted for evaluation;
- Assess serious adverse reports and recommend appropriate action(s);
- Review the progress reports and monitor ongoing studies as appropriate;
- Check progress and final reports;
- Maintain confidentiality of the documents and deliberations of IRB meetings;
- Declare any conflict of interest; and
- Participate in continuing education activities in research methodology and research ethics.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the Makati Medical Center IRB Secretariat. Sign, date and submit your latest curriculum vitae (IRB Form 1.2) and a copy of the Confidentiality and Conflict of Interest Agreement (IRB Form 1.3).

Respectfully yours,

<NAME OF MEDICAL DIRECTOR>

Medical Director
Makati Medical Center

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

Date (MMM/DD/YYYY)

<NAME OF INDEPENDENT CONSULTANT>
Independent Consultant
<Address>

Dear <Name of Independent Consultant>:

I have the honor to appoint you as an INDEPENDENT CONSULTANT of the Makati Medical Center Institutional Review Board (MMC IRB) for a period of _ _ _ _ _ year(s), effective <date> until <date>. As an Independent Consultant, you will have the following roles and responsibilities:

- Participate in the IRB or Subcommittee Panels for Investigator-Initiated Research Protocols (SPARES) meetings (without the right to vote)
- Impart professional insights, review, discuss and consider research proposals submitted for evaluation in relevance to your expertise on <identify expertise>
- Return comments or approvals of the research proposals within a week upon receipt of the proposals
- Maintain confidentiality of the documents and deliberations of MMC IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in research methodology and research ethics, when necessary

If you agree with the terms of this appointment, please sign on the space provided below, indicate the date, and return one (1) copy of this letter to the Makati Medical Center IRB Secretariat. Submit this appointment letter with your latest curriculum vitae (IRB Form 1.2) and a copy of the Confidentiality and Conflict of Interest Agreement (IRB Form 1.3).

Respectfully yours,

<NAME OF MEDICAL DIRECTOR>
Medical Director

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

Date (MMM/DD/YYYY)

<NAME OF NON-AFFILIATED MEMBER>

Non-Affiliated Member

<Address>

Dear <Name of Non-Affiliated Member>:

I have the honor to appoint you as a MEMBER of the Makati Medical Center Institutional Review Board (MMC IRB) for a period of _____ year(s), effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Ensure scientific soundness depending on your background and/or to review the informed consent form from the study participant's point of view
- Participate in the IRB meetings
- Review, discuss and consider research proposals submitted for evaluation as a non-affiliated member
- Assess serious adverse reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, indicate the date, and return one (1) copy of this letter to the Makati Medical Center IRB Secretariat. Submit this appointment letter with your latest curriculum vitae (IRB Form 1.2) and a copy of the Confidentiality and Conflict of Interest Agreement (IRB Form 1.3).

Respectfully yours,

<NAME OF MEDICAL DIRECTOR>

Medical Director

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

Date (MMM/DD/YYYY)

<NAME OF LAY MEMBER>

Lay Member

<Address>

Dear <Name of Lay Member>:

I have the honor to appoint you as a MEMBER of the Makati Medical Center Institutional Review Board (MMC IRB) for a period of ____ year(s), effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Primary role is to assume the perspective of the study participants
- Participate in the IRB meetings
- Review, discuss and consider research proposals submitted for evaluation as a representative of the lay
- Review the informed consent form from the study participant's point of view
- Assess serious adverse reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, indicate the date, and return one (1) copy of this letter to the Makati Medical Center IRB Secretariat. Submit this letter of appointment with your latest curriculum vitae (IRB Form 1.2) and a copy of the Confidentiality and Conflict of Interest Agreement (IRB Form 1.3).

Respectfully yours,

<NAME OF MEDICAL DIRECTOR>

Medical Director

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

Date (MMM/DD/YYYY)

<NAME OF LAY AND NON-AFFILIATED>

Lay and Non-Affiliated Member

<Address>

Dear <Name of Lay and Non-Affiliated Member>:

I have the honor to appoint you as a MEMBER of the Makati Medical Center Institutional Review Board (MMC IRB) for a period of _ _ _ _ year(s), effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Ensure scientific soundness depending on your background and/or to review the informed consent form from the study participant's point of view
- Participate in the IRB meetings
- Review, discuss and consider research proposals submitted for evaluation as the lay and non-affiliated member
- Assess serious adverse reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, indicate the date, and return one (1) copy of this letter to the Makati Medical Center IRB Secretariat. Submit this appointment letter with your latest curriculum vitae (IRB Form 1.2) and a copy of the Confidentiality and Conflict of Interest Agreement (IRB Form 1.3).

Respectfully yours,

<NAME OF MEDICAL DIRECTOR>

Medical Director

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

INSTITUTIONAL REVIEW BOARD

TO THE SECRETARIAT, IRB MEMBER OR PRINCIPAL INVESTIGATOR: ENCODE THE NECESSARY INFORMATION. PRINT NAME AND AFFIX SIGNATURE ON THE SPACE PROVIDED.

Name (Last Name, First Name, Middle Name)	
Address	
Contact Numbers A. Telephone B. Mobile C. Fax	
Date of 1st Appointment	
Educational Background	
Research and Ethics Training(s)	
Work Experience	
A. Occupation	
B. Previous Work Experience	
C. Present Work Experience	
D. Research-Related Experience	

Financial Disclosure and/or Conflict of Interest

Signature above Printed Name

Date (MMM/DD/YYYY)

TO THE UNDERSIGNED AND IRB CHAIR: PRINT NAME AND AFFIX SIGNATURE ON THE SPACE PROVIDED.

In view of the selection of <Name of Undersigned> of Makati Medical Center (MMC) as a member/ consultant of the Makati Medical Center Institutional Review Board (MMC IRB), and hereinafter referred to as the **Undersigned**

Whereas:

the **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the selection of the **Undersigned** as a member/ consultant of the MMC IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an MMC IRB member/ consultant is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the MMC IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of the MMC IRB member/ consultant's functions are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the Institutional Review Board (IRB) to carry out its mandate.

Confidentiality

This Agreement encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the **Undersigned** in conjunction with and/or in the course of the performance of his/her duties as a member/ consultant of the MMC IRB.

Any written information provided to the **Undersigned** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the MMC IRB.

As such, the **Undersigned** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "Confidential Information"). Moreover, the

INSTITUTIONAL REVIEW BOARD

Undersigned agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that his/her performance under this Agreement is consistent with **Makati Medical Center's (MMC's)** policies and any contractual obligations owed to third parties.

The confidentiality agreement shall remain despite the lapse or termination of engagement with MMC IRB.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the MMC IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the MMC IRB that no member/ consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the MMC IRB.

The **Undersigned** will immediately disclose to the Chair of the MMC IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the MMC IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an MMC IRB member/consultant has a potential conflict, the investigator may request that the member/ consultant be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair of MMC IRB. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member/ consultant in question. The MMC IRB elects to investigate the applicant's claim of the potential conflict.

When MMC IRB member/consultant has a conflict of interest, the MMC IRB member/ consultant should notify the Chair and may not participate in the MMC IRB review or approval except to provide information requested by MMC IRB.

Examples of conflict of interest cases may include, but is not limited to, any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member/consultant's personal biases may interfere with his/her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[*To the Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the MMC IRB. A copy will be given to you for your records.]

In the course of my activities as a member/consultant of the MMC IRB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the MMC IRB's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to immediately return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an MMC IRB member/consultant.

Whenever I have a conflict of interest, I shall immediately inform the Chair in writing not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

Conforme:

Signature above Printed Name

Date (MMM/DD/YYYY)

MMC IRB, CHAIR
Signature above Printed Name

Date (MMM/DD/YYYY)

INSTITUTIONAL REVIEW BOARD

TO THE SECRETARIAT: PROVIDE THE NECESSARY INFORMATION AND UPDATE AS NEEDED. ATTACH PHOTOCOPIES OF THE CERTIFICATES.

Name <small>(Last Name, First Name, Middle Name)</small>	
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Basic Courses	Organizer	Venue	Date <small>(MMM/DD/YYYY)</small>	Funding Source
1. Good Clinical Practice (GCP) Training				
2. Research Ethics				
3. IRB Standard Operating Procedures (SOP)				

Continuing Ethics Education: Research Ethics Workshops, Conferences, Meetings, Lectures	Organizer	Venue	Date <small>(MMM/DD/YYYY)</small>	Funding Source
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

***ATTACH PHOTOCOPY OF CERTIFICATE**