
 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-006
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: December 2020
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**FM-E-IRB-2019-006 Rev. 04
Confidentiality/Conflict of Interest Agreement**



PHILIPPINE HEART CENTER
Institutional Ethics Review Board
 8/F Medical Arts Building
 East Avenue, Quezon City, 1100 Philippines
 Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

Confidentiality/Conflict of Interest Agreement Form

Know all Men by these Presents:

In view of the appointment of _____, as _____ of the Philippine Heart Center Institutional Ethics Review Board (PHC-IERB), and hereinafter referred to as the **Undersigned**, and 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 procedures;
- the appointment of the **Undersigned** as a member of the PHC-IERB 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 IERB member 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 PHC-IERB 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 said appointed IERB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IERB to carry out its mandate.

Confidentiality

This Agreement thus 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/Independent Consultant of the PHC-IERB.

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 IERB.

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review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IERB.

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 "information"). Moreover, the *Undersigned* agrees that the information shall be used only for deliberation 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 her performance of this agreement is consistent with PHC's policies and any contractual obligations owed to third parties.

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 IERB 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 IERB 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 IERB.

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


If an applicant submitting a protocol believes that an IERB member has a potential conflict of interest, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IERB member(s) in question. The Board may elect to investigate the applicant's claim of the potential conflict of interest.

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

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's/consultant's personal biases may interfere with his or her impartial judgment.

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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 PHC-IERB. A copy will be given to you for your records.]


In the course of my activities as a member of the PHC-IERB, 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 Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chairperson upon termination of my functions as a Board member.

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

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

Title/Name Date:

IERB Chair Date:

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**FM-E-IRB-2019-081 Rev. 02
Appointment Letter**



Philippine Heart Center
Institutional Ethics Review Board
 8/F Medical and Arts Building
 East Avenue, Quezon City, 1100, Philippines
 Tel./Fax no.: 9252401 loc.3899; Email add: iebphc@gmail.com

Appointment Letter Template

Date:

(Member)

Position
 Philippine Heart Center
 East Avenue, Quezon City

Dear Dr. _____:

This is to confirm that upon the recommendation of the Deputy Executive Director, Education, Training and Research Services, you are hereby appointed as a _____ consultant member of PHC Institutional Ethics Review Board (IERB) effective January 1, 20__ to December 31, 20__ with honorarium of:

1. One Thousand Pesos (Php) per IERB regular meeting
2. One Thousand pesos (Php) per protocol assigned for continuing review
3. Two Thousand five hundred Pesos (Php) as primary reviewer of FDA protocol.
4. One Thousand Pesos (Php) per FDA protocol review meeting.
5. Three Thousand Pesos (Php) per SJREB review meeting.

As a member you are entitled to receive trainings as prescribed by Philippine Health Research Ethics Board (PHREB).

Please conform with your signature above your name.

Very truly yours,

(Name, Title)
 Executive Director

Conforme:


(Name, Title)
 Member

(Name, Title)
 Acting Deputy Executive Director, ETRS

SUBSCRIBED AND SWORN TO before me this _____ day of _____, 20__ affiant exhibiting her residence Certificate No. _____ issued at _____ on _____.

Doc No. _____
 Page No. _____
 Book No. _____
 Series of _____

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 Rev. 02

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**FM-E-IRB-2019-086 Rev. 01
Independent Consultant Appointment Letter Template**



Philippine Heart Center
Institutional Ethics Review Board
 8/F Medical and Arts Building
 East Avenue, Quezon City, 1100, Philippines
 Tel./Fax no.: 9252401 loc.3899; Email add: ihphc@gmail.com

Independent Consultant Appointment Letter Template

Date:

(Independent Consultant)
 Position
 Philippine Heart Center
 East Avenue, Quezon City

Dear Dr. _____:

This is to confirm that upon the recommendation of the Deputy Executive Director, Education, Training and Research Services, you are hereby appointed as a _____ consultant member of PHC Institutional Ethics Review Board (IERB) effective January 1, 20__ to December 31, 20__ with honorarium of _____.

The responsibilities of an independent consultant are as follows:

1. Submission or accomplishment of the following documents
 - a. Copy of curriculum vitae
 - b. Signed Confidentiality/Conflict of interest (PHC-IERB-FR-06-01)
2. Provision of the following consultation services
 - a. Expert review of the study protocols which require scientific or medical expertise not represented in the current composition of the board or those which the board has ascertained to require additional expert review.
 - b. Completion of the FDA Assessment Form (PHC-IERB-FR-71-02) (if it is FDA protocol).
 - c. Participation during the full board meeting when the study protocol will be discussed, though without decision point privileges.

Please conform with your signature above your name.


Very truly yours,

(Name, Title)
 Executive Director

Conforme:

(Name, Title)
 Independent Consultant

(Name, Title)
 Deputy Executive Director, ETRS

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**FM-E-IRB-2019-009 Rev. 04
IERB Member Training Record Form**



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Institutional Ethics Review Board
 8/F Medical and Arts Building
 East Avenue, Quezon City, 1100, Philippines
 Tel. /Fax no.: 9252401 loc.3899 ; Email add: irbphc@gmail.com

IERB Member Record Form


Surname		First Name		Middle Name	
Position in ERC: Date of Appointment (dd/mm/yyyy): Term of Office:				Address: Contact No.: Email:	
Ethics Course	Training Provider	Venue	Date dd/mm/yyyy	PHC Funded: Yes/No	
1.					
2.					
3.					
Continuing Ethics Education: Research Ethics Workshop, Conference, Meeting, Lectures					
Ethics Course	Training Provider	Venue	Date(dd/mm/yyyy)	PHC Funded Yes/No	
1.					
2.					
3.					
As Resource Person/Speaker					
Ethics Course	Training Provider	Venue	Date(dd/mm/yyyy)	PHC Funded Yes/No	
1.					
2.					
3.					

Certified Correct:

Secretariat Name: (Last Name, First Name, Middle Initial)

Signature:

Date (dd/mm/yyyy):

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**FM-E-IRB-2019-080 Rev. 02
Training Request Form**



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Institutional Ethics Review Board
 8/F Medical and Arts Building
 East Avenue, Quezon City, 1100, Philippines
 Tel. /Fax no.: 9252401 loc.3899 ; Email add: irbphc@gmail.com

Training Request Form

Reference No.	
Name of Member	
Date of First Appointment	
Expertise	
Type of Training Requested	<input type="checkbox"/> Good Clinical Practice <input type="checkbox"/> Good Research Practice <input type="checkbox"/> Research Ethics <input type="checkbox"/> Standard Operating Procedures <input type="checkbox"/> Continuing Ethics Education <input type="checkbox"/> Other Educational Activities _____
Detailed of Participation	<input type="checkbox"/> Participant only <input type="checkbox"/> Resource Person <input type="checkbox"/> Others: _____
Amount Requested	
Other source of funding if any:	
Signature	
Date	<dd/mm/yyyy>
Endorsement	I endorse the application of <member> for the <training requested>. I certify that the supporting documents pertaining to the application are authentic and that <member> has been an active member of PHC-IERB since <date of appointment>. <Signature above Title and Full Name> Chair, PHC-IERB Date: <dd/mm/yyyy>
Approval	<Signature above Title and Full Name> Executive Director Date: <dd/mm/yyyy>

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**FM-E-IRB-2019-011 Rev. 04
Independent Consultant Letter Template**



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Institutional Ethics Review Board
 8/F Medical Arts Building
 East Avenue, Quezon City, 1100 Philippines
 Tel./Fax no. 9252401 loc.3899; email add: irbphc@gmail.com

INDEPENDENT CONSULTANT LETTER TEMPLATE

Date

Dear _____:

The **(NAME OF ERB)** is inviting you to be an Independent Consultant, in your capacity as a **(EXPERTISE)**, to provide expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which board has ascertained to require additional expert review.

The responsibilities of an independent consultant are as follows:

1. Submission or accomplishment of the following documents
 - a. Copy of curriculum vitae
 - b. Signed Confidentiality/Conflict of interest (PHC-IERB-FR-06-01)
2. Provision of the following consultation services
 - a. Expert review of the study protocols which require scientific or medical expertise not represented in the current composition of the board or those which the board has ascertained to require additional expert review.
 - b. Completion of the FDA Assessment Form (PHC-IERB-FR-71-02) (if it is FDA protocol).
 - c. Participation during the full board meeting when the study protocol will be discussed, though without decision point privileges

If you agree to accommodate this request, please sign the *conforms* below and submit the documents indicated in *1.a* and *1.b* above, to facilitate processing of your appointment. As an independent consultant, you will be entitled to standard honorarium package effective during your appointment period.

Thank you.

Very truly yours,

Chair

Name & Signature of Independent Consultant
 CONFORME

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