



PHILIPPINE HEALTH RESEARCH ETHICS BOARD
Philippine National Health Research System
c/o Philippine Council for Health Research and Development
Department of Science and Technology

PCHRD	
Records Section	
Rec'd by:	<i>Noraine</i>
Time:	10:10 AM
Date:	7/8/2020
Ref. No:	001709

PHREB Resolution No. 20-002
Series of 2020
July 2, 2020

RESOLUTION

Approval of the “**PHREB Resolution on the Honoraria Rates of
Accreditors**”
per 56th PHREB meeting dated 23 June 2020

Whereas, the Philippine Health Research Ethics Board promotes the establishment of functional and effective ethics review committees;

Whereas, it is the Philippine Health Research Ethics Board's responsibility to monitor and evaluate the performance of institutional ethics review committees in accordance with PHREB procedures and guidelines;

Whereas, in order to perform its monitoring and evaluating functions, PHREB accreditors must conduct accreditation visits to Level 3 research ethics committees; and

Whereas, PHREB recognizes the need to compensate the accreditors for the work that they do;

The Philippine Health Research Ethics Board, in consultation with its Committee on Standards and Accreditation (CSA), hereby resolves:

To allow the payment of honoraria, on the basis of compensation rates and procedures in accordance with existing laws, to accreditors conducting accreditation visits and post visit activities such as evaluation of the action plans and evidence of compliance.

The payment of honoraria for the Lead Accreditor (Team leader) shall be in the amount of *Thirty-Three Thousand Nine Hundred Pesos (Php 33,900.00)* and the Member Accreditors shall be in the amount of *Twenty-Eight Thousand Nine Hundred Pesos (Php 28,900.00)* per REC application. The honorarium will cover the actual accreditation visit and post visit activities.

The Philippine Health Research Ethics Board hereby approves and promulgates this resolution.

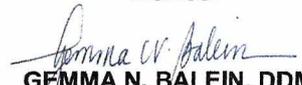
ADOPTED, on the 23th day of June 2020 during the online PHREB Board Meeting, by:

PHILIPPINE HEALTH RESEARCH ETHICS BOARD

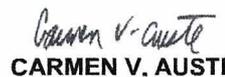

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Philippine Health Research
Ethics Board

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PHREB Accreditation Training and Visit Agenda

Accreditation Objectives:

- A. To conduct an independent evaluation of the REC and to provide feedback on its practices and overall performance:
 - To review existing written institutional Standard Operating Procedures (SOP) and adherence to these procedures.
 - To observe compliance to international, national and local standards.
- B. To make recommendations as appropriate to ensure best standards of quality and transparency in ethical review for the REC.

Scope of REC Accreditation Activities

- Review the legal and regulatory framework as well as documents related to the establishment of the REC.
- Review REC membership and staff list, terms of reference and training records.
- Review REC SOPs.
- Interview REC representatives (committee members and secretariat).
- Review protocol files, meeting agendas, minutes and communications.
- Review Serious Adverse Events (SAEs) and other follow-up reports.
- Observe REC meeting.
- Document findings and observations during the accreditation visit.
- Write the accreditation report.
- REC standard operating procedures
- REC forms for communication with applicants, regulatory authorities, or the authority under which the REC is established
- Agenda and minutes of three REC meetings
- Documents for reviewing serious adverse events (SAEs)
- REC policy and procedures for follow-up or post-approval review
- Protocol list in the past 3 years
- Protocol files
- Communication Files
- REC database
- Training curriculum and workshops

Site Visit - Day 1

9:00-10:30	<p>Opening Meeting (with REC Members and Staff)</p> <ul style="list-style-type: none"> ▪ Opening Prayer and National Anthem (at the option of REC – 5 mins) ▪ Welcome Remarks: <p>Institutional Official/ EAMC-IERB Chair: PHREB Coordinator</p> <p>Presentation of the Accreditation Plan:</p> <ul style="list-style-type: none"> ▪ Discussion of the purpose and method of the accreditation visit and evaluation ▪ Discussion of accreditation visit methodology <p>Presentation of REC Establishment, Profile and Review Flowcharts:</p> <ul style="list-style-type: none"> ▪ EAMC-IERB Chair: ▪ Open Forum (10 mins) <p>Review of the visit agenda: Accreditation Team</p> <p>Review of the REC documentation available for the visit and evaluation</p>
10:30-12:30	Observation of REC Meeting
12:30-13:30	Lunch
13:30-16:30	REC Office Visit

	<p>Review of the REC's Legal and Regulatory Framework and Mandate</p> <ul style="list-style-type: none"> ▪ Discussion of the national and international guidance documents under which the REC operates ▪ Discussion with the responsible member and/or staff of the REC about document requirements and procedures <p>Review of REC files and documentation</p>
16:30-17:30	<p>Summary of the Day's Findings (Closed Door Team Meeting)</p> <ul style="list-style-type: none"> ▪ Listing of the strengths of the REC ▪ Indications of areas for further consideration

- *Interview with REC members and staff will be arranged during the first 2 days when interviewees are available.*

Site Visit - Day 2 - (28 February 2019)

9:00-12:30	<p>Review of the REC Membership File</p> <ul style="list-style-type: none"> ▪ Examination of the REC membership & Independent Consultants' files ▪ Examination of documentation of expertise of REC and staff ▪ Review REC training curriculum and records <p>Review of the REC Standard Operating Procedures</p> <ul style="list-style-type: none"> ▪ Examination of the REC Standard Operating Procedures ▪ Examination of documents available to applicants, regulatory authorities, or the authority under which the REC is established
12:30-13:30	Lunch
13:30 – 16:30	<p>Review of Protocol Files</p> <ul style="list-style-type: none"> ▪ Examination of protocols reviewed by the REC <p>Review of the REC SAE Review and Follow-up Procedures</p> <ul style="list-style-type: none"> ▪ Examination of the REC procedures for receiving and reviewing SAEs ▪ Examination of the REC policy and procedures for follow-up review
16:30 – 17:30	Summary of the Day's Findings (Closed Door Team Meeting)

Post Accreditation Visits Activities

1. evaluation of the action plans and evidence of compliance which is done two to three times until the compliance is satisfactory.