



## I. STRUCTURE & COMPOSITION

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## 1. Objectives

This SOP describes the Terms of Reference (TOR) which provide the organizational framework for the structure and composition of the University of the Philippines Manila Research Ethics Board (UPMREB). This SOP also describes and provides the procedures, templates, and forms that are related to nomination, appointment, privacy and confidentiality, training, and compensation; and identifies who should read, agree to, sign, and date these forms.

## 2. Scope

This SOP applies to the constitution of the UPMREB and the composition of review panels, including the Serious Adverse Events Committee, within the UPMREB, which will carry out the task of providing an independent review of research protocols involving human participants that are submitted to the UPMREB by members of the faculty, students, hospital staff, residents, fellows and other trainees and employees of the University of the Philippines Manila (UPM), and non-UPM principal investigators (PIs). Protocols involving non-human living vertebrates are referred to the Institutional Animal Care and Use Committee (IACUC).

This SOP describes the general ethical basis or values on which the UPMREB is based, the panel composition and appointment of UPMREB personnel, and duties and responsibilities of UPMREB personnel, including attendance, training, expected review deliverables, and disclosure of conflict of interest.

## 3. Responsibilities

It is the responsibility of the UPM Chancellor to constitute and establish the UPMREB. The Chancellor is also responsible for appointing the UPMREB Chair, Coordinator, Panel Members, and Secretariat Staff; and providing the terms of reference for these appointments in accordance with prevailing university policies, guidelines, and regulations.

It is the responsibility of the Vice Chancellor for Research to monitor the administrative operations of the UPMREB through the Director for Research Management and Translation (BOR 1266<sup>th</sup> meeting).

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It is the responsibility of the Director for Research Management and Translation (DRMT) to assist the Vice Chancellor for Research with regards to planning, operationalization, and monitoring of UPMREB activities (BOR 1266<sup>th</sup> meeting).

It is the responsibility of the UPMREB Chair, Coordinator, Panel Members, Serious Adverse Events Committee Members, and Secretariat Staff to study, comprehend, comply with, and respect the procedures and guidelines set by the UPMREB as approved by appropriate university officials.

It is the responsibility of all newly appointed UPMREB Panel Members to read, understand, accept, and sign required appointment forms at the start of their appointment or reappointment to the UPMREB. If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in the UPMREB or to be disallowed in the deliberations of certain protocols.

It is the responsibility of new UPMREB personnel to undergo training during the course of his appointment and existing UPMREB personnel to continuously update themselves and train on relevant knowledge and skills. The UPMREB Chair shall enjoin UPMREB personnel to attend trainings/seminars/ workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore, UPM is responsible for allocating an annual budget for specific trainings and other educational activities for UPMREB personnel.

#### **4. Regular Constitution and Functions**

##### **4.1. Organizational Structure of the UPMREB**

- 4.1.1. The Chancellor appoints the UPMREB Chair and Coordinator to facilitate the discharge of functions of the UPMREB along the line of authority indicated by the following chart:

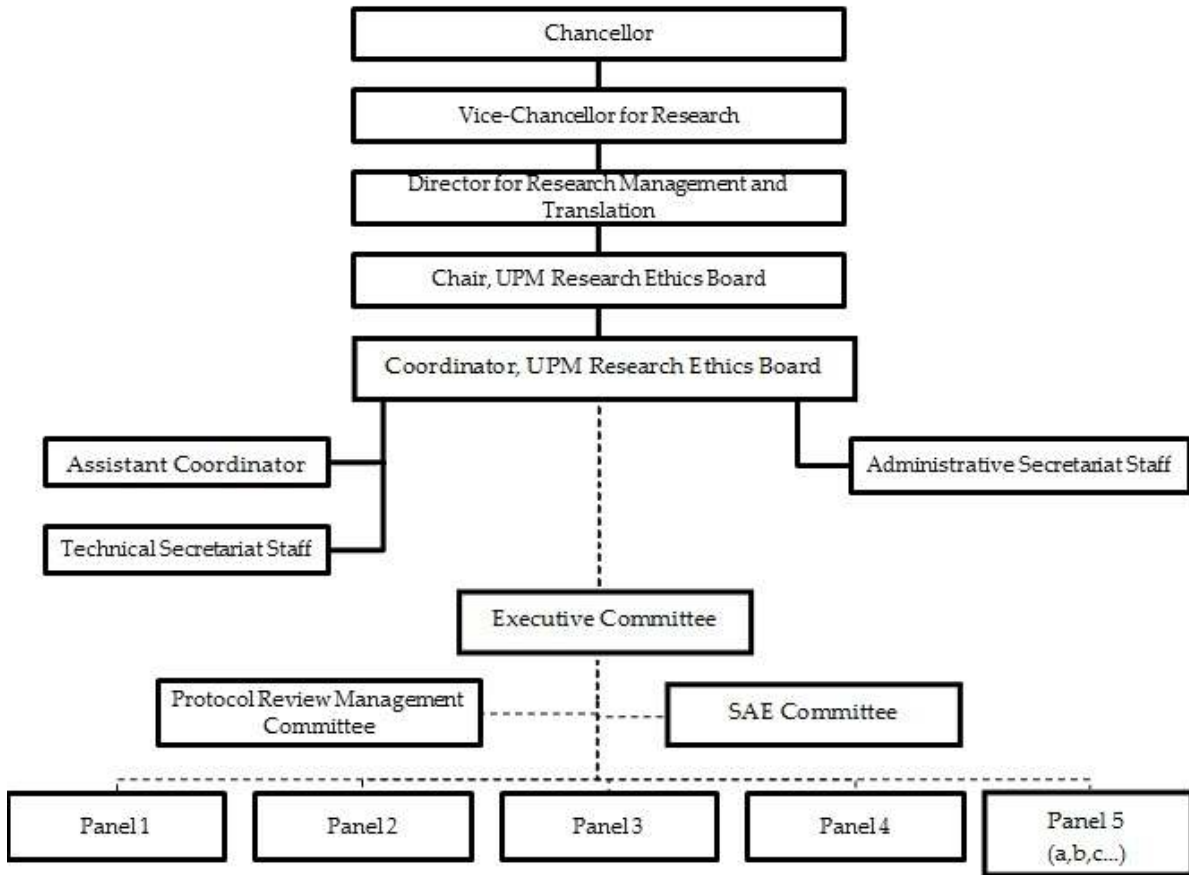


Figure 1: Organizational Chart

4.1.2. The UPMREB is established by authorization of the UPM Chancellor and exercises its mandate through the following structure:

- The UPM Chancellor, as the appointing officer
- The UPMREB Chair, as the recommending officer
- The Research Ethics Board, as the implementing office

4.1.3. Only the Chancellor has the authority to dissolve the UPMREB after due process.

4.1.4. At any point in time, should the UPMREB cease to exist, UPMREB panels are automatically dissolved.

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#### **4.2. Executive Committee**

4.2.1. The UPMREB Executive Committee is composed of the UPMREB Chair, Coordinator, panel chairs, and panel secretaries.

4.2.2. The following are the functions of the UPMREB Executive Committee:

- 4.2.2.1. Address review issues and administrative concerns common to all panels
- 4.2.2.2. Assess results of internal audit and recommend course of action
- 4.2.2.3. Discuss member participation in continued ethics training
- 4.2.2.4. Resolve complaints, queries, and reports on ethical misconduct related to a protocol approved by UPMREB
- 4.2.2.5. Deliberate on the proposed SOP draft

#### **4.3. UPMREB Review Panels**

4.3.1. The UPMREB is composed of the UPMREB Chair, Secretariat, several independent review panels, and the Serious Adverse Events Committee.

4.3.2. Independent review panels may be classified as:

- 4.3.2.1. Regular review panels tasked to perform institutional review and issue ethical clearance or ethical approval to study protocols submitted for its consideration; or
  - 4.3.2.2. Special review panels tasked to perform review of study protocols for purposes outside of regular institutional review or issuance of ethical clearance such as those that may be requested by specific agencies and stakeholders, or as required by specific regulations.
- 4.3.3. The UPMREB Serious Adverse Events Committee is tasked to review all types of serious adverse events (SAEs), including suspected unexpected serious adverse reactions (SUSARs) occurring at the

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clinical trial site approved by any of the UPMREB panels or occurring offsite for the given project/related project involving risks to participants and give recommendations for action of respective panel/s.

#### **4.4. Composition of UPMREB Regular Review Panels**

- 4.4.1. The UPMREB is composed of the UPMREB Chair, Secretariat, and independent review panels.
- 4.4.2. The UPMREB can create new panels as the need arises.
- 4.4.3. Each panel is composed of at least seven (7) regular panel members.
- 4.4.4. In anticipation of circumstances when regular members are unavailable, which could affect quorum, UPMREB appoints a set of alternate members to serve in any panel. Similarly, members of one panel may serve as alternate members in other panels should the need arises.
- 4.4.5. Each panel has a Panel Chair and a Panel Secretary from among the members. The Panel Chair and Panel Secretary are appointed by the UPMREB Chair and approved by the UPM Chancellor.
- 4.4.6. Each panel is an independent body composed of scientific and/or medical members, and non-scientific members wherein at least one (1) non-affiliated and one (1) non-scientific member are present. Medical members refer to medical doctors.
- 4.4.7. The Panel Members should have various backgrounds and should have adequate representation of members with regard to age and sex.
- 4.4.8. Members are selected according to their personal capacities; based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of UPMREB.
- 4.4.9. Initial appointment of members is for a period of one (1) year and re-appointment is for a period of two (2) years. Appointments may be



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renewed on the recommendation of the UPMREB Chair and upon approval of the Chancellor. The UPMREB Chair likewise should have a fixed term of four (4) years to ensure continuity of policy structures in place.

- 4.4.10. Panel assignments should take into consideration the appropriate mix of old and new members.
- 4.4.11. Panel Members may be requested to participate in the meetings of other panels, upon recommendation of the UPMREB Chair, and in coordination with the Panel Chairs.
- 4.4.12. The UPMREB may further be supported in its deliberation on specific protocols or requests for advice on specific ethical and / or technical issues by Independent Consultants (see **SOP I-7 SELECTION OF INDEPENDENT CONSULTANTS**).

### 4.5. Composition of the Serious Adverse Events (SAE) Committee

- 4.5.1. The UPMREB Chair will constitute an SAE Committee, which will consist of Panel Members and/or one/more co-opted external members to review and recommend actions on serious adverse events reports submitted for review to the UPMREB.
- 4.5.2. The SAE Committee will consist of five (5) to seven (7) members who are recommended by the SAE Committee Chair and approved by the UPMREB Chair.
- 4.5.3. The SAE Committee will have a Secretary from among the members as recommended by the SAE Committee Chair and approved by the UPMREB Chair.

### 4.6. Composition of Special Review Panels

- 4.6.1. The UPMREB may constitute panels for purposes outside of regular institutional review or issuance of ethical clearance, such as those that may be requested by specific agencies and stakeholders, or as required by specific regulations.

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4.6.2. The special review panel will be constituted, and its members appointed, according to the requirements of such requests or regulations referred to in 4.6.1.

#### **4.7. Composition of the Protocol Review Management Committee (PRMC)**

4.7.1. The Committee is composed of the UPMREB Chair, Coordinator and panel secretaries. The composition of this committee may be expanded or reduced, as needed, upon recommendation of the UPMREB Chair.

4.7.2. The PRMC was created to assess the completeness, accuracy, and adequacy of review documents prior to panel meetings to ensure that meetings are conducted efficiently. This assessment includes verification of accomplished assessment forms, agenda of the meeting, and minutes of previous meeting. The PRMC can call meetings with investigators to clarify requirements related to board recommendations and actions.

4.7.3. The PRMC is a management committee and as such has no review function.

#### **4.8. Resignation, disqualification, and replacement of members**

4.8.1. A member may resign his/her position by submitting a letter of resignation to the Chancellor through the Panel Chair and the UPMREB Chair.

4.8.2. A member may not be reappointed for non-compliance of duties and responsibilities stated herein.

4.8.3. A member who has resigned and members who will not be reappointed will be replaced by new members upon recommendation of the UPMREB Chair and approval of the UPM Chancellor.

#### **4.9. General Duties and Responsibilities of UPMREB Personnel**

4.9.1. UPMREB Review Panel members and personnel should submit their properly signed and updated **CURRICULUM VITAE [UPMREB FORM 1(B)2012]**, which will be filed at the UPMREB Membership File



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(contains CV, Terms of Appointment, and copies of Training Certificates of each member).

- 4.9.2. Members are required to sign **UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the UPMREB in the course of its work.
- 4.9.3. Members should be willing to publicize their full name, profession, and affiliation to the UPMREB upon request.
- 4.9.4. Members must commit to record and make available upon request, all financial relationships, and any conflict of interest within or related to the UPMREB.

#### **4.10. Specific Duties and Functions of UPMREB Personnel**

- 4.10.1. UPMREB Chair
  - 4.10.1.1. Prepare the budget and propose membership
  - 4.10.1.2. Recommend policy amendments and changes
  - 4.10.1.3. Preside over meetings among Panel Chairs and general assemblies
  - 4.10.1.4. Represent the UPMREB in the research organizational structure of UP Manila
  - 4.10.1.5. Represent UPM in national and international ethics fora
  - 4.10.1.6. Oversee the operations of the UPMREB panels and SAE Committee
  - 4.10.1.7. Supervise the management of the UPMREB Office
  - 4.10.1.8. Act on suggestions, complaints, and queries from stakeholders
  - 4.10.1.9. Preside over the PRMC meeting



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### 4.10.2. UPMREB Coordinator

- 4.10.2.1. Ensure UPMREB compliance with international, national, and institutional policies governing human subject research and human subject protections
- 4.10.2.2. Recommend updates in UPMREB policies and procedures in accordance with emerging national and international policy trends
- 4.10.2.3. Prepare new UPMREB documents as needed
- 4.10.2.4. Maintain and update UPMREB manual of policies and standard operating procedures
- 4.10.2.5. Supervise the issuance of all UPMREB communication in respect of UPMREB panel decisions and actions
- 4.10.2.6. Recommend the development, implementation, and monitoring of UPMREB policies and procedures to the UPMREB Chair
- 4.10.2.7. Manage the UPMREB office under the supervision of the UPMREB Chair
- 4.10.2.8. Ensure the basic training, orientation, and continuing education of UPMREB review panel members and staff
- 4.10.2.9. Provide information required by research investigators regarding UPMREB application processes
- 4.10.2.10. Liaise with stakeholders outside UPM
- 4.10.2.11. Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the UPMREB review panel members
- 4.10.2.12. Preside over the PRMC meeting in the absence of the UPMREB Chair



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- 4.10.2.13. Perform direct supervision, programming, and monitoring of the activities of UPMREB Administrative and Technical Staff
- 4.10.2.14. Oversee the proper management of UPMREB Databases, and physical and electronic protocol files
- 4.10.2.15. Oversee the generation of statistical data and other related information
- 4.10.2.16. Prepare and finalize financial and related reports
- 4.10.2.17. Review requisition and procurement of office supplies and materials
- 4.10.2.18. Supervise the issuance, utilization, and control of office supplies and materials
- 4.10.2.19. Coordinate with concerned offices regarding release of funds
- 4.10.2.20. Perform other UPMREB-related tasks that may be assigned to him/her by the UPMREB Chair
- 4.10.3. Panel Chair
  - 4.10.3.1. Preside over UPMREB panel meetings
  - 4.10.3.2. Liaise directly with the UPMREB Chair
  - 4.10.3.3. Sign on behalf of the panel regarding protocol-related decisions and communications
  - 4.10.3.4. Assist the UPMREB Chair in budget planning and the preparation and submission of midyear and annual reports to be submitted to the Chancellor
  - 4.10.3.5. Perform other UPMREB-related tasks that may be assigned to him/her by the UPMREB Chair

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#### 4.10.4. Panel Secretary

- 4.10.4.1. Oversee UPMREB protocols reviewed by respective UPMREB panel and assign primary reviewers to review protocols submitted to the UPMREB
- 4.10.4.2. Oversee preparation and accuracy of the agenda and minutes of the meeting
- 4.10.4.3. Supervise the preparation of communication pertinent to protocol-review-related actions to the PI
- 4.10.4.4. Perform other UPMREB-related tasks that may be assigned to him/her by the UPMREB Chair or respective Panel Chair
- 4.10.4.5. Attend the PRMC meeting

#### 4.10.5. UPMREB Panel Member/Alternate Panel Member

- 4.10.5.1. The role of the scientific and/or medical member is to focus on the review of the study protocol, while the role of the non-scientific member is to focus on the review of the informed consent process and form.
- 4.10.5.2. The roles of the affiliated and non-affiliated members in terms of the review are similar, however, the non-affiliated member is expected to provide an external perspective to ensure the independence of the position of the UPMREB, even from possible bias posed by its own institution that may the impact rights, safety, and well-being of human subjects in research.
- 4.10.5.3. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation (See **SOP II: STUDY PROTOCOL REVIEW** for timelines)
- 4.10.5.4. Familiarize him/herself with the SOPs of the UPMREB, his/her terms of reference, and the international and national guidelines on research ethics



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- 4.10.5.5. Participate actively in the panel meetings and other UPMREB meetings. It is expected that a member will have at least 80% attendance during the period of appointment because attendance is integral to the effectiveness of the UPMREB as a review board.
- 4.10.5.6. Panel Members and Alternate Panel Members are entitled to vote for a decision during full board meetings. Alternate Panel Members are those who will be called upon to attend panel meeting as a substitute to members who will be absent, for purposes of maintaining quorum. Alternate Panel Members who are invited as primary reviewers are entitled to vote for a decision.
- 4.10.5.7. Participate in initial review (initial submission and resubmission) and continuing review (amendments, progress reports, final reports, non-compliance reports, early termination reports, and SAE/SUSAR reports) of protocols submitted for consideration of UPMREB, and recommend appropriate action on serious adverse events based on monitoring reports from SAE Committee.
- 4.10.5.8. Participate in Site Visits and similar activities as needed
- 4.10.5.9. Maintain confidentiality of the documents and deliberations of UPMREB meetings
- 4.10.5.10. Declare any conflict of interest in general and for specific protocols for review
- 4.10.5.11. Participate in required training as stipulated in **SOP I-6: TRAINING OF REGULAR UPMREB REVIEW PANEL MEMBERS AND PERSONNEL** with proof of attendance in such training activity submitted to the Coordinator
- 4.10.5.12. Submit an updated and signed CV at the start of each calendar year



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- 4.10.5.13. Refer to the UPMREB Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors before acting on them and after consulting Panel Members
- 4.10.5.14. Do other UPMREB-related duties that may be requested of him/her by the UPMREB Chair or respective Panel Chair
- 4.10.6. Serious Adverse Events Committee Chair
  - 4.10.6.1. Preside over SAE Committee meetings
  - 4.10.6.2. Liaise directly with other UPMREB personnel
  - 4.10.6.3. Invite Independent Consultants to provide special expertise for specific serious adverse events reports
  - 4.10.6.4. Perform other UPMREB-related tasks that may be assigned to him/her by the Chancellor or UPMREB Chair
- 4.10.7. Serious Adverse Events Committee Secretary
  - 4.10.7.1. Oversee preparation and accuracy of the agenda and minutes of the meeting
  - 4.10.7.2. Supervise the preparation of communication pertinent to SAE-review-related actions to the Panel
  - 4.10.7.3. Perform other SAE Committee-related tasks that may be assigned to him/her by the SAE Committee Chair
- 4.10.8. Serious Adverse Events Committee Members
  - 4.10.8.1. Familiarize him/herself with the **SOP on Post-Approval Review (SOP III)** and his/her terms of reference
  - 4.10.8.2. Participate actively in the SAE Committee meetings. It is expected that a member will attend all scheduled SAE Committee meetings within the year because attendance is integral to the effectiveness of the SAE Committee.



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- 4.10.8.3. Recommend appropriate action on serious adverse events reports
- 4.10.8.4. Participate in Site Visits and similar activities as needed
- 4.10.8.5. Maintain confidentiality of the documents and deliberations of SAE Committee Meetings
- 4.10.8.6. Declare any conflict of interest in general and for specific protocols for review
- 4.10.8.7. Submit an updated and signed CV at the start of each calendar year
- 4.10.8.8. Do other SAE Committee-related duties that may be requested of him/her by the SAE Committee Chair
- 4.10.9. Special Review Panel Members
  - 4.10.9.1. Functions of special review panel members may vary according to its respective rationale.
  - 4.10.9.2. These functions will be determined upon creation of the special review panel, and described through its terms of reference.
- 4.10.10. UPMREB Assistant Coordinator
  - 4.10.10.1. Ensure UPMREB compliance with international, national, and institutional policies governing human subject research and human subject protections under the supervision of UPMREB Coordinator
  - 4.10.10.2. Recommend updates in UPMREB policies and procedures in accordance with emerging national and international policy trends
  - 4.10.10.3. Prepare new UPMREB documents as needed
  - 4.10.10.4. Maintain and update UPMREB manual of policies and standard operating procedures



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- 4.10.10.5. Supervise the issuance of all UPMREB communication in respect of UPMREB panel decisions and actions
- 4.10.10.6. Manage the UPMREB office under the supervision of the UPMREB Coordinator
- 4.10.10.7. Ensure the basic training, orientation, and continuing education of UPMREB review panel members and staff
- 4.10.10.8. Provide information required by research investigators regarding UPMREB application processes
- 4.10.10.9. Perform other UPMREB-related tasks that may be assigned to him/her by the UPMREB Coordinator and Chair
- 4.10.11. UPMREB Administrative Secretariat Staff
  - 4.10.11.1. Assist the Coordinator in the performance of tasks related to maintenance of UPMREB databases and generation of statistical data
  - 4.10.11.2. Assist the Coordinator in preparing and processing UPMREB administrative documents
  - 4.10.11.3. Assist the Coordinator in tasks related to accounting and release of funds
  - 4.10.11.4. Perform other related functions that maybe assigned by the UPMREB Chair, Coordinator, Assistant Coordinator and respective Panel Chair or Panel Secretary
- 4.10.12. UPMREB Technical Secretariat Staff
  - 4.10.12.1. Manage protocol submissions
  - 4.10.12.2. Organize an effective and efficient tracking procedure for each protocol received
  - 4.10.12.3. Prepare and distribute protocol files for review





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- 4.10.12.4. Maintain the UPMREB Active Files and Archives, **SUBMISSIONS LOG [UPMREB FORM 4(M)2012]**, References and other document files, especially their security and confidentiality
- 4.10.12.5. Organize UPMREB meetings (see **SOP II-5: FULL BOARD MEETING**)
- 4.10.12.6. Prepare and maintain meeting agenda and minutes
- 4.10.12.7. Inform UPMREB review panel members and personnel about training workshops and arrange for the latter's participation in such workshops
- 4.10.12.8. Organize the preparation, review, revision, and distribution of SOPs and guidelines
- 4.10.12.9. Provide the necessary secretariat support for UPMREB-related activities like Site Visits and communicating decisions to the PIs
- 4.10.12.10. Perform other related functions that maybe assigned by the UPMREB Chair, Coordinator, Assistant Coordinator, and respective Panel Chair or Panel Secretary

### **4.11. Appointment of UPMREB/Regular Review Panel/SAE Committee Members/Staff Workflow**

ACTIVITY	RESPONSIBILITY
Nominate UPMREB Panel Chair/Secretary/Member/SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Members ↓	UPMREB Chair
Sign conforme ↓	Panel Chair/Secretary/Member/ SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Members
Appoint Members/Panel Chair/Panel Secretary/	UPM Chancellor

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SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Members ↓	
File appointment documents	Secretariat Staff

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- 4.11.1. The UPM Vice-Chancellor for Research nominates or recommends the appointment of UPMREB Chair/Coordinator through a letter of invitation to the prospective UPMREB Chair/Coordinator, with a description of functions and responsibilities detailed in 4.10 above, using **UPMREB FORM 1(G)2014: UPMREB NON-PANEL BASED PERSONNEL NOMINATION AND APPOINTMENT**.
- 4.11.2. The UPMREB Chair nominates or recommends the appointment of Panel Chairs/Secretaries/Members/ SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Members through a letter of invitation to the prospective Panel Chairs/Secretaries/Members/ SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Members, with a description of functions and responsibilities detailed in 4.10 above, using **UPMREB FORM 1(A)2012: UPMREB PANEL-BASED PERSONNEL NOMINATION AND APPOINTMENT**.
- 4.11.3. The UPMREB Chair nominates or recommends the appointment of Assistant Coordinator/Secretariat Staff through a letter of invitation to the prospective Secretariat Staff with a description of functions and responsibilities detailed in 4.10 above, using **UPMREB FORM 1(G)2014: UPMREB NON-PANEL-BASED PERSONNEL NOMINATION AND APPOINTMENT** or **UPMREB FORM 1(A)2014: UPMREB PANEL-BASED PERSONNEL NOMINATION AND APPOINTMENT**.
- 4.11.4. The person nominated to be a UPMREB Chair/Coordinator/Panel Chair/Secretary/Member/ SAE Committee Chair/ SAE Committee Secretary/ SAE Committee Member/Assistant Coordinator/Secretariat



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Staff must indicate agreement to the nomination by signing a conforme.

4.11.5. The nomination or recommendation by the Chair is reviewed and endorsed by the Vice-Chancellor for Research, and approved by the Chancellor.

4.11.6. Upon appointment, the UPMREB member submits an updated **UPMREB FORM 1(B)2012: CURRICULUM VITAE**.

4.11.7. The Secretariat Staff stores the appointment documents in the UPMREB Membership Files.

### 5. Confidentiality and Conflict of Interest Agreement Workflow

ACTIVITY	RESPONSIBILITY
Prepare <b>UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE</b> ↓	Secretariat Staff
Accomplish <b>UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE</b> ↓	Chair, Coordinator, Panel Chairs, Panel Secretaries, Panel Members, SAE Committee Chair, SAE Committee Secretary, SAE Committee Members, Assistant Coordinator, Secretariat Staff
Store documents	Secretariat Staff

### DETAILED INSTRUCTIONS

#### 5.1. Preparation of Confidentiality Agreement (CA) and Conflict of Interest (COI) disclosure forms of the UPMREB for Regular Review Panel Members

5.1.1. The UPMREB Secretariat provides a copy of **UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** to new members of the UPMREB panel as soon as they

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are appointed; these are submitted to UPMREB upon renewal of appointment as Panel Members, or earlier, upon change of COI status.

## 5.2. Accomplishment of forms

- 5.2.1. A copy of **UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** must be filled out and signed by all UPMREB personnel. A COI does not necessarily disqualify a person from becoming a member of the UPMREB for as long as he/she declares it beforehand, understands his/her responsibility as a UPMREB review panel member (that is, to provide an unbiased review of a protocol for the protection of research participants), and declines from participating in protocol deliberations when his/her COI could affect the result of panel decisions.
- 5.2.2. The UPMREB personnel reads, signs the forms, and dates his/her signature on the forms then submits them to the UPMREB Secretariat Staff.
- 5.2.3. The UPMREB Secretariat Staff accepts the signed/unsigned form, makes duplicate copies of each, and files the originals together with the letter from the Chancellor about the member's appointment, his/her CV and terms of reference, in the UPMREB Membership Files.
- 5.2.4. The Secretariat Staff gives a copy of each signed and dated form to the UPMREB Panel Member who must keep them in his/her own personal files.

## 5.3. Storage of signed form in the UPMREB Membership File.

- 5.3.1. The Secretariat Staff keeps one (1) copy of the signed and dated **UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE** in the UPMREB Membership File.
- 5.3.2. This form is required to be updated when appointment is renewed.

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## 6. Training of Regular UPMREB Review Panel Members and Personnel Workflow

ACTIVITY	RESPONSIBILITY
Set training requirements ↓	Coordinator
Find available training seminars, lectures, workshops ↓	Members/Secretariat Staff/Coordinator
Signify intention to attend training or the UPMREB Chair instructs member/s to attend ↓	Members/Secretariat Staff
Attend training and keep the training record ↓	Members/Secretariat Staff/Coordinator
Store and update training record in UPMREB Membership Files under "Training of UPMREB review panel members"	Secretariat Staff

### DETAILED INSTRUCTIONS

#### 6.1. Identification of required trainings, seminars, and workshops

- 6.1.1. The Coordinator periodically reviews compliance with training requirements for UPMREB Panel Chairs, Panel Secretaries, Panel Members, and Secretariat Staff.
- 6.1.2. The following are required courses:
  - Basic Research Ethics & Good Clinical Practice
  - UPMREB Standard Operating Procedures
  - Continuing Ethics Education
  - Other educational activities on international trends including international specialists' meetings organized for the exchange of experiences and information

#### 6.2. Search for available training activities

- 6.2.1. The Panel Member/Secretariat Staff/Coordinator gets information about training courses, workshops, conferences, etc. which are

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periodically announced on websites, bulletin boards, and various media channels and selects the ones most appropriate.

6.2.2. The UPMREB Coordinator periodically reviews member training records and recommends the attendance to specific training activities or organizes training workshops.

6.2.3. In-house training provided by UPMREB will be regularly included in the meeting agenda of the different panels and similarly documented in the **UPMREB FORM 1(D)2012: TRAINING RECORD**.

### **6.3. Communication of intention to attend training program**

6.3.1. The UPMREB member requesting for training informs the UPMREB, in writing, of intention to enrol in the course (for possible funding by UPMREB) and requests for funds for training. Request is made through the UPMREB Chair.

6.3.2. The Administrative Staff accomplishes a copy of **UPMREB FORM 1(E)2012: TRAINING REQUEST FORM** with supporting documents, including, but not limited to, *Registration Form* and *Program* at least one (1) month before the training date.

6.3.3. The UPMREB Chair recommends participation of the member/s, the Vice Chancellor for Research endorses the request to the Chancellor for his final action.

### **6.4. Attendance in training**

6.4.1. The Member or Secretariat Staff attends the training and submits proof of attendance to the Coordinator, such as *certificate of participation or completion* and *official receipt* (for paid training courses).

6.4.2. The Coordinator verifies validity of submitted documents.

6.4.3. Attendees are encouraged to echo their experience to the UPMREB.



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## 6.5. Storage & Filing

- 6.5.1. The Secretariat Staff fills out **UPMREB FORM 1(D)2012: TRAINING RECORD** to document the training/workshop/conference activities in chronological order.
- 6.5.2. The Secretariat Staff makes a copy of the form and files the copy in the UPMREB Membership File.
- 6.5.3. The Secretariat Staff updates the training record annually.

## 7. Selection of Independent Consultants Workflow

ACTIVITY	RESPONSIBILITY
Invite Independent Consultants to the UPMREB ↓	UPMREB Chair
Sign conforme and <b>UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE</b> ↓	Independent Consultant
Appoint the roster of Independent Consultants ↓	UPM Chancellor
Store roster of Independent Consultants in the Independent Consultants File	Secretariat Staff

## DETAILED INSTRUCTIONS

### 7.1. Invitation of Independent Consultants

- 7.1.1. The UPMREB Chair determines the external expertise requirements of the different UPMREB panels based on protocols submitted for review during previous years and the available expertise in the current UPMREB composition.
- 7.1.2. The UPMREB Chair sends invitations to various professionals with specific scientific expertise to be part of the UPMREB roster of Independent Consultants representing expertise not present in the current panels.

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7.1.3. Similarly, in the course of protocol review, a UPMREB Panel Member or the UPMREB Panel Chair may determine that a protocol should also be reviewed by an Independent Consultant.

7.1.4. The invitation includes the responsibilities and functions of the Independent Consultant as follows:

7.1.4.1. Accomplish the following forms when requested:

- **UPMREB FORM 1(B)2012: CURRICULUM VITAE**
- **UPMREB FORM 1(F)2012: SERVICE AGREEMENT FOR INDEPENDENT CONSULTANTS**
- **UPMREB FORM 1(C)2012: CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE**

7.1.4.2. Review assigned protocols that concern his/her specialty using the **UPMREB FORM 2(C)2012: STUDY PROTOCOL ASSESSMENT FORM** and **UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM**.

7.1.4.3. Attend the UPMREB panel meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the UPMREB Secretariat Staff if unable to attend the meeting.

7.1.4.4. Return all protocol-related materials to the UPMREB Secretariat Staff after review.

7.1.4.5. Submit an updated and signed CV annually.

## **7.2. Confirmation of invitation**

7.2.1. The Independent Consultant signifies agreement to the invitation by signing the conforme attached to the letter of invitation.

7.2.2. The signed conforme is submitted to the UPMREB Secretariat Staff.



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### 7.3. Appointment of Independent Consultants

- 7.3.1. The UPMREB Chair recommends a roster of Independent Consultants who have been invited and confirmed invitation to the UPM Chancellor.
- 7.3.2. The UPM Chancellor appoints the roster through the Office of the UPM Vice-Chancellor for Research.
- 7.3.3. The appointment is for two (2) years.
- 7.3.4. Appointment may be terminated by either resignation of the consultant, or by the UPM Chancellor.

### 7.4. Storage of roster of Independent Consultants

- 7.4.1. The UPMREB Secretariat Staff files the appointment-related documents in the Independent Consultants File.
- 7.4.2. The Independent Consultants File contains the originally signed conforme representing the terms of reference of appointment and CV.

## 8. Compensating Members and Consultants Workflow

ACTIVITIES	RESPONSIBILITY
Recommend honorarium ↓	UPMREB Chair
Approve honorarium ↓	UPM Chancellor
Communicate honorarium information to personnel and Independent Consultants	Secretariat Staff

## DETAILED INSTRUCTIONS

### 8.1. Recommendation of honorarium

- 8.1.1. The UPMREB Chair initiates the recommendation of honorarium or increase thereof, either after a dialogue with UPMREB review panel members or with the Chancellor.



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- 8.1.2. The compensation covers a fixed amount for review of protocols and a fixed amount for attending meetings and other UPMREB related-activities.
- 8.1.3. The recommendation will be submitted to the UPM Chancellor through the submission of the UPMREB budget.

### 8.2. Approval of honorarium

- 8.2.1. The Chancellor may approve or disapprove the recommendation.
- 8.2.2. Approval or disapproval will be indicated in the approval of the UPMREB budget or amendment thereof.

### 8.3. Monitoring and Communication of honorarium information

- 8.3.1. The UPMREB Panel Members are informed through written notification of the honorarium package both upon appointment and whenever there are changes subject to the UP Manila governing rules and regulations.
- 8.3.2. The Administrative Staff prepares the voucher for honorarium based on the attendance and number of protocols reviewed for submission to the Accounting Office.
- 8.3.3. The Administrative Staff monitors timely processing of the vouchers from the time it was submitted to the Accounting Office.
- 8.3.4. Any delays in processing the vouchers are reported as soon as possible to the UPMREB Coordinator for appropriate action.
- 8.3.5. The Administrative Staff notifies the panel members of the availability of the honorarium for pick-up at the Cashier's Office.
- 8.3.6. UPMREB personnel and Independent Consultants acknowledge the information upon receipt of notification.