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II. STUDY PROTOCOL REVIEW

1. Objectives

This SOP describes how the UPMREB Secretariat manages study protocol submission packages from initial submission and/or resubmission to panel action, including review classifications and panel review assignments. This SOP further aims to provide guidance to how the reviewers evaluate a study protocol submitted to the UPMREB either for the first time (initial submission) or with modifications per UPMREB Panel recommendations (resubmissions).

2. Scope

The UPMREB reviews research conducted by members of the faculty, students, hospital staff, residents, fellows and other trainees and employees of the University of the Philippines Manila (UPM). The UPMREB can review study protocols for a study site that has no local ethics review committee provided there is authorization from the site (see Section IV of **UPMREB FORM 2B: REGISTRATION AND APPLICATION FORM**).

This SOP applies to actions by regular UMPREB review panels from the time of initial registration and study protocol package submission, to the filing of the original study protocol package in the Active Study File cabinet, and the preparation of copies of the package for distribution to the reviewers and deliberations during board meeting. Actions by special review panels will be defined in a separate guideline as each special review panel is constituted.

Applications for UPMREB review are submitted and processed via iREB. iREB is a web portal for UPMREB which facilitates online protocol submission and processing. Principal investigators register and submit their study protocol package in iREB which will then be accessible to the Secretariat Staff for processing. iREB allows processing functions such as classifying, reviewing, and generating reports. iREB is accessible via a designated url. In case iREB experiences server-related problems, a parallel electronic submission will be observed. Secretariat Staff notifies principal investigators and reviewers for instructions.

3. Responsibilities

It is the responsibility of the Secretariat Staff to screen, manage, and process study protocol iREB registration and package submission. The Secretariat Staff assigns the review panel according to the cut-off date.

II. STUDY PROTOCOL REVIEW

It is the responsibility of the UPMREB Chair/Coordinator to decide whether the study protocol is for full board review, for expedited review, or for exemption. The Panel Chair/Panel Secretary is responsible for assigning primary reviewers. It is the responsibility of the Panel Secretary to ensure that the deliberations and discussions are adequately documented.

It is the responsibility of the assigned reviewers to access iREB submissions assigned to them and check the completeness of the study protocol package, systematically review the study protocol, and write their comments after each item listed in the study protocol assessment forms and informed consent checklist, include consideration of relevant guidelines when doing the review, and present findings in the full board panel meeting (for full review study protocols).

The Principal Investigator (PI) is responsible for registering the study protocol in the Research Grants Administration Office (RGAO), accomplishing the online registration of study protocol in iREB, and submitting a complete set of documents to the UPMREB.

4. Initial Review Workflow

<table>
<tr><th colspan="3">ACTIVITY</th><th>RESPONSIBILITY</th></tr>
<tr><td colspan="3">Screen iREB study protocol submissions and notify PI for screening issues or acknowledgement of submission
↓</td><td>UPMREB Secretariat Staff</td></tr>
<tr><td colspan="3">Receive iREB study protocol submissions
↓</td><td>Secretariat Staff</td></tr>
<tr><td colspan="3">Classify study protocol submissions
↓</td><td>UPMREB Chair/Coordinator</td></tr>
<tr><td colspan="3">Assign primary reviewers
(Refer to the SJREB Sub-workflow for protocols included for SJREB review)
↓</td><td>Panel Chair/Panel Secretary</td></tr>
<tr><td colspan="3">Review the protocol and accomplish UPMREB FORM2(C)2012: STUDY PROTOCOL ASSESSMENT FORM and UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM
↓</td><td>Primary Reviewers</td></tr>
<tr><th>FULL BOARD REVIEW</th><th>EXPEDITED REVIEW</th><th>EXEMPTED</th><th></th></tr>
<tr><td>Assess the completeness, accuracy, and adequacy of review documents and finalize agenda</td><td>Assess the completeness, accuracy, and adequacy of review forms</td><td>Assess the completeness, accuracy, and adequacy of the checklist for exemption</td><td>Protocol Review Management Committee (Full Board)/ Panel Secretary (Expedited)</td></tr>
</table>

II. STUDY PROTOCOL REVIEW

↓	↓	↓	
Include the protocol in the agenda of the next full board meeting ↓			Secretariat Staff
Present review findings during full board meeting ↓			Primary Reviewers
Deliberate on full board action on the protocol ↓			Panel Members
Communicate Panel Action			Secretariat Staff
If approved: Send approval package to RGAO for transmittal to PI and send notification of decision to PI **If major modification**: Send notification with recommendations to PI; process resubmission by full board review **If minor modification**, send notification with recommendations to PI; process resubmission by expedited review at the level of the Panel Chair **If disapproved:** Send notification of decision to PI with justification	**If approved:** Send approval package to RGAO for transmittal to PI and send notification to PI **If major modification**: Send notification with recommendations to PI then process resubmission by expedited review **If minor modification**, send notification with recommendations to PI; process resubmission by expedited review at the level of the Panel Chair **If disapproved**: Send to full board review and process accordingly **SJREB protocols are processed through expedited review. Parallel submission will be observed. UPMREB will review site-specific issues while SJREB review is ongoing.**	**If exempted:** Send exemption package to RGAO for transmittal to PI and send notification to PI. **If reclassified:** process according to new review classification	

DETAILED INSTRUCTIONS

4.1. Screening of study protocol submissions

4.1.1. The principal investigator registers the study protocol submission in IREB after issuance of RGAO Reference Number. Refer to the section on Frequently Asked Questions in the UPMREB website for registration to RGAO and iREB at reb.upm.edu.ph.

4.1.2. The Principal Investigator uploads all necessary documents applicable for review, as enumerated in the **UPMREB FORM 2(A)2012: REVIEW CHECKLIST**:

Basic Documents (must submit for initial review)

- □ Review Checklist **[UPMREB FORM 2(A)2012]**
- □ Registration and Application Form **[UPMREB FORM 2(B)2012]**
- □ Study Protocol Assessment Form **[UPMREB FORM 2(C)2012]**
- □ Research Grants Administration Office (RGAO) Endorsement (refer to UPMREB General Policies and Guidelines for description of RGAO)
- □ Study protocol
- □ Data collection forms (including CRFs)
- □ Diagrammatic workflow
- □ CV of PI and study team members
- □ Electronic copy of study protocol, **UPMREB FORM 2(A)2012, UPMREB FORM 2(B)2012, UPMREB FORM 2(C)2012,** and **UPMREB FORM 2(D)2012**
- □ Proof of payment of ethics review fee (as applicable)

Study-specific Documents (submit as needed)

- □ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
- □ Informed Consent Assessment Form (for studies with human participants) **[UPMREB FORM 2(D)2012]**
- □ Informed consent form in English (for studies with human participants)
- □ Informed consent form in local language (for studies with human participants)

- □ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- □ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- □ Training Certificate on Health Research Ethics of PI, Co-I and the rest of the study team or Certificate of Good Clinical Practice (GCP) for clinical trials obtained within the last three (3) years
- □ Recruitment advertisements (as needed by the study protocol)
- □ Other information or documents for participants (such as diaries, etc.)
- □ Material Transfer Agreement (for any research involving transfer of biological specimens)
- □ Memorandum of Agreement or Terms of Reference (for collaborative studies)
- □ RGAO-endorsed Clinical Trial Agreement (for sponsor-initiated clinical trials done in UP-PGH; processed separately by the UPM Legal Office and to be submitted to RGAO upon receipt of notification of ethical approval from UPMREB)
- □ Site Resources Checklist for Clinical Trial Outside UP-PGH By UPM Personnel **[UPMREB FORM 2(E)2012]**
- □ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- □ National Commission for Indigenous People Clearance (for studies with indigenous populations; can be processed while UPMREB review is ongoing)
- □ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

4.1.3. The Secretariat Staff ensures completeness of submitted forms and documents in iREB using the above checklist.

4.1.4. The Secretariat Staff accepts complete protocol submissions only and returns incomplete or incorrect submissions.

4.1.5. The Secretariat Staff notifies the principal investigator through iREB or e-mail regarding results of screening process:

- Incomplete protocol submissions are returned to principal investigators, indicating the reasons, along with study protocol-specific instructions on how these will be addressed (i.e. uploading applicable documents, revising specific sections into a correct version, etc.). iREB notifies the Principal Investigators automatically for returned protocol submissions.

- The Secretariat Staff checks the previous studies of the principal investigator and reminds them to submit the final report for these studies, as applicable.

- Principal investigators with complete protocol package receive system-generated Acknowledgement Letter

4.1.6. The Principal Investigators are given **seven (7) calendar days** to comply with screening requirements, after which, the submission will be deleted in the iREB Secretariat Worklist to maintain only active applications.

4.1.7. iREB serves as the primary system for processing study protocol applications. In case of server-related problems, applications for initial review will be submitted to UPMREB e-mail and principal investigators will be notified of screening results through e-mail.

4.1.8. Study protocols qualified for SJREB review are given instructions to submit to SJREB and endorsed to the SJREB Secretariat through e-mail. A parallel submission with UPMREB and SJREB will be observed for UPMREB to facilitate processing of protocol submission (**See SOP II-7: SINGLE JOINT RESEARCH ETHICS BOARD SUB-WORKFLOW FOR INITIAL REVIEW)**.

4.2. Receipt of study protocol submissions

4.2.1. The Secretariat Staff screens the documents uploaded in iREB.

4.2.2. The Secretariat Staff accepts the protocol submission in iREB, assigns a code to the package and indicates the panel to which the protocol is assigned for review. Review panel will be determined by cut-off date and category of principal investigators (See 4.4.1 for category of panel investigators and 4.5.1 for cut-off date).

4.2.3. Upon meeting the screening requirements, the Secretariat Staff forwards the protocol submissions to the iREB account of the UPMREB Coordinator for review classification.

4.2.4. The Secretariat Staff acknowledges receipt of study protocol and communicates to the PI the assigned code, review panel, review classification, and date of full board meeting in which the study protocol will be reviewed (for full board protocols) using **UPMREB FORM 2(K)2012: ACKNOWLEDGEMENT LETTER.**

4.2.5. The Secretariat Staff encodes the received study protocol submissions for initial review in the **UPMREB FORM 4(R)2017: STUDY PROTOCOL DATABASE**. Other submissions are logged into the **UPMREB FORM 4(M)2012: SUBMISSIONS AND ISSUANCE LOG**. Accepted iREB submissions are automatically registered in the iREB database.

4.3. Classification of submission

4.3.1. The UPMREB Coordinator classifies the study protocol review pathway as either **Expedited Review, Full Board Review** or **Exempt from Ethical Review:** Research that qualify for exemption from ethical review will be filtered through the criteria listed in the ***2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017***).

4.3.1.1. Criteria for Expedited Review:

- The research poses low risk.
- The study does not involve vulnerable populations.
- The study does not involve the collection of stigmatizing information.
- The study uses anonymized or archived samples.
- Continuing review of clinical trials that do not involve further recruitment of participants.
- Continuing review of studies previously classified under expedited review.
- Study protocol amendments that are administrative in nature and do not affect the study protocol.

- Study protocol amendments that do not change the overall risk profile of the study.

4.3.1.2. Study protocols that do not meet the criteria for expedited review or exemption are classified under full board review.

4.3.2. Undergraduate researches are classified for expedited review and shall fulfill the following criteria stipulated in the **UPMREB Policies and Guidelines (UPMREB GL 01**):

- Research that is of minimal risk
- Non-therapeutic or non-interventional
- Research that will compromise the security, safety, and well-being of students shall not be allowed.

4.3.3. Undergraduate research classified to be involving more than minimal risk are submitted to UPMREB with the Faculty Adviser as the principal investigator. The Faculty Adviser serves as the supervisor of the research and is responsible for the accountability and ethical conduct of the study.

4.3.4. Researches that do not involve human participants nor identifiable human tissue, biological samples, and human data are technically exempt from review, but will be subject to expedited review at the level of the Panel Chair.

4.3.5. In special cases, protocols may be forwarded by the UPMREB Coordinator to the UPMREB Chair for classification.

4.3.6. The Secretariat Staff forwards the classified protocol submission to the Panel Chair/Secretary for assignment of reviewers.

4.3.7. In case of iREB server-related problems, parallel electronic and manual processing will be observed for sending protocols for classification, assignment of reviewers and review proper. Electronic processing will be coursed through UPMREB e-mail.

4.4. Assignment of Primary Reviewers

4.4.1. Study protocol submissions will be assigned to either one of the review panels. Review Panels 1 and 2 review protocols submitted by UP Manila personnel including faculty, graduate students, and researchers. Review

Panels 3 and 4 review protocols submitted by UP-PGH personnel such as residents, fellows, nurses, and other PGH researchers. Review Panel 5 reviews protocols submitted by undergraduate students. Other review panels may be created as the need arises **(See SOP I-4.4.2).**

4.4.2. The Panel Chair/Secretary assigns one (1) scientific reviewer and one (1) non-scientist as primary reviewers of the study protocol. Reviewers are selected on the basis of their expertise. The scientific/medical reviewer is tasked to review technical soundness and related ethical issues while the non-scientist reviewer is tasked to review the informed consent process and forms. In the case of clinical trials, a non-scientist reviewer can be represented by a member who is not a medical doctor. Study protocols classified as exempt from ethical review will be assigned to the Panel Chair/Secretary to further assess whether the study protocol is qualified for exemption.

4.4.3. Study protocols may be assigned to an independent consultant if there are no available experts among the regular members. In these cases, the Panel Chair serves as the other scientific reviewer.

4.4.4. Upon assignment of reviewers, iREB automatically forwards the submission to the account of the assigned primary reviewer. The Secretariat Staff notifies the primary reviewers for protocol assignments in their iREB accounts using **UPMREB FORM 2(J)2014: NOTICE OF REVIEW**, within three days from receipt of protocol submission.

4.4.5. The Primary reviewer acknowledges receipt of study protocol package for review and agrees to review within the time frame. Otherwise, the protocol will be re-assigned to another primary reviewer if there is no response within three days.

4.4.6. The Secretariat Staff files the study protocol package along with the UPMREB letters in a properly coded Study protocol electronic file folder

4.4.7. Study protocol review is done in iREB. In case iREB experiences server-related concerns, protocol review will be facilitated via e-mail.

4.5. Study Protocol Review

4.5.1. Studies that do not qualify for expedited review and received by the Secretariat Staff **seventeen (17)** calendar days before the full board meeting are included in the agenda.

4.5.2. For known holidays, the deadline of submission for inclusion in the full board meeting will be moved to the working day preceding the holiday, or will be covered by the issuance of a UPMREB memorandum, in cases of extended period of break (e.g. Christmas).

4.5.3. For protocols classified as exempted, the Panel Chair/Secretary accomplishes the **UPMREB FORM 2(L)2019 Checklist for Exemption from Ethical Review** and for protocols classified as expedited or full board, Primary reviewers accomplish **UPMREB FORM 2(C)2012: STUDY PROTOCOL ASSESSMENT FORM** and **UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM** completely and comprehensively, and check for completeness of the documentation and information about the PI/s, study sites, and other documents as required by the study protocol under review such those listed in **SOP II-4.1**: **SCREENING OF STUDY PROTOCOL SUBMISSIONS** applicable to the study.

4.5.4. The UPMREB reviewers are required to review both the protocol and the ICF to ensure that protocol and ICF are consistent with each other, however reviewers are not required to fill out both the UPMREB FORM 2(C)2012: STUDY PROTOCOL ASSESSMENT FORM and UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM.

4.5.4.1. The medical/scientific primary reviewer reviews the study protocol document in accordance with the assessment points and elements detailed in **UPMREB FORM 2(C)2012: STUDY PROTOCOL ASSESSMENT FORM.** He/she is not required to review the informed consent form.

4.5.4.2. The non-scientist primary reviewer reviews the informed consent document in accordance with the assessment points and elements detailed in **UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM.** He/she is not required to review the study protocol document.

4.5.5. In addition to the review elements described above, the primary reviewers should ensure study protocol compliance with existing international and national guidelines and policies including, but not limited to, the ***2017 National Ethical Guidelines for Health and Health-related Research*** and **Data Privacy Act of 2012.**

4.5.6. For research involving children and adolescents, the primary reviewers should ensure study protocol compliance with the ***International Ethical Guidelines for Health and Health-related Research Involving Humans 2016***[1] **Guideline 17** such as in (1) obtaining consent for the continued participation if participants reach the legal age of maturity during the research, (2) special parental authority, (3) deliberate objection of children and adolescents who are too immature to give assent, or (4) observation of the study by a parent or guardian.

4.5.7. The primary reviewers assesses the competence of the principal investigator by taking in consideration the number of other ongoing studies they have.

4.5.8. For full board study protocols, the primary reviewer accomplishes the aforementioned forms, completely signed and dated, using either his/her iREB account, forwards the electronic form through e-mail, or returns the signed paper documents to the Secretariat Staff **within five (5) to seven (7)** calendar days prior to the Panel meeting.

4.5.9. The Secretariat Staff assesses the completeness, accuracy, and adequacy of review documents and prepares the meeting agenda using the **UPMREB FORM 2(G) 2012: MEETING AGENDA:**

4.5.9.1. The Secretariat Staff indicates the date, time, and venue of the meeting, and lists the regular members and alternate members who are invited to attend.

4.5.9.2. The Secretariat Staff encodes all full board study protocols according to order:

- Study Protocol for Initial Review
- Resubmission or Study Protocols for Modification

[1] Also referred to as the Council for International Organizations of Medical Sciences (CIOMS) Guidelines

- Study Protocol for Clarificatory Interview
- Withdrawal of Study Protocol Applications
- Study Protocol Amendment Applications
- Continuing Review Applications
- Final Reports
- Study Protocol Noncompliance (Deviation or Violation) Reports
- Early Study Termination Reports
- Queries, Notifications, and Complaints
- SAE and SUSAR Reports
- Site Visit Reports

4.5.9.3. The Secretariat Staff prepares the following reports in Annex 1 and Annex 2 by encoding all expedited and exempted study protocol submissions with decision letters prior to the Protocol Review Management Committee (PRMC) Meeting:

- **Annex 1 Report of Protocol Submissions Classified as Exempted from Ethical Review**

- **Annex 2 Report of Protocol Submissions for Expedited Review and Full Board Protocols with Modification Expedited at the Level of the Chair**

4.5.10. The Protocol Review Management Committee (PRMC) (Refer to SOP I-4.7.1) will hold a meeting **three (3)** working days prior to the Panel meeting, or as agreed upon by the PRMC members to assess the completeness, accuracy, and adequacy of review documents and finalize the agenda of the full board meeting. As the PRMC members go through each item in the agenda, they will determine whether a particular expert should be invited during the panel meeting.

4.5.11. For expedited review study protocols, the primary reviewer accomplishes the aforementioned forms, completely signed and dated, using their iREB accounts, forwards the electronic form through e-mail, or returns the signed paper-based review to the Secretariat Staff within **seven (7)** calendar days from receipt of package.

4.5.12. The Secretariat Staff reminds the reviewer through email to send the protocol reviews. Reviews not returned within seven (7) calendar days are forwarded to the Panel Chair to decide on the course of action.

4.5.13. The primary reviewers signify their decision by marking the appropriate section of the aforementioned forms and affixing their signature in the space provided. Decision points are: **APPROVE, MAJOR MODIFICATIONS, MINOR MODIFICATIONS, DISAPPROVE OR PENDING.**

4.5.14. The primary reviewers review the study protocol resubmission and assess whether panel recommendations are met using **UPMREB FORM 2(H)2012: REVIEW OF RESUBMITTED PROTOCOL FORM.**

4.5.15. Study protocol resubmissions with major modifications are processed for full board review. Study protocol resubmissions with minor modifications are processed for expedited review at the level of the Panel Chair. The Panel Chair may determine from the resubmitted documents when review is finalized at the level of the primary reviewers.

4.5.16. Expedited study protocol may be referred for full board review:

4.5.16.1. If upon assessment of the primary reviewer he/she found any information in the protocol and/or the ICF that would require full board review; or (upon evaluation of the chair to include in FB)

4.5.16.2. If any of the primary reviewers disapprove the study protocol

4.5.17. The primary reviewers of full board study protocols present their findings in the panel meeting where issues are deliberated. If necessary, the panel may invite the PI for a clarificatory interview before they deliberate on the panel action. Final panel action is after the clarificatory interview. See related procedure in **SOP II-5.4.4.**

4.5.18. For decisions on resubmissions and post approval submissions, the panel may request information or clarificatory interview from the PI, as the need arises.

4.5.19. The PRMC may also organize a consultation meeting with the PI to clarify and explain board recommendations, as the need arises.

4.5.20. In the event that a PI decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the UPMREB. All requests for withdrawal will be discussed during full board meetings regardless of initial review classification. Upon noting the request, study protocol will be archived as stipulated in **SOP IV-8: ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

4.6. Communication of Panel Action

4.6.1. The Secretariat Staff drafts the letter based on the returned electronic review forms for expedited protocols, and approved minutes for full board protocols. Approval of the minutes of the meeting is detailed in **SOP IV-4.0**.

4.6.2. The Secretariat staff notifies PI regarding panel decision through a certificate of approval, or a notice of action indicating panel recommendations. The PI may be requested to provide additional information or submit additional documents.

4.6.3. For expedited review, PI will be notified of the decision through e-mail at least fourteen (14) days from the date received by the UPMREB.

4.6.4. For protocols exempted from ethical review, PI will be notified of the decision through e-mail at least seven (7) days from the date received by the UPMREB

4.6.5. For full board review protocols, PI will be notified of the decision through e-mail within seven (7) days after the meeting and instructed to claim the signed letter at the UPMREB Office, or certificate of approval at RGAO.

4.6.6. Response to the panel recommendations may be facilitated within ninety (90) days upon issuance of the **NOTICE OF PANEL ACTION [UPMREB FORM 4(C)2019]** and is summarized in a cover letter addressed to the Panel Chair. Failure to respond within 90 days from the date of this letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review.

4.6.7. The revisions are integrated into a revised study protocol/package and **REGISTRATION APPLICATION FORM [UPMREB FORM 2(B)2012].**

4.6.8. The Secretariat Staff is responsible for screening the resubmission as detailed in II-4.1.3-4.2.1.

4.7. Inquiry or Appeals of UPMREB Decisions

4.7.1. Investigators can submit an inquiry or appeal of board recommendations within the allowable resubmission period of ninety (90) days.

4.7.2. Processing of inquiries or appeals will follow the regular cut off dates of submissions described above in 4.5.1.

5. Full Board Meeting Workflow

ACTIVITY	RESPONSIBILITY
Set regular meeting schedule ↓	Panel Chair/Panel Secretary/Panel Members/Secretariat Staff
Distribute meeting files ↓	Secretariat Staff
Determine quorum ↓	Secretariat Staff
Call the meeting to order ↓	Panel Chair
Call the meeting to order ↓	Panel Chair
Confirm/Certify quorum ↓	Panel Secretary
Declare conflict of interest ↓	Panel Chair/Panel Secretary/Panel Members
Review initial study protocol submissions and resubmissions ↓	Panel Chair/Panel Secretary/Panel Members
Conduct clarificatory interview ↓	Panel Chair/Panel Secretary/Panel Members
Review post-approval submissions (including SAEs) ↓	Panel Chair/Panel Secretary/Panel Members
Report results of exempted review ↓	Panel Chair/Panel Secretary/Panel Members
Review report of results of expedited review ↓	Panel Chair/Panel Secretary/Panel Members
Adjourn meeting ↓	Panel Chair

Collect, store, and dispose meeting materials	Secretariat Staff

DETAILED INSTRUCTIONS

5.1 Regular meeting schedule

5.1.1 The UPMREB panel must set its regular monthly meeting, e.g., "first Monday" of the month to facilitate preparations and regular attendance of Panel Members.

5.1.2 The Secretariat Staff confirms venue reservation for the scheduled meeting date and time **one (1) week** before the face-to-face meeting. For virtual meetings, the Secretariat Staff will schedule a meeting and obtain the meeting details such as meeting ID, meeting link, and password.

5.1.3 The Secretariat Staff ensures that the venue, equipment, and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment replacement or purchase of necessary supplies.

5.1.4 The Secretariat Staff sends notice of the meeting **one (1) week** before the meeting and sends reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in their formal invitation to attend the meeting.

5.1.5 Members should confirm their attendance within **three (3)** days before the meeting.

5.2 Distribution of members' meeting files

5.2.1 The Secretariat Staff distributes the meeting files which includes the approved **UPMREB FORM 2(G) 2012: MEETING AGENDA,** together with the approved minutes **[UPMREB FORM 4(A) 2012: FORMAT OF THE MINUTES OF THE MEETING]** of the previous meeting agenda, and related study protocols or study protocol synopses to meeting attendees (members, invited PIs, independent consultants, and others) after the PRMC meeting or

at least **three (3) days** before the panel meeting through email and messenger or courier service. For details regarding preparation of the Minutes, refer to **SOP IV-4: MINUTES OF THE MEETING.** For virtual meetings, the Secretariat Staff saves the meeting files in a secured cloud-based folder and sends the access link to members, along with the virtual meeting room access.

5.2.2 The Secretariat Staff distributes the tablets containing meeting files to the members at the start of the face-to-face meeting. The tablets are collected afterwards. For virtual meetings, the members may access the meeting files in a secured cloud-based folder.

5.2.3 The Panel Members must bring all meeting-related materials and files sent to them (**See SOP II-5.2.1)** during the actual meeting to serve as their reference during the review.

5.2.4 The Secretariat informs the principal investigator that their study protocol is included in the agenda and asks them to be on stand-by in case the panel requests for clarifications

5.3. Determination of quorum

5.3.1. The panel secretary determines that there is a quorum. Confirmation of quorum is done at the start of the meeting and reconfirmation is done every time a decision needs to be made. Quorum is defined as the presence of at least 50% + 1 of regular members or the alternate member representing the absence of the regular member (See SOP II-5.3.3.), at least five of whom are described as follows:

- Scientific and/or medical member(s) with expertise on the study protocols being reviewed
- At least one (1) non-scientist
- At least one (1) member independent of the institution (who can be represented by the non-scientist as the case may be)
- Representation of both female and male members
- A member/or invited guest with expertise on the item to be discussed

5.3.2. In studies involving children, a pediatrician or child development expert should be present. The pediatrician is needed for quorum and is able to vote for decisions during the meeting.

5.3.3. In case of anticipated lack of quorum, the UPMREB Coordinator will search for a suitable corresponding alternate from any other UPMREB Panels. They will represent the regular panel members who cannot attend the panel meeting and are able to vote for decisions during the meeting. The alternate members who serve as primary reviewers may only vote on the protocols they reviewed; therefore, the number of votes may be higher than the number of regular members

5.3.4. On the appointed meeting time, the Panel Secretary determines quorum viability and informs the Panel Chair to indicate readiness to call the meeting to order.

5.4. Calling the meeting to order and completion of required procedures prior to review proper

5.4.1. The Panel Chair, or a designated member in the Panel Chair's absence, calls the meeting to order upon confirmation of quorum by the Secretary.

5.4.2. The UPMREB also allows, at the discretion of the Panel Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe UPMREB meetings. Non-members (who are not PIs) attending any UPMREB Panel Meeting are required to sign a **CONFIDENTIALITY AGREEMENT FOR GUESTS/OBSERVERS [UPMREB FORM 2(I) 2012]**.

5.4.3. The Secretariat Staff documents the proceedings of the meeting under the supervision of the Panel Secretary, as soon as the meeting is called to order by the Panel Chair, noting the time. The Secretariat Staff documents the development of the agenda, specifically all board opinions and action with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator. For details regarding preparation of the **Minutes of the Meeting,** refer to **SOP IV-4: MINUTES OF THE MEETING.**

5.4.4. The Panel Chair calls upon the Secretary to formally confirm quorum by citing the attendance requirements.

5.4.5. The Panel Chair calls for declaration of Conflict of Interest (COI) in respect of any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretary. The Panel Chair instructs the members

who declared COI to recuse themselves from the deliberation of the respective study protocol for which the COI declaration was made.

5.4.6. The Panel Chair presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The Panel Chair then declares approval of the Minutes of the previous meeting.

5.4.7. The Panel Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat Staff for inclusion in the Minutes of the current meeting.

5.4.8. The Panel Chair finalizes the agenda of the meeting.

5.4.9. Full board review of study protocol and study protocol-related submissions typically includes review of the following in sequence:

- Study Protocol for Initial Review
- Resubmission or Study Protocols for Modification
- Study Protocol for Clarificatory Interview
- Withdrawal of Study Protocol Applications
- Study Protocol Amendment Applications
- Continuing Review Applications
- Final Reports
- Study Protocol Noncompliance (Deviation or Violation) Reports
- Early Study Termination Reports
- Queries, Notifications, and Complaints
- SAE and SUSAR Reports
- Site Visit Reports

5.4.10. The Panel Chair may allow some modifications of the sequence of review in exigent circumstances. For example, if a clarificatory interview is included in the agenda, the panel may opt to move this up in the review sequence.

5.4.11. The Panel Chair instructs the member who had previously declared conflict of interest (COI) to recuse himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such panel members may be

called in by the panel to answer questions to assist in the board in arriving at a board action, but under no circumstances participate in the decision.

5.4.12. The Panel Chair encourages all members present in the meeting to actively participate in all the discussions. All actions on study protocol submissions being reviewed are decided upon by majority of votes.

5.5. Discussion of initial study protocol submissions and resubmissions

5.5.1. For initial review, the Panel Chair calls the primary reviewers to present findings on respective study protocols based on study protocol assessment points specified in **UPMREB FORM 2(C) 2012: STUDY PROTOCOL ASSESSMENT FORM** and elements detailed in **UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM.**

5.5.2. The scientific and non-scientist primary reviewers reviews both the study protocol and the ICF (see **SOP II-4.5.4.**). During the deliberation, the scientific primary reviewer is instructed to focus presentation of findings on scientific soundness and its impact on human subject protection, while the non-scientist primary reviewer is instructed to focus presentation of findings on the informed consent process and informed consent form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies.

5.5.3. The Panel Members deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.

5.5.4. For review of resubmissions, the Panel Chair calls the primary reviewers to present findings on the response of the PI to the previous recommendations of the panel summarized in **UPMREB FORM 2(H) 2012: REVIEW OF RESUBMITTED STUDY PROTOCOL FORM.**

5.5.5. In case of unavailability of the primary reviewers to attend the meeting, said members are required to forward the completed assessment forms to the Secretariat Staff **seven (7)** days before the meeting. The findings summarized therein will be presented by the Panel Chair or his designee when the study protocol is deliberated on.

5.5.6. For decision on both initial study protocol submission and resubmission, the Panel Chair calls to vote for any of the following actions:

- *Approve*
- *Major Modification, which require full board deliberation*
  - *Criteria for Major Modifications: major issues are found relating to social value, objectives, inclusion and exclusion criteria, recruitment procedure, risk-benefit ratio, in the protocol and the ICF.*

- *Minor Modification, subject to expedited review at the level of the Panel Chair*
  - *Criteria for Minor Modifications: Lack of details or description in study protocol and ICF elements; revisions to improve clarity and/or comprehension; lack of training certificates, TOR, MOA, etc.*
- *Disapprove*
- *Pending, if major clarifications are required before a decision can be made*
  - *Criteria for Pending: Needs to provide vital information, additional document before making a decision*

5.5.7. Primary Reviewers of study protocols for initial review should be present in the board meeting. In case of unavailability of the primary reviewers to attend the meeting, discussion of the study protocol may still proceed at the discretion of the Panel Chair. Said members are required to forward the completed assessment forms to the Secretariat Staff seven (7) days before the meeting. The findings summarized therein will be presented by the Panel Chair or his designee when the study protocol is deliberated on. If the Panel Chair feels that the present Panel composition does not have the expertise to proceed with the review, the discussion of the study protocol may be deferred till the next meeting or a special meeting. Also, the Panel may request comments or clarificatory interview from the PI.

5.5.8. The UPMREB allows investigators and other resource persons (such as an Independent Consultant commissioned by the UPMREB or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the part of the panel meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the board). They will not be counted during determination of quorum and will not be able to vote for full board actions during the panel meeting.

5.5.9. Disapproved protocols may be revised and submitted as a new study protocol application for initial review. Disapproved protocols will be classified as *INACTIVE* and documents will be made available for three years from date of action.

5.6. Conduct of Clarificatory Interview

5.6.1. The Panel conducts, if any, clarificatory interviews with PIs and/or study team members whose submissions raise ethical issues that are better addressed by the PI himself/herself. PIs will be notified to be available for a potential clarificatory interview during the panel meeting where the PI's protocol will be discussed.

5.6.2. The Secretariat Staff sends **UPMREB FORM 4(D) 2012: LETTER FOR CLARIFICATORY INTERVIEW** to PIs called for interview**.** PIs may also request a clarificatory interview with the Panel by formally expressing their intention in writing.

5.6.3. PIs or study team members to be interviewed by the Panel must sign **UPMREB FORM 2(I) 2012: CONFIDENTIALITY AGREEMENT FOR GUESTS/OBSERVERS** prior to the interview. They are allowed inside the meeting room only during the actual interview, after which they will be requested to leave.

5.6.4. Clarificatory interviews may be conducted in person or through tele/video conference.

5.6.5. During the interview, the Panel Chair will specify items that require clarification. Clarification is a mechanism to aid in understanding the protocol and facilitate UPMREB action. The Panel Chair calls to vote for action depending on the type of submission (**See SOP II-5.5 and SOP II-5.7)**.

5.7. Discussion of post-approval submissions

5.7.1. The Panel Chair presents, if any, **STUDY PROTOCOL AMENDMENT SUBMISSION FORMS [UPMREB FORM 3(A) 2012]** that entail major amendments substantially affecting previous risk-benefit assessment on the study protocol. For details on classification of amendments and subsequent processing requirements, refer to **SOP III-4.1: STUDY PROTOCOL AMENDMENT**. The Panel Chair calls on the members to vote for any of the following actions:

- *Approve*
- *Minor modification to the study protocol amendment , subject to expedited review at the level of the Panel Chair*
- *Major modification to the study protocol amendment, subject to full board review*

- *Disapprove*
- *Pending, if major clarifications are required before a decision can be made*

5.7.2. The Panel Chair presents, if any, submissions for Continuing Review of study protocols previously approved through full board and any **CONTINUING REVIEW APPLICATION FORMS [UPMREB FORM 3(B) 2012]** ascertained to have altered previous risk-benefit assessment on the study protocol. For details on how continuing review applications are processed, refer to **SOP III-4.2: CONTINUING REVIEW APPLICATION**. The Panel Chair calls to vote for any of the following actions:

- *Approve*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.7.3. The Panel Chair presents, if any, reports of the SAE Committee. The SAE primary reviewer should attend the panel meeting to present analysis and to recommend action to the panel. For details on how SAE/SUSAR Reports are processed and which SAE reports are subject to discussion in the full board meeting, refer to **SOP III-5: SERIOUS ADVERSE EVENT (SAE) AND SUSPECTED UNEXPECTED SERIOUS ADVERSE EVENT (SUSAR) REPORTS.** The Panel Chair calls on the Panel members to deliberate on the recommendations of the SAE Committee and vote on panel action such as:

- *No further action*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.7.4. The Panel Chair presents, if any, reports on **SITE VISITS [UPMREB FORM 3(F) 2012: CHECKLIST FOR SITE VISIT].** For details on how Site Visits are conducted and reported, refer to **SOP III-6: SITE VISIT**. The Panel Chair calls on the Panel Members to vote for any of the following actions:

- *No further action*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.7.5. The Panel Chair presents, if any, **STUDY PROTOCOL NON-COMPLIANCE (DEVIATION OR VIOLATION) REPORTS [UPMREB FORM 3(D) 2012]** of study protocols previously approved through full board. Noncompliance may be in the form of noncompliance with post-approval requirements. For details on how Study Protocol Noncompliance (Deviation or Violation) Records are processed, refer to **SOP III-4.4: STUDY PROTOCOL NON-COMPLIANCE (DEVIATION ORVIOLATION) REPORT.** The Panel Chair calls on the Panel Members to vote for any of the following actions:

- *No further action*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.7.6. The Panel Chair presents, if any, **EARLY STUDY TERMINATION REPORT FORMS [UPMREB FORM 3(E)2012]** of study protocols previously approved through full board. For details on how Early Study Termination Applications are processed, refer to **SOP III-4.5: EARLY STUDY TERMINATION REPORT.** The Panel Chair calls on the Panel Members to vote for any of the following actions:

- *Approve*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.7.7. The Panel Chair presents, if any, **QUERIES, NOTIFICATIONS AND COMPLAINTS [UPMREB FORM 3(I)2012].** For details on how queries are processed, refer to **SOP III-4.6: QUERIES, NOTIFICATIONS AND COMPLAINTS**. The Panel Chair calls on the Panel Members to vote for any of the following actions:

- *No further action*
- *Request information*
- *Recommend further action*
- *Pending, if major clarifications are required before a decision can be made*

5.8. Report results of request for exemption

5.8.1. The Panel Chair reports results of exemption review. The Panel Chair or his designee reviews and approve study protocols for exemption.

5.8.2. Exemption from ethical review is issued through a **REQUEST FOR CERTIFICATION OF EXEMPTION FROM ETHICAL REVIEW [UPMREB FORM 4(Q)2019]**.

5.8.3. Protocols that do not qualify for exemption based on the assessment of the Panel Chair or Secretary, will follow the workflow according to its new classification, either Expedited or Full Board.

5.8.4. Exempted study protocols can be re-classified as expedited review at the level of the Panel Chair within seven days upon receipt of protocol package.

5.8.5. Modifications made to previously exempted protocols will be subject to re-assessment of the Panel chair or secretary. If the changes made does not affect the previous risk-benefit assessment or qualification for exemption, the panel staff will draft and issue **UPMREB FORM 4(V)2021 Panel Action for Exemption.** On the other hand, modifications that significantly affect previous risk-benefit assessment or qualification for exemption may be submitted as new protocol for initial review.

5.9. Review of results of Expedited Review

5.9.1. The Panel Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review. This report is being presented for the information of the members, and is not meant to generate discussion for board action unless serious issues emerge during this presentation, which is considered an exception.

5.9.2. The submissions are reported in the same sequence as full board review with similar corresponding actions (see **SOP II-5.5** and **SOP II-5.7**).

5.10. Report results of protocol submissions processed by SJREB

5.10.1. The Panel Chair reports all the study protocols and study protocol-related submissions that were processed by SJREB. This report is being presented for the information of the members, and is not meant to generate discussion for

board action unless serious issues emerge during this presentation, which is considered an exception.

5.10.2. The submissions are reported in the same sequence as full board review with similar corresponding actions (see **SOP II-5.5** and **SOP II-5.7**).

5.11. *Adjournment of the meeting*

5.11.1. Before closing the meeting, the Panel Chair calls for any non-study protocol matters that need attention or action, as the need arises.

5.11.2. With no further matters for discussion, the Panel Chair formally adjourns the meeting, with the time noted by the Secretariat Staff who is documenting the meeting.

5.12. Collection and storage or disposal of meeting materials

5.12.1. The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND UPMREB DOCUMENTS**.

5.12.2. The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and **SOP IV-8: ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

6. Special Meetings Workflow

ACTIVITY	RESPONSIBILITY
Prepare for conduct of special meeting ↓	Secretariat Staff
Conduct special meeting ↓	Panel Chair/Panel Secretary/Panel Members
Collect, store, and dispose meeting materials	Secretariat Staff

DETAILED INSTRUCTIONS

6.3. Preparation for Conduct of Special Meeting

6.3.1. A special meeting may be called by the Chair or is proposed by a member of the UPMREB or the Executive Director of the National Institutes of Health.

6.3.2. The decision to call a special meeting is based on the following criteria:

6.3.2.1. Urgent issues (if delay will affect or have impact on the public benefit, national economy, etc.)

6.3.2.2. Occurrence of unexpected serious adverse events

6.3.2.3. A matter of life and death

6.3.2.4. Other similar situations

6.3.3. The Secretariat informs the UPMREB members, including the invited persons, about the special meeting.

6.4. Conduct of Special Meeting

6.4.1. The panel secretary determines that there is a quorum. Confirmation of quorum is done at the start of the meeting and reconfirmation is done every time a decision needs to be made. Quorum is defined as the presence of at least 50% + 1 of regular members or the alternate member representing the absence of the regular member (See SOP II-5.3.3.), at least five of whom are described as follows:

- Scientific and/or medical member(s) with expertise on the study protocols being reviewed
- At least one (1) non-scientist At least one (1) member independent of the institution (who can be represented by the non-scientist as the case may be)
- Representation of both female and male members
- A member/or invited guest with expertise on the item to be discussed

6.4.2. A special meeting may be conducted between the members through tele/video conference.

6.4.3. The meeting is conducted in the same sequence as full board review with similar corresponding actions (see **SOP II-5.5** and **SOP II-5.7**).

6.4.4. Independent Consultants may be invited for a special meeting or during clarificatory interview for purposes of clarifying study protocol-related issues related to their fields of expertise. As in the case of regular meeting, they will not be counted for quorum and are not allowed to vote for full board actions (see **SOP II-5.5.8**)

6.3 Collection and storage or disposal of meeting materials

6.3.1 The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP IV-9: MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND UPMREB DOCUMENTS**.

6.3.2 The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP IV-7: ACTIVE FILES** and **SOP IV-8: ARCHIVED (INACTIVE/ COMPLETED/ TERMINATED) FILES.**

7. Single Joint Research Ethics Board (SJREB) Sub-Workflow for Initial Review

ACTIVITY	RESPONSIBILITY
Receive study protocols qualified for SJREB review ↓	Panel Secretariat Staff
Receive request from SJREB for reviewers ↓	UPMREB Coordinator
Coordinate with SJREB Secretariat Staff regarding reviewers and UPMREB representative ↓	Panel Secretariat Staff
Notify primary reviewer for review and request to attend SJREB meeting ↓	Panel Secretariat Staff
Accept or decline invitation for SJREB review ↓	UPMREB Members or Independent Consultants
Obtain minutes of the meeting and decision letter from SJREB ↓	Panel Secretariat Staff
Conduct of study protocol review ↓	UPMREB Members or Independent Consultants

II. STUDY PROTOCOL REVIEW

Notify Principal Investigator of the decision	Panel Secretariat Staff

DETAILED INSTRUCTIONS

The Single Joint Research Ethics Board (SJREB) conducts the institutional joint ethics review process in the Department of Health (DOH). It is a joint review mechanism among Philippine Health Research Ethics Board (PHREB) duly accredited Research Ethics Committees (RECs) of DOH hospitals and may include other non-DOH RECs from both public and private organizations that will accept the results of SJREB.

7.3. Receive study protocols qualified for SJREB review

7.3.1. Multi-site protocols involving at least three (3) sites in the Philippines with at least one (1) DOH hospital are endorsed for single joint review.

7.3.2. UPMREB receives an invitation from SJREB to participate in the review of a specific protocol and submits the letter of intent signed by the UPMREB Chair to the SJREB Secretariat.

7.3.3. Study protocols qualified for SJREB is processed by UPMREB through expedited review.

7.4. Receive request from SJREB for reviewers

7.4.1. SJREB may request primary reviewers for study protocols included for SJREB review. These requests are coursed through the UPMREB Coordinator.

7.4.2. SJREB may request for primary reviewers that are not yet members of UPMREB. For study protocols for initial UPMREB review, the requested reviewers are invited as independent consultants. Meanwhile, non-members who are requested as additional reviewers to a previously reviewed study protocol by UPMREB are invited as an SJREB Independent Consultant.

7.5. Coordinate with SJREB Secretariat Staff regarding reviewers and UPMREB representative

7.5.1. The Panel Secretariat Staff coordinates with the SJREB Secretariat regarding the request for reviewers and representatives.

7.5.2. Study protocols may be assigned to an independent consultant if there are no available experts among the regular members. In these cases, the Panel Chair serves as the primary scientific reviewer.

7.6. Notify primary reviewer for review and request to attend SJREB meeting

7.6.1. The Chair assigns primary reviewers to the study.

7.6.2. The Panel Secretariat Staff notifies the assigned reviewers and forwards the complete UPMREB and SJREB package.

7.6.3. The Panel Secretariat Staff invites the reviewer to attend the SJREB full board meeting.

7.7. Accept or decline invitation for SJREB review

7.7.1. The primary reviewer accepts or declines request for review through the Panel Secretariat Staff.

7.7.2. In the event that the reviewer agrees to review but cannot attend the meeting, the UPMREB Chair assigns a representative to present the reviewer's assessment during the SJREB meeting.

7.8. Obtain SJREB minutes of the meeting

7.8.1. The Secretariat Staff will obtain the decision letter and minutes of the meeting from SJREB to be filed in the protocol folder.

7.8.2. The Secretariat Staff will send the excerpt of the SJREB minutes of the meeting to the reviewer who failed to attend the discussion of a particular protocol.

7.9. Conducts study protocol review

7.9.1. Upon assignment of reviewers, iREB automatically forwards the submission to the account of the assigned primary reviewer. The Secretariat Staff notifies the primary reviewers for protocol assignments in their iREB accounts using **UPMREB FORM 2(J)2014: NOTICE OF REVIEW**, within three days from receipt of protocol submission.

7.9.2. The Primary reviewer acknowledges receipt of study protocol package for review and agrees to review within the time frame. Otherwise, the protocol will be re-assigned to another primary reviewer if there is no response within three days.

7.9.3. The primary reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements detailed in **UPMREB FORM 2(C)2012: STUDY PROTOCOL ASSESSMENT FORM** and **UPMREB FORM 2(D)2012: INFORMED CONSENT ASSESSMENT FORM.**

7.9.4. Primary reviewers will review site-specific issues while SJREB is ongoing. UPMREB accepts the decisions made by SJREB.

7.9.5. The primary reviewer accomplishes the aforementioned forms, completely signed and dated, using their iREB accounts, forwards the electronic form through e-mail, or returns the signed paper-based review to the Secretariat Staff within **seven (7)** calendar days from receipt of package.

7.10. Notify Principal Investigator of the decision regarding protocol submission

7.10.1. Upon SJREB approval of the protocol submission, UPMREB Secretariat Staff receives endorsement of approval from SJREB.

7.10.2. UPMREB Secretariat Staff informs PI to submit the revised documents and address any site-specific concerns raised by UPMREB.

7.10.3. UPMREB issues a **CERTIFICATION OF APPROVAL [UPMREB FORM 4(B)2019]** of the site-specific documents and cites the documents SJREB has approved.

8. Case Report

8.1. Definition

8.1.1. Case reports and case series involve a small number of human participants, but are not considered research subjects, based on the premise that they do not involve research objectives and a corresponding protocol, for UPMREB consideration. There being no research protocol, case reports are outside the scope of review conducted by UPMREB. Human participants in case reports

are entitled to compliance of researchers with universal ethical principles of respect for persons, beneficence, and justice, as well as applicable local regulations, including the Data Privacy Act of 2012 (RA 10173). Thus, it is the responsibility of the case report author/s to ensure satisfactory compliance with the aforementioned principles and all applicable regulations, and to obtain informed consent from the human subjects involved, if personally identifiable information will be used in any way.

8.2. Detailed Instructions

8.2.1. The Secretariat Staff ensures completeness of documents related to the case report received through the UPMREB email address (upmreb@post.upm.edu.ph).

8.2.2. The Secretariat Staff accepts complete case report submissions only and returns incomplete or incorrect submissions.

8.2.3. The Secretariat Staff notifies the case report author through e-mail regarding results of screening process:

8.2.3.1. Incomplete case report submissions are returned to case report author, indicating the reasons, along with instructions on how these will be addressed (i.e. uploading applicable documents, revising specific sections into a correct version, etc.).

8.2.3.2. Case report authors with complete submissions are notified that their submission is acknowledged.

8.3. Receipt of case reports

8.3.1. The Secretariat Staff screens the documents electronically submitted files

8.3.2. The Secretariat Staff accepts the submission but does not assign a code to the package. The Secretariat Staff indicates the panel to which the case report is assigned. Review panel will be determined by cut-off date and category of principal investigators (See 4.4.1 for category of panel investigators and 4.5.1 for cut-off date).

8.4. Communication of Exemption

8.4.1. The Secretariat Staff drafts the letter upon receipt of the case report using the **UPMREB FORM4(U)2021: LETTER OF EXEMPTION FROM ETHICAL REVIEW FOR CASE REPORTS**

8.4.2. The letter of exemption will be sent through the e-mail of the case report author at least fourteen (14) days from the date received by the UPMREB.