2.1 Management of protocol submissions

1. OBJECTIVES

This SOP applies to ensure a standard process of submission of protocols for review, particularly the responsibilities and procedures for initial review and resubmission.

2. SCOPE

This SOP describes how the UPHS- IERB Secretariat manages study protocol submission packages from initial submission and/or resubmission including review classifications. It covers the actions from the time of submission to the filing of the original protocol package in the Active Study File cabinet and the preparation of copies of the package for distribution to the reviewers.

3. FLOW CHART FOR MANAGING INITIAL SUBMISSIONS

Activity	Responsibility
Receive the initial protocol package for review and check the completeness of the *Application Form* **[Form 2.1(A) 2018**], required documents and number of copies thereof ↓	• Secretariat
Assign a code to the protocol and stamp it onto all documents and forms submitted	• Secretariat
Sign **Form 2.1(A) 2018** to document the receipt of protocol package and give one receiving copy of duly signed form to the PI or designated representative submitting the package, and attach another duly signed form to the protocol package.	• Secretariat
Log the received protocol in the *Log of Submissions* **[Form 2.1(B) 2011**	• Secretariat
Classify the protocol review pathway as either Expedited Review or Full Board Review & assign Primary Reviewer	• Secretary-General

Schedule protocol for Full Board or expedited review	• Secretariat
File the protocol package in a properly coded Protocol File folder and place it in the Active Study File cabinet	• Secretariat

4. DETAILED INSTRUCTIONS FOR INITIAL SUBMISSION

4.1. A protocol package for initial review must be received together with duly signed and accomplished forms and Ten (10) sets of study related documents (as applicable) as follows:

Institutional Forms

- Application Form (FORM 2.1(A)2018)
- Certification of Technical Review approval
- Completed Study Protocol Assessment Form (FORM 2.1 (C) 2018)
- Completed Informed Consent Assessment Form (FORM 2.1 (D) 2018)
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Study Related Documents

- Cover Letter
- Full Study Protocol
- Data collection forms (including CRFs)
- Informed consent (for studies with human participants) already containing the institutional boxed clause regarding contraceptive use both in English and Local Language (Pilipino and other appropriate regional dialects) where applicable.
- Assent form in English (for studies involving minors)
- Assent form for minors in local language (for studies involving minors)
- SAE forms (for clinical trials)
- Study budget
- List of study team members with CV and current licenses of PI and study team
- Declaration of Conflict of Interest
- Information to participants (including advertisements)

Other Documents

- Investigator's Brochure (for clinical trials)
- Current GCP Training Certificate of PI, Co-I and Research Assistant (for clinical trials)
- Clinical Trial Agreement (for clinical trials)
- Memorandum of Agreement (for collaborative studies)
- Previous ethical review approvals/clearances or disapprovals (for those with prior ethical clearance in other countries or other sites in the Philippines)
- Material Transfer Agreement (for genetic research)
- Other related documents i.e. indigenous people organization
- Certification of Technical Review approval for students, faculty, medical staff, employees of the institution, residents in training and fellows in training

4.2. The IERB Secretariat ensures completeness of submitted forms and documents using the checklist indicated in the Application Form (FORM 2.1(A) 2018).

4.3. The Secretariat Staff receiving the protocol assigns an Institutional code to the package and stamp it onto to all the forms and documents submitted. The Institutional code will include the year and the order of receipt of application, i.e. UPH-IERB *yyyy* ###. The code will be communicated to the principal investigator in subsequent communications regarding the protocol.

4.4. Sign FORM 2.1(A) 2018 to document the receipt of protocol package and give one copy of duly signed form to the PI or designated representative submitting the package, and attach another duly signed form to the protocol package.

4.5. The Secretariat staff must encode the submitted protocol in the database and log the submission using Log of Submissions [Form 2.1(B) 2014].

4.6. The Secretary-General classifies the protocol review pathway as full board review, expedited review, or exemption. (Chapter 2.2 and 2.3) as provide in National Ethical Guidelines for Health and Health related Research 2017 as follows:

Exempt from Review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by a designated member of the REC. "Exempt from Review" is a decision made by the REC.

4.6.1 *Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.*

4.6.2. *Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the REC for exemption from review:*

4.6.2.1. *Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;*

4.6.2.2. *Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:*

4.6.2.2.1. *There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and*

4.6.2.2.2. *The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.*

4.6.2.3. *Protocols that involve the use of publicly available data or information.*

4.6.3. If for full board review, the Principal Investigator is invited and scheduled to present in the next scheduled meeting. The Secretary General assigns an appropriate primary reviewer.

4.6.4. For expedited review, the Secretary-General assigns one medical reviewer and one non-medical or lay member as reviewers of the protocol. Only those protocols with low risk intervention submitted by resident trainees may be classified for expedited review based on a set criterion (Form 2.1 (C). ***Expedited Review*** *can be done by the REC for proposals that do not need a full review such as the following:*

4.6.4.1. chart review

4.6.4.2. survey of non-sensitive nature

4.6.4.3. use of anonymous or anonymized laboratory/pathology samples or stored tissues or data

4.6.5. Expedited review refers to the number of REC members doing the initial review rather than the length of time it requires. Reviewers are selected on the basis of their expertise or specialization. The scientific reviewers review the technical soundness that is related to ethical issues while the non-scientific reviewer reviews the informed consent process and forms.

4.6.6. Submissions after the approval (e.g., protocol or informed consent amendments, progress or final reports, monitoring reports) shall be subject to either full or expedited review.

4.7. For protocols classified as Exempted from IERB review

4.7.1. The Secretary General sends an Exemption notification letter to the investigator. The letter will include the following information:

4.7.1.1. That the investigator is required when applicable, to provide the IERB written notification of changes or amendments to the protocol including any change in the title during conduct of the study.

4.7.1.2. That the investigator is required to submit, in a timely manner, the final paper to the IERB

4.7.2. The secretariat files the protocol package in a properly coded Protocol File folder and places it in the Active Study File cabinet.

4.8. For protocols classified as Expedited Review

4.8.1.The secretariat forwards one copy of each protocol package to each reviewer

4.8.2. The secretariat files the protocol package in a properly coded Protocol File folder and places it in the Active Study File cabinet.

4.9. For protocols requiring a full board review

4.9.1. The secretariat sends one copy of the protocol package to all UPHS IERB members including the primary reviewer.

4.9.2. The Secretary General will send a letter of invitation to the PI for a scheduled presentation.

4.9.3. The secretariat files the protocol package in a properly coded Protocol File folder and places it in the Active Study File cabinet.

4.9.4. For protocol packages received on or before the 5th of the month, the secretariat includes this protocol in the agenda for the IERB meeting of that month otherwise these protocols will be included in the next scheduled regular meeting.

4.10. Any query, comment, or recommendation resulting from the initial presentation either expedited or full board evaluation of a protocol must be addressed in writing within 10 working days from receipt thereof. Failure to comply may result in the delay of UPHS IERB decision. No response to the queries, comments, or recommendations within one (1) year shall be considered abandonment of application and a re-application will be required with the corresponding fees.

5. FLOWCHART FOR MANAGING SUBMISSIONS OF ANSWERS TO QUERIES AND COMMENTS

Activity	Responsibility
Receive submitted written response to queries or comments and forward to UPHS IERB chairman	• Secretariat
⇩	
Review and decide on approving/disapproving the protocol or for re-deliberation in the next Full board meeting	• Chair or Secretary General
⇩	
Communicate IERB decision on submitted answers to queries and comments to the principal investigator	• Secretariat
⇩	
File the submitted answers to queries/comments and approved protocol	• Secretariat

6. DETAILED INSTRUCTIONS MANAGING SUBMISSIONS OF ANSWERS TO QUERIES/COMMENTS

6.1. Receive submitted written response to queries or comments and forward to UPHS IERB Chairman

6.1.1. There should be a cover letter by the proponent responding to the queries, comments or requested clarifications and summarizing the revisions made in the protocol with corresponding page numbers.
6.1.2. Four (4) copies of the revised versions of the study protocol and related study documents will be attached to such submission.

6.2. For protocols classified as Expedited Review

6.2.1. The secretariat forwards one copy of the answer to queries/comments to the reviewers for decision. An Unfavorable decision elevates the protocol for full board review.
6.2.2. The secretariat files one copy of the answer to queries/comments and the decision in its properly coded Protocol File folder already in the Active Study File cabinet.

6.3. For protocols requiring a full board review

6.3.1. The secretariat includes the answer to queries on the agenda for the next meeting and files one copy in the properly coded Protocol File folder already in the Active Study File cabinet.
6.3.2. All submitted answers to queries or comments received by the Secretariat on or before 10 working days prior to the scheduled IERB meeting will be included in the agenda for the regular monthly meeting.

6.4. Review and decide on approving/disapproving the protocol or for re-deliberation in the next Full board meeting.

6.5. Communicate IERB decision on submitted answers to queries and comments to the principal investigator.

6.6. File the submitted answers to queries/comments and approved protocol.