

REQUIREMENTS

- 1. Application for Initial Review Form 2.1
- 2. Protocol Summary Form 2.2

To download the forms, Go to website:

https://ncmh.gov.ph



Requirements Checklist at Page 2 of FORM 2.1

Submit:

(1) Hard Copy with Red Folder to NCMH-REC office located at Pavilion 1 *and;*

Send SOFT COPY to ncmhrec@gmail.com



REVIEW TIMELINE

The results of the initial review shall be released;

Expedited – within 21 days

Full board – within 42 days

After the submission of all required documents.



REVIEW FEE

Protocols from:

Professional Researchers

Full board - ₱ 10,000 Expedited - ₱ 5,000

Trainees of other Institutions

(Fellows, Residents, and Graduate Students)

Full board - ₱ 5,000

Expedited - ₱ 3,000

(Undergraduate students)

Full board - ₱ 1,000

Expedited - ₱ 800

Protocols from trainees of NCMH

Free of Charge





NCMH-Research Ethics Committee is a Level 2 accredited REC granted by the Philippine Health Research Ethics Board (PHREB).

A Level 2 accredited REC reviews all types of researches except clinical trials required for FDA registration of new drugs.

PI submit the Requirements

NO Complete? YES

INITIAL REVIEW

PROCESS FLOW

Secretariat receive and manage the submission

Chair classify the type of review and assign Primary Reviewers

1

Secretariat send the Protocol Package, Form 2.3 and 2.4 to Primary Reviewers

Primary Reviewers Review the Protocol and return the accomplished Form 2.3 and 2.4 to Secretariat Committee decides on action during the meeting



Primary Reviewers present their assessment during meeting



Secretariat Include the Protocol in the Agenda of the next meeting



Full Board

Expedited



The comments and decision are consolidated by the Secretariat

PI receive
Notification letter
3.10 and process
Resubmission by
expedited Review

IF MINOR MODIFICATION

REC Decision

IF APPROVED ⇒

PI receive Approval Letter 2.7 and Certification of Approval 2.6

IF MAJOR MODIFICATION



PI receive Notification letter 3.10 and process Resubmission by Full Board Review

To view NCMH-REC SOP Go to website: ncmh.gov.ph

POST-APPROVAL

PROCESS FLOW

PI submit the Post Approval Package

Complete?

YES

Secretariat receive and manage the submission

Chair and previous reviewer classify the type of review based on the pre-approval review type

Primary Reviewers Review the Protocol and return the accomplished Post Approval Forms

REMINDER:

FR – Submit not more than 60 days from completion of study protocol

PR & ACR - Submit at least 42 days before the expiration of the ethical clearance.

Committee decides on action during the meeting

Primary Reviewers present their assessment during meeting

Secretariat Include the Protocol in the Agenda of the next meeting

Full Board

Expedited

The comments and decision are consolidated by the Secretariat

PI receive Notification letter 3.10 and repeat process of Post Approval

FOR (PA, PR, ACR, FR)

IF THE PROTOCOL STILL NEEDS TO BE MODIFIED

> **REC Decision**

PI receive Notification letter 3.10

FOR (DV. SAE, RNE & ET)

IF APPROVED



PI receive Approval Letter 2.7

FOR (PA, PR, ACR, FR)

PA PROTOCOL **AMENDMENT**

PR **PROGRESS** REPORT

ACR APPLICATION FOR CONTINUING REVIEW

FINAL REPORT

DV DEVIATION & VIOLATION

SAE **SERIOUS** ADVERSE EVENT REPORTABLE NEGATIVE **EVENTS**

ET **EARLY** TERMINATION

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