SOP 3 MANAGEMENT OF PROTOCOL SUBMISSIONS

3. Management of Protocol Submissions

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3.1 Management of Initial Protocol Submissions

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SOP 3.1 MANAGEMENT OF INITIAL PROTOCOL SUBMISSION

1. Objective of the Activity

To describe the procedure on managing initial protocol submission protocol package, *to ensure that study documents are complete, properly recorded and evaluated to determine the type of review, and appropriate and timely CRERC action. This SOP further aims to provide guidance on how a study protocol submitted to the CRERC is evaluated to determine the type of initial review.*

2. Scope

CRERC aims for efficiency and effectiveness in its operations. *This set of instructions applies to the initial submission of protocol package for ethical review, and starts with the CRERC Administrative Secretary receiving the protocol package, and ends with the filing of the initial protocol package.*

The CRERC accepts the following protocols for review: 1) MDMRCI-ARMCI funded researches, 2) researches to be conducted in MDMRCI-ARMCI**,** 3) researches to be conducted by personnel of MDMRCI and ARMCI, 4) researches referred from the DOST, DOH, RHRDC XI, CHED, NGOs, higher educational institutions, and hospitals without Research Ethics Committee on the condition that the proponent and the host hospital/institution where the study will be conducted accept the review of MDMRCI-ARMCI CRERC, and agree to abide by the rules and regulations that the MDMRCI-ARMCI CRERC follows. The other research sites should also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor the procedures that the Committee may deem necessary. These conditions should be written in a document and signed by the other hospitals/institutions that accept MDMRCI-ARMCI CRERC review.

3. Responsibilities

*The Administrative Secretary **a**) checks if the submission is complete using the submission checklist, CRERC Form No. 3.4 Document Submission Checklist, **b**) assigns the CRERC Protocol Code No., **c**) records the submission in CRERC Form 9.1 Log of Protocol-Related Submissions, and in the CRERC Form 9.5 Protocol Database, **d**) files all the documents in the appropriately labelled protocol file folder, and **e**) informs the CRERC Chair and Member Secretary of the submission.*

The CRERC Chair determines the type of review. This task is performed by the Member-Secretary if the Chair has conflict of interest.

4. Work Flow

No.	Activities	Person/s Responsible
1	Receive the initial protocol package for review and check its completeness using CRERC Form 3.4 Document Submission Checklist	Administrative Secretary
2	Assign a permanent CRERC Protocol No. to the	Administrative

	protocol	Secretary
3	*Record the submission in the Log of Protocol-Related Submissions and in the Protocol Database, and inform the CRERC Chair and Member-Secretary of the submission*	Administrative Secretary
4	Determine the type of review	CRERC Chair or Member-Secretary
5	File the initial protocol package in a properly labelled protocol file folder and place it in the active study file cabinet	Administrative Secretary

5. Detailed Instructions

5.1 Receive the initial protocol package for review and check its completeness using CRERC Form 3.4 Document Submission Checklist.

5.1.1 The Administrative Secretary using the Form 3.4 Document Submission Checklist verifies that all the required documents are in the protocol document package. Ensure that CRERC Form 3.1 Application for Initial Review, CRERC Form 3.2 Protocol Summary Sheet, and CRERC Form 3.3 Protocol Format Checklist are completely filled up, signed and dated by the Researcher/Principal Investigator (PI).

5.1.2 *The Administrative Secretary* should also ensure that investigator-initiated study protocol contains all the items outlined in CRERC Form 3.3 Protocol Format Checklist and includes CRERC Form 3.2 Protocol Summary Sheet.

5.1.3 All MDMRCI-ARMCI funded protocols need technical review. The Technical Review Committee should have addressed the technical issues in the study protocol. For research protocol of resident physicians and fellows on training, endorsement from the department and the Technical Review Committee of the hospital concerned is required.

5.1.4 For doctoral or masteral thesis of employees of MDMRCI and ARMCI or other researchers (not connected with the hospital), check for approval and endorsement from the thesis adviser/panel.

5.1.5 For non-MDMRCI-ARMCI funded and non-pharmaceutical funded/initiated protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.

5.1.6 For clinical intervention studies, when the study site or an additional study site is outside MDMRCI/ARMCI, CRERC Form 3.5 Site Resources Checklist is required as well as the pertinent Memorandum of Agreement or approval letter from the head of the institution/clinic/agency where the study site is located.

5.1.7 If the protocol document package is found to be incomplete, the Administrative Secretary photocopies the CRERC Form 3.4 Document Submission Checklist where the lacking document is highlighted and returns the incomplete protocol package and the photocopy of the accomplished Form 3.4 Document Submission Checklist to the applicant Researcher or his/her representative.

5.1.8 The Administrative Secretary checks the previous studies of the Researcher/PI and reminds him/her to submit long overdue Progress/Annual Report or the Final/Closure Report, if applicable.

The new submission should not be processed until the Researcher/PI complies with his/her reportorial responsibilities.

5.1.9 If submission is found to be in order, the Administrative Secretary stamps "Received" and the date of receipt on the document package.

5.2 Assign a permanent CRERC Protocol No. to the protocol

5.2.1 If all the required documents in the protocol package are verified to be complete, the Administrative Secretary checks if the protocol has version number and date in the footer. If none, the Administrative Secretary writes the version number and date on the protocol, informed consent form/s (ICF) and other protocol-related documents; also stamps the date received, and assigns CRERC Protocol Number as follows and writes this on the protocol and all related documents:
Protocol Number has 8 digits – first four digits stand for the year of receipt of the protocol, YYYY, next two digits for the month of receipt of the protocol, MM (e.g. 11 for November), next two digits for NN for the sequence number (which starts at 01) of the protocol received during the month. For example, if the protocol titled "A Phase 3 Study to Evaluate XYZ Monotherapy Compared to Standard Chemotherapy or ABC Combined with LMN in Front-Line, PD-L1-Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer" is the first study protocol received by CRERC in November 2017, the CRERC Protocol No.is 2017-11-01, and should be used to identify this protocol.

5.2.2 The Administrative Secretary writes the Protocol Number on the space provided in Form 3.1, Form 3.2, Form 3.3. and Form 3.4 and Form 3.5 (if applicable); photocopies Form 3.1 Application of Initial Review Form, and gives this to the Researcher/PI or the person submitting the package with the instruction to use this Protocol Number to identify the protocol in all submissions and in all his/her communications to the CRERC.

5.3 *Record the submission in CRERC Form 9.1 Log of Protocol-Related Submissions and in CRERC Form 9.5 Protocol Database, and inform the CRERC Chair and Member-Secretary of the submission*

5.3.1 The Administrative Secretary records the required details of the new protocol package in CRERC Form 9.1 Log of Protocol-Related Submissions.

5.3.2 The Administrative Secretary creates a new entry in CRERC Form 9.5 Protocol Database for the initial protocol submission using the new protocol number.

5.3.3 The Administrative Secretary informs the CRERC Chair or Member-Secretary of the submission through e-mail.

5.4 Determine the type of review

5.4.1 CRERC Chair (or the Member-Secretary if the Chair has COI) determines the type of review. There are three (3) types of review:
Exempt from review – for negligible risk protocols
Expedited review – for low-risk protocols
Full-Board review – for medium to high-risk protocols.

Determination of the type of review is guided by the following:

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A. EXEMPT

- Provided that the following do not involve more than minimal risks, these protocols may be considered for exemption from review:
  a) Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests
  b) 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: i) 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 ii) 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.
  c) Protocols that involve the use of publicly available data or information.

B. EXPEDITED

These submissions are for expedited review

a) The research poses minimal risk.
b) The study does not involve vulnerable participants.
c) The study does not involve the collection of stigmatizing information
d) The study uses anonymized or archived bio-samples
e) Resubmitted protocols initially reviewed by Full Committee but with minor revision, or resubmitted protocol initially reviewed by expedited procedure
f) Study protocol amendments that are administrative in nature and do not affect the study protocol
g) Study protocol amendments that are minor and do not change the overall risk profile of the study
h) Continuing review of clinical trials that do not involve further recruitment of participants
i) Continuing review of studies previously classified under Expedited Review
j) Final Report of studies previously classified under Expedited Review

C. FULL COMMITTEE

- a) Clinical trials about investigational new drugs, biologics, or medical device in various phases (Phase 1, 2, 3)
  Phase 4
  b) Phase 4 intervention research involving drugs, biologics, or medical device
  c) Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g., related to sexual preferences, violence against women or children, induced abortion), or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm
  d) Intervention protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, persons deprived of liberty, minors, and those incapable of giving consent) that require additional protection from the CRERC during review

e) Protocols that involve collection of identifiable biological specimens especially from vulnerable groups.

5.5 File the initial protocol package in a properly labelled protocol file folder and place it in the active study file cabinet. (Refer to SOP 9.1Management of Active Study Protocol Files)

6. Related Forms

CRERC Form 3.1 Application for Initial Review
CRERC Form 3.2 Protocol Summary Sheet
CRERC Form 3.3 Protocol Format Checklist
CRERC Form 3.4 Document Submission Checklist
CRERC Form 3.5 Study Site Resources Checklist
CRERC Form 9.1 Log of Protocol Related Submissions
CRERC Form 9.2 Log of Outgoing Protocol Related Communications
CRERC Form 9.5 Protocol Database

7. SOP Document History

Version No.	Version Date	Description of Changes
01	23 Jan 2015	Refer to SOP v 01
02	21 May 2015	Refer to SOP v 02
03	05 Feb 2016	Refer to SOP v 03
04.1	17 May 2019	Refer to SOP v 04.1
05	31 Oct 2021	▪ Changed Purpose to Objective, and Process Flow/Steps to Workflow to harmonize with PHREB's section titles. ▪ Added in the section on Scope, a description of the start and end tasks of the SOP ▪ Added the detailed responsibilities of the Administrative Secretary ▪ Added 5.1.2 – for the Administrative Secretary to give the accomplished Form 3.4 Document Submission Checklist to the PI or PI's representative indicating the lacking document/s ▪ Added 5.1.3 – for the Administrative Secretary to check if Researchers/PI has not submitted long overdue report/s ▪ Incorporating Task # 3 of version 4.0 in Task # 2 ▪ Added as Task #3 – the recording of details of the submission in Form 9.1 Log of Protocol Related Submissions ▪ Remove Task #5 of version 4.0 – assigning and distributing the protocol package to the primary reviewers since this is also in the SOP on Expedited Review and SOP on Full Committee Review ▪ Introduced three new forms – *CRERC Form 3.4 Document Submission Checklist, CRERC Form 3.5 Site Resources Checklist, CRERC Form 9.1 Log of Protocol Related Submissions and CRERC Form 9.5 Protocol Database* ▪ Used Administrative Secretary instead of CRERC Secretariat or Administrative Staff