



MDMRCI and ARMCI Cluster Research Ethics Review Committee



CRERC Form 3.4 DOCUMENT SUBMISSION CHECKLIST

CRERC Protocol No:¹	Click or tap here to enter text.
Study Protocol Title:	Click or tap here to enter text.
Principal Investigator:	<Title, Name, Surname>
Submitted by:	<Signature over Printed Name>
Study Protocol Submission Date Received: <i>(to be accomplished by CRERC Admin Secretary)</i>	<dd/mm/yyyy>
Verified Complete by: <i>(to be accomplished by CRERC Admin Secretary)</i>	<Signature over Printed Name>

Initial Submission (all the following documents must have 2 print copies and one e-copy except proof of payment)

- ☐ CRERC Form 3.1 Application Form for Initial Review
- ☐ CRERC Form 3.2 Protocol Summary (for investigator-initiated protocol)
- ☐ CRERC Form 3.3 Protocol Format Checklist ((for investigator-initiated protocol)
- ☐ CRERC Form 3.4 Document Submission Checklist
- ☐ Study Protocol (with version no. and date; includes budget and Gantt Chart, for investigator-initiated studies)
- ☐ Informed Consent Forms (English, Tagalog, and Cebuano-Davao with version no. and date), if applicable
- ☐ Assent Forms (English, Tagalog, and Cebuano-Davao with version no. and date), if applicable
- ☐ Data collection forms (including CRFs)
- ☐ CV of PI and other members of the Research Team
- ☐ Valid GCP Training Certificate
- ☐ CRERC Form 3.6 Disclosure of No Conflict-of Interest
- ☐ Proof of payment of review fee (if applicable)

Resubmission

- ☐ CRERC Form 3.4 Document Submission Checklist
- ☐ CRERC Form 4.6 Protocol Resubmission
- ☐ Revised Protocol (with updated version no. and date in the footer)
- ☐ Revised Informed Consent Forms (with updated version no. and date in the footer)
- ☐ Revised protocol-related document (with updated version no. and date in the footer)

N. B. All modifications must be highlighted (underlined, boldfaced, italicized or highlighted)

Protocol Amendment

- ☐ CRERC Form 3.4 Document Submission Checklist
- ☐ CRERC Form 7.1 Application for Protocol Amendment

¹ To be issued upon initial processing by CRERC Administrative Secretary



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- ☐ Amended Protocol
- ☐ Amended ICF
- ☐ Amended other protocol-related document; specify: _____

Continuing Review

- ☐ CRERC Form 3.4 Document Submission Checklist
- ☐ CRERC FORM 7.3 Application for Continuing Review
- ☐ ICFs currently in use
- ☐ Valid GCP Training Certificates of members of Research Team

Study-specific Documents (to be included in the initial submission package)

- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, QoL questionnaire, etc.)
- ☐ Material Transfer Agreement or Terms of Reference (for any research involving transfer of biological specimens)
- ☐ Medical Insurance (for clinical trials)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ CRERC FORM 3.6 Site Resources Checklist (if study site is outside MDMRCI)
- ☐ Certificate of Approval of Technical Review Committee (for investigator-initiated studies)
- ☐ Certificate of approval and endorsement from the thesis adviser/panel (for proponents doing their masteral or doctoral thesis)
- ☐ 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 (NCIP) Clearance (for studies involving indigenous populations; can be processed while CRERC review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials; can be processed while CRERC review is ongoing)
- ☐ Request for Waiver of Informed Consent
- ☐ Others (specify): [Click or tap here to enter text.](#)

N.B. All submitted documents must be signed and dated

Classification of Review: (To be accomplished by CRERC)	☐ Expedited ☐ Full Committee ☐ Exempt
Classified by the CRERC Chair	<Signature over Printed Name>