

## 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=""></title,>              |
| Submitted by:  | <signature name="" over="" printed=""></signature> |
| Study Protocol Submission Date Received: (to be accomplished by CRERC Admin Secretary) | <dd mm="" yyyy=""></dd>                            |
| Verified Complete by:<br>(to be accomplished by<br>CRERC Admin Secretary)              | <signature name="" over="" printed=""></signature> |

| 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  |
| <ul> <li>Study Protocol (with version no. and date; includes budget and Gantt Chart, for investigator-initiated studies)</li> </ul>                                 |
| □ Informed Consent Forms (English, Tagalog, and Cebuano-Davao with version no. and date), if applicable   |
| <ul> <li>☐ Assent Forms (English, Tagalog, and Cebuano-Davao with version no. and date), if applicable</li> <li>☐ Data collection forms (including CRFs)</li> </ul> |
| ☐ 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   |
|   |

<sup>&</sup>lt;sup>1</sup> To be issued upon initial processing by CRERC Administrative Secretary



## MDMRCI and ARMCI Cluster Research Ethics Review Committee



| Classified by the<br>CRERC Chair  |  |
|---|--|
| Classification of Review:<br>(To be accomplished by CRERC)  | ☐ Expedited ☐ Full Committee ☐ Exempt  |
| N.B. All submitted documents mu   | st be signed and dated   |
| □ Valid GCP Training Certificate  Study-specific Documents (to be italian processed while processed while processed will a green processed while processed will a green processed while processed will a green processed will a gree | (for collaborative studies) ources Checklist (if study site is outside MDMRCI) chnical Review Committee (for investigator-initiated studies) indorsement from the thesis adviser/panel (for proponents doing esis) ovals/clearances (for students/personnel of foreign universities is or those with prior ethical review) igenous People (NCIP) Clearance (for studies involving be processed while CRERC review is ongoing) ispective regulatory authorities (such as FDA approval for clinical is e CRERC review is ongoing) ined Consent here to enter text. |
| Continuing Review  ☐ CRERC Form 3.4 Document ☐ CRERC FORM 7.3 Applicati ☐ ICFs currently in use   |  |
| <ul><li>☐ Amended Protocol</li><li>☐ Amended ICF</li><li>☐ Amended other protocol-related</li></ul>   | ted document; specify:   |

<Signature over Printed Name>