**Review Checklist**

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| **STUDY PROTOCOL INFORMATION** |
| **MMMC-RERC Code:** |  |
| **Study Protocol Title:** |  |
| **Principal Investigator:** |  |
| **Study Protocol Submission Date:***(to be accomplished by MMMC-RERC Administrative Staff)* |  |
| **Verified Complete by:***(to be accomplished by MMMC-RERC Administrative Staff)* |  |
| **Classification of Review:***(to be accomplished by MMMC-RERC Administrative Staff)* | * **EXPEDITED**
* **FULL BOARD**
* **EXEMPT FROM REVIEW**
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| **Classified by the:*** **MMMC-RERC CHAIR**
* **MMMC-RERC ADMINISTRATIVE STAFF**
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**Basic Documents (must submit)**

* Review Checklist **[MMMC-RERC F-2-A]**
* Printed Registration and Application Form**[MMMC-RERC F-2-B]**
* Study Protocol Assessment Form **[MMMC-RERC F-2-C]**
* Informed Consent Assessment Form (for studies with human participants) **[MMMC-RERC F-2-D]**
* Study Protocol
* Informed consent form in English (for studies with human participants)
* Informed consent form in local language (for studies with human participants)
* Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form )
* Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form )
* Data collection forms (including CRFs)
* Diagrammatic workflow
* CV of PI and study team members
* Proof of payment of ethics review fee (as applicable)

**Study-specific Documents (submit as needed)**

* Investigator’s Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
* Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
* Recruitment advertisements (as needed by the study protocol)
* Other information or documents for participants (such as diaries, etc.)
* Material Transfer Agreement (for any research involving transfer of biological specimens)
* Memorandum of Agreement (for collaborative studies)
* Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
* Site Resources Checklist for Clinical Trial Outside MMMC By MMMC Personnel **[MMMC-RERC F-2-F]**
* Site Resources Checklist for Clinical Trial Outside MMMC By non-MMMC Personnel **[MMMC-RERC F-2-G]**
* 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 with indigenous populations; can be processed while MMMC-RERC review is ongoing)