**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** |
| **Classified by the:**[ ]  **MMMC-RERC CHAIR** [ ]  **MMMC-RERC MEMBER-SECRETARY** |  |

**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)