**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)