# Registration and Application Form

**For Initial Review and Resubmission**

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| **SECTION I: APPLICATION INFORMATION** |
| 1. **MMMC-RERC CODE:**
 |  |
| 1. **Type of Submission**
 | [ ]  2.1 Initial Review[ ]  2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions |
| 1. **Date of Submission:**
 |  |
| 1. **Study Category**
 | [ ]  4.1 Research involving human participants[ ]  4.2 Research involving non-human living vertebrates[ ]  4.3 Others (indicate):  |
| 1. **Type of study:**
 | [ ]  5.1 **Pre-clinical Research**[ ]  5.2 **Non-clinical trial**, specifically (choose one):[ ]  5.2.1 Diagnostics[ ]  5.2.2 In vitro study[ ]  5.2.3 Stem Cell Research[ ]  5.2.4 Herbal Research[ ]  5.2.5 Complementary and Alternative Medicine Research[ ]  5.2.6 Review of medical records[ ]  5.2.7 Epidemiological study[ ]  5.2.8 Socio-behavioral Research[ ]  5.2.9 Health informatics[ ]  5.2.10 Operations/process research[ ]  5.3 **Clinical Trial Type 1**(*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* intended for marketing registration[ ]  5.4 **Clinical Trial Type 2** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* **NOT** intended for marketing registration[ ]  5.5 **Post Marketing Surveillance**[ ]  5.6 **Sponsored-initiated**[ ]  5.7 Others, please indicate:  |
| 1. **Category of Investigator**
 | [ ]  6.1 MMMC Research Center initiated study[ ]  6.2 MMMC- Affiliated[ ]  6.2.1 Active and; Associate-Active, Visiting Consultants[ ]  6.2.2 Residents-in-training[ ]  6.2.3 Fellows-in-training[ ]  6.2.4 Residents/Fellows graduated completing research requirements[ ]  6.2.5 Nursing[ ]  6.2.6 Other Researchers[ ]  6.3 Others, please specify:  |
| 1. **Purpose of study**
 | [ ]  7.1 Academic requirement (Thesis, Dissertation, Training Requirement) [ ]  7.2 Independent research work[ ]  7.3 Multi-institutional or multi-country collaboration[ ]  7.4 Others (indicate): |
| 1. **Study Title**
 |  |
| 1. **Study Protocol Synopsis**
 | *Please write a synopsis* ***(maximum 500 words)*** *of the study in the space provided below based on the specified components, and indicate page where such components may be found in the full study protocol or in annexes/appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol*1. **Technical Synopsis**
	1. Objectives/Expected output
	2. Literature review rationalizing the design
	3. Research design
	4. Sampling design, sample size
	5. Inclusion criteria, exclusion criteria, withdrawal criteria
	6. Data collection plan
	7. Specimen collection and processing plan (including plans for specimen storage and duration of storage)
	8. Data analysis plan (including statistical basis for design, as applicable)
	9. Rationalization for choice of study site (including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable) (Cross reference information with statements provided in the informed consent)
 |
|  | 1. **Ethical Considerations Section**

*This should be stated in the study protocol, as applicable.** 1. Protection of privacy and confidentiality of research information including data protection plan
	2. Vulnerability of research participants
	3. Risks of the study (including social risks)
	4. Benefits of the study
	5. Patient-related compensations/reimbursements/entitlements
	6. Informed consent process and recruitment procedures
 |
|  | * 1. Terms of reference of collaborative study (as applicable, such as intellectual property agreements and similar concerns)
	2. Terms of available study-related insurance
 |
| 1. **Study Duration**
 | (in months) |
| 1. **Use of special populations or vulnerable groups**
 | [ ]  11.1 Children (under 18)[ ]  11.2 Indigenous People[ ]  11.3 Elderly[ ]  11.4 People on welfare/social assistance[ ]  11.5 Poor and unemployed[ ]  11.6 Patients in emergency care[ ]  11.7 Homeless persons[ ]  11.8 Refugees or displaced persons[ ]  11.9 Patients with incurable diseases[ ]  11.10 Others (indicate):[ ]  11.11 Not applicable |
| 1. **Study site**
 |  |
| 1. **Funding agency:**
 | **13.1 (NAME):** |
| **TYPE OF FUNDING AGENCY** |
| 1. **Study Budget**
 | NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet |
| 1. **Previous ethics approval or clearance issued by other sites**
 | [ ]  15.1 Name of Institutional Review Board or Ethics Review Committee:[ ]  15.2 Date of ethics approval:[ ]  15.3 Date of expiration of ethics approval:[ ]  15.4 Not applicable |
| 1. **Principal Investigator**
 | <Title, Name, Surname> |
| 1. **Birthday**
 | <dd/mm/yyyy> |
| 1. **PI Address**
 | <Institutional Address> |
| 1. **PI Telephone:**
 |  |
| 1. **PI Facsimile:**
 |  |
| 1. **PI Mobile:**
 |  |
| 1. **PI Email:**
 |  |
| 1. **Other Ongoing studies**
 | [ ]  23.1 Title:[ ]  23.1.1 MMMC-RERC Code (if applicable): | [ ]  23.3 Title:[ ]  23.3.1 MMMC-RERC Code (if applicable): |
| [ ]  23.2 Title:[ ]  23.2.1 MMMC-RERC Code (if applicable): | [ ]  23.4 Title:[ ]  23.4.1 MMMC-RERC Code (if applicable): |
| 1. **Declaration of Conflict of Interest of PI**
 | [ ]  24.1 I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site |
| [ ]  24.2 I have personal/family financial interest in the results of the study |
|  | NATURE: |  |
| [ ]  24.3 I Have proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing) |
|  | NATURE: |  |
| [ ]  24.4 I have significant financial Interests as defined in US 45 CFR Part 94 (Note: This category is only for applications for which this regulation may apply. For information, refer to http://www.ecfr.gov) |
|  | NATURE |  |
| 1. **Other investigators with corresponding task description**
 | Co-Investigator:Task description: |
| Co-Investigator:Task description: |
| 1. **Submitted by:**
 | <Title, Name, Surname> |
| Study designation |  |
| 1. **PI signature**
 |  |