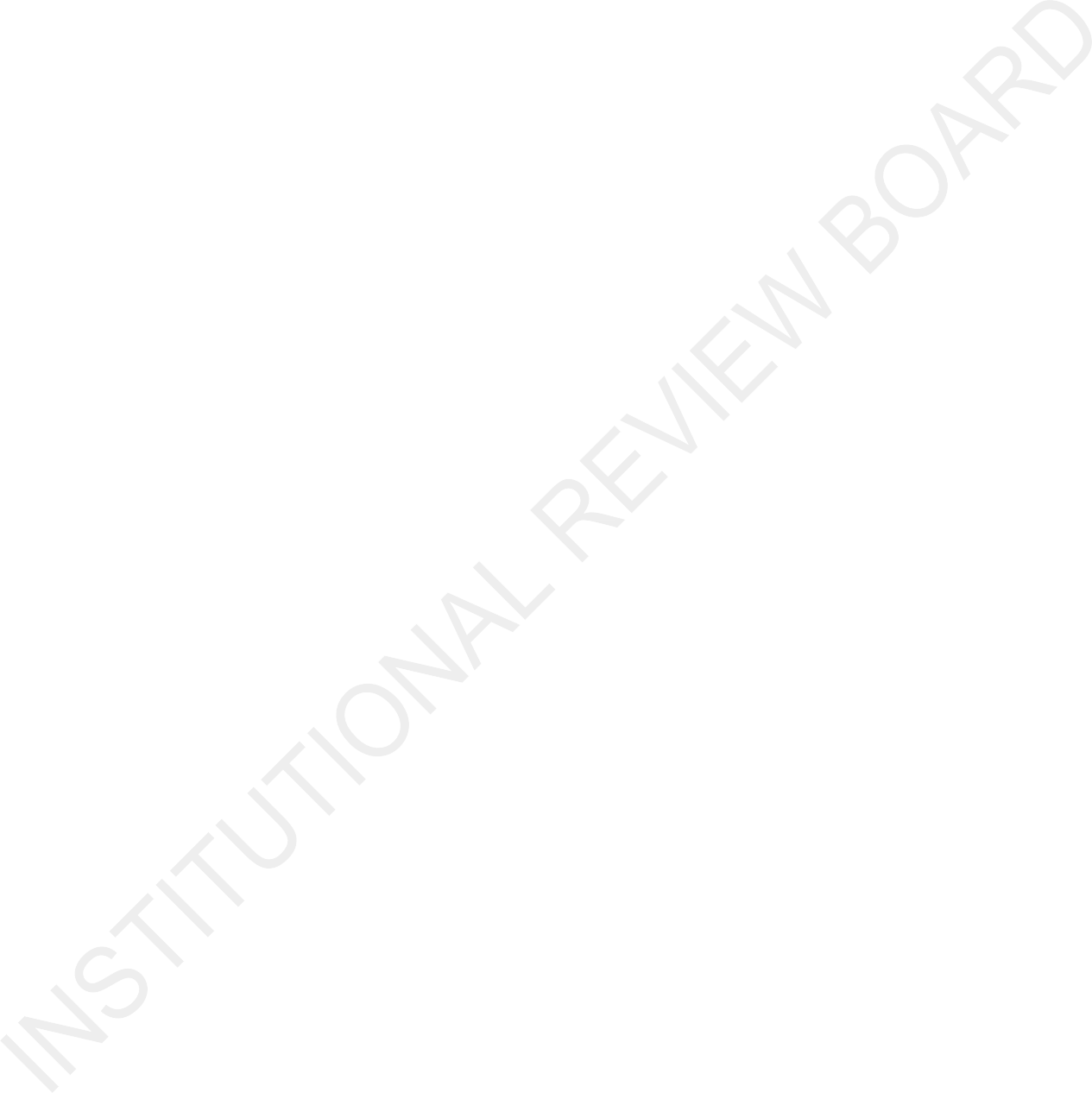
**(Form 2.7A)**

**TO THE PRINCIPAL INVESTIGATOR:** OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. INDICATE WITH A () CHECK MARK THE APPROPRIATE TICK BOX.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Submission**  **(MMM/DD/YYYY)** |  | | **IRB Protocol Number** | | |  | |
|  | | | | | | | |
| **Sponsor** |  | | **Sponsor’s Protocol Number** | | |  | |
|  | | | | | | | |
| **Principal Investigator** |  | | **Co-investigator(s)**  **(if any)** | | |  | |
|  | | | | | | | |
| **Principal Investigator’s Contact Number** |  | | **Principal Signature** | | |  | |
|  | | | | | | | |
| **Department**  **(for Residents/Fellows)** |  | | | | | | |
|  | | | | | | | |
| **Protocol Title** |  | | | | | | |
|  | | | | | | | |
| **Total Number of Participants** |  | **Number of Study Sites** | |  | **Duration of the Study** | |  |
|  | | | | | | | |
| **Type of Research** | Clinical Trial, phase: | |  |  | Epidemiological | |  |
| Basic Science | |  |  | Social Science | |  |
| Prospective | |  |  | Others: | |  |
|  | | | | | | | |
| **Study Design** | Prospective | |  |  | Retrospective | |  |
|  | | | | | | | |
| **Description of the Study in brief** (check () all that applies) | Phase: \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ | | | | | | |
| Randomized | | Drug | |  | Use of Generic Materials | |
| Double Blind | | Medical Device | |  | Multicenter Study | |
| Single Blind | | Vaccine | |  | Global Protocol | |
| Open Label | | Diagnostics | |  | Sponsor Initiated | |
| Observational | | Questionnaire | |  | Investigator Initiated | |

|  |  |
| --- | --- |
| **For external protocols, has a MOA been signed** | Yes  Not Applicable  No |



**between MMC the external organization?**

|  |  |
| --- | --- |
| **Has this study protocol**  **been reviewed by other IRBs?** | Yes *\*If yes, what was the IRB decision? \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_*  No |

**TO THE PRINCIPAL INVESTIGATOR:** FOR THE APPLICATION FOR EXEMPTION FROM REVIEW, INDICATE WITH A () CHECK MARK THE APPROPRIATE TICK BOX APPLICABLE FOR YOUR SUBMISSION.

|  |  |
| --- | --- |
| **Criteria for Exemption** | Does not involve human participants nor identifiable tissue, biological samples and data |
| Study design is meta-analysis and/or systemic with identifiable data |
| Case Reports |
| Study with less than minimal risk or harm |
| Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests |

Submitted by:

**Signature above Printed Name Date (MMM/DD/YYYY)**