**PROTOCOL INFORMATION**

**(Form 2.7A)**

**TO THE PRINCIPAL INVESTIGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT YOUR NAME AND DATE AND SIGN THIS FORM BEFORE SUBMISSION. TICK 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 | | | | |
| Behavioral | | | | | Others: | | | | |
|  | | | | | | | | | | | |
| **Study Design** | | Prospective | | | | | Retrospective | | | | |
|  | | | | | | | | | | | |
| **Description of the Study in brief** (tick the appropriate boxes for all that apply). | | 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 | |

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| --- | --- |
| **For external protocols, has a MOA been signed between MMC the external organization?** | Yes  Not Applicable  No |

|  |  |
| --- | --- |
| **Has this study protocol been reviewed by other IRBs / Single Joint Ethics Review Board (SJREB)?** | Yes *\*If yes, which IRB and what was the IRB decision?*  No |

**TO THE PRINCIPAL INVESTIGATOR:** *FOR THE APPLICATION FOR EXEMPTION FROM REVIEW, TICK THE APPROPRIATE TICK BOX.*

|  |  |
| --- | --- |
| **Criteria for Exemption** | Does not involve human participants nor identifiable tissue, biological samples and data |
| Study design is meta-analysis and/or systemic with non-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)**