**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 NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

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| **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** (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 | |

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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?** | 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.*

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| --- | --- |
| **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)**