**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.*

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |

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