**(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)**