**(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)** | Click here to enter text. | **IRB Protocol Number** | Click here to enter text. |
|  |
| **Sponsor** | Click here to enter text. | **Sponsor’s Protocol Number** | Click here to enter text. |
|  |
| **Principal Investigator** | Click here to enter text. | **Co-investigator(s)****(if any)** | Click here to enter text. |
|  |
| **Principal Investigator’s Contact Number** | Click here to enter text. | **Principal Signature** | Click here to enter text. |
|  |
| **Department****(for Residents/Fellows)** | Click here to enter text. |
|  |
| **Protocol Title** | Click here to enter text. |
|  |
| **Total Number of Participants** | Click here toenter text. | **Number of Study Sites** | Click here toenter text. | **Duration of the Study** | Click here toenter text. |
|  |
| **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: \_ \_ Click here to enter text. \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ |
| 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 ApplicableNo |

**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:

 Click here to enter text. Click here to enter text.

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