**APPLICATION FORM FOR PROTOCOL REVIEW – INITIAL SUBMISSION (Form 2.1A)**

**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.*

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| **Date of Submission (MMM/DD/YYYY)** |  | **IRB Protocol Number** |  |
|  |
| **Sponsor** |  | **Sponsor’s Protocol Number** |  |
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| **Principal Investigator** |  | **Co-investigator(s) (if any)** |  |
|  |
| **Telephone Number/ Messaging App** | **Mobile Number** | **Email Address** |
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|  |
| **Department** **(for Residents/Fellows/Consultants)** | [ ] Resident[ ] Fellow[ ] Consultant[ ] Others (Please specify): |
| **Clinical Departments**[ ] Anesthesiology[ ] Cardiology[ ] Dermatology[ ] Emergency Department[ ] Internal Medicine[ ] Neuro Sciences[ ] Neuro Surgery[ ] Neurology[ ] Obstetrics & Gynecology[ ] Ophthalmology[ ] Orthopaedic[ ] Otorhinolaryngology[ ] Pediatrics[ ] Psychiatry[ ] Pulmonary Medicine[ ] Rheumatology[ ] Surgery Office | **Nursing & Patient Care Services**[ ] Nursing Education, Research & Development[ ] Cancer Center[ ] General Medicine[ ] Oncology**Pharmacy Services**[ ] Clinical Pharmacy**Professional Cluster Services 1**[ ] Anatomic Pathology[ ]  Cellular Therapeutics Center[ ]  Center for Tropical & Travel Medicine[ ]  Nuclear Medicine[ ]  Pathology & Laboratory[ ]  Pulmonary Laboratory**Professional Cluster Services 2**[ ] Center for Osteoporosis & Bone Health**Medical Education & Research Division**[ ] Clinical Research Center[ ] Others (Please specify):  |
|  |
| **Conflict of Interest Declaration** **(Relationship with sponsor)** | Are you a regular employee of the sponsor? | [ ] Yes | [ ] No |
| Did you do consultancy or part time work for the sponsor? | [ ] Yes | [ ] No |
| In the past year, did you receive Php250, 000 or more from the sponsor? | [ ] Yes | [ ] No |
| Other ties with the sponsor  | [ ] Yes  | [ ] No |
| Do you have any involvements in any other similar or competing trials? *(\*For COVID-19 vaccine protocols and other protocol)*  | [ ] Yes  | [ ] No |
| **Conflict of Interest Declaration** *For non-sponsored protocols*  |  | [ ] Yes  | [ ] No |
|  |
| **Principal Investigator’s Signature** |  |
|  |
| **Protocol Title** |  |

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| **Requirement Checklist (Initial Submission)**Legend:\* mandatory \*\* if applicable |
| [ ] Letter of Intent (Indicate the Name of IRB Chair)\* [ ] Endorsement Letter/Technical Approval from the Department (for in-house residents and fellows only)\*[ ] Protocol (Indicate page numbers)\*[ ] Application-Form-Initial-Submission (2.1A)\*[ ] Protocol Summary Sheet (2.5)\*[ ] Protocol Information (2.7A)\*[ ] Protocol Evaluation Form (2.7B)\*[ ] Informed Consent Evaluation Form (Form 2.8)\* |
| **Supporting Documents to be included with initial protocol submission.**Legend:\* mandatory \*\* if applicable |
| [ ] Ethical Considerations and Statement of Agreement \* (must be stated in the protocol)[ ] Memorandum of Agreement (for Non-Makati Medical Center sites only) \** If MOA exists with the Institution, Submit Proof of Signed Memorandum of Agreement with the institution to IRB.
* If MOA is newly submitted, please submit a Memorandum of Agreement to IRB (submit draft via email first)

[ ] Informed Consent Form* English\*\*
* Filipino\*\*
* Local Dialect\*\*

[ ] Assent Forms* English\*\*
* Filipino\*\*

[ ] Request for Waiver of Informed Consent \*\*[ ] Case Report Forms (CRF)/ Data Collection Form \*[ ]  Community consultation with documented permission from relevant Local administrative authorities (barangay captain, mayor, etc) \*\*[ ] List of personnel involved in recruitment, testing, vaccination, follow-up with definition of roles and necessary credentials\*\* | [ ] Recruitment Materials \*\*[ ]  Detailed Recruitment Plan specific to the community they are going to recruit from: \*\** specific barangay/barrio info
* estimated population and how to recruit from this community

[ ] Infrastructure documentations of the ff: \*\** where will the recruitment will be done
* where the Information gathering will be done.
* dedicated area for testing and or vaccination

[ ] Local Government Unit Approval to Conduct study \*\*[ ] FDA Approval / FDA Acknowledgment Receipt \*\*[ ] Research Study Insurance\*\*[ ] Investigator’s Brochure\*\*[ ] Gantt Chart \*\*[ ] Flow Chart \*\*[ ] Study Budget \*\*[ ] Brief PowerPoint Presentation of the study \*[ ] Curriculum Vitae of Principal Investigator and Co-investigator/s\*[ ] GCP Certificate of Principal Investigator and Co-investigator/s \*[ ] Protocol Review Fee Receipt \*\* |

**PROTOCOL REVIEW FEE**

Protocol Review Fee (P67, 200.00) for sponsored study protocols conducted by consultants and investigators not affiliated with Makati Medical Center.

Protocol Review Fee (33,660.00) for Investigators initiated protocols that is not affiliated with Makati Medical Center.

(\*Please make your check payable to Makati Medical Center – This fee is non-refundable and non-transferable once review is initiated.

**CANCELLATION FEE**

A cancellation fee of (Php15,000.00) will be charged to the sponsor or proponent if the protocol is not presented on date of review without any valid reason.

Submitted by:

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

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening.

You may contact the IRB Admin Staff through the following:

1. Telephone: 8888-8999 Loc. 7166, 3973, 3972, and 7178
2. Email: irbmmc.admin@makatimed.net.ph