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**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 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)** |  |
|  |
| **Telephone Number** | **Mobile Number** | **Fax Number** | **Email Address** |
|  |  |  |  |
|  |
| **Preferred Contact** | [ ] Telephone | [ ] Mobile | **Department** **(for Residents/Fellows)** |  |
| [ ] Fax | [ ] Email |
|  |
| **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 only)*  | [ ] Yes  | [ ] No |
| **Conflict of Interest Declaration** *For non-sponsored protocols*  |  |  |  |
|  |
| **Principal Investigator’s Signature** |  |
|  |
| **Protocol Title** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document Title** | **No. of Copies** |  | **Document Title** | **No. of Copies** |
| [ ] Protocol Summary Sheet (2.5)\* | 1 |  | [ ] Recruitment Materials\*\* | 1 |
| [ ] Protocol Evaluation Form (2.7A, 2.7B)\* | 1 | [ ] Gantt Chart\* | 1 |
| [ ] Informed Consent Evaluation Form (Form 2.8)\* | 1 | [ ] Flow Chart\* | 1 |
| [ ] Letter of Intent\*  | 1 | [ ] Study Budget\* | 1 |
| [ ] Endorsement Letter/Technical Approval (for in-house residents and fellows only)\* [ ] Protocol\* | 11 | [ ] FDA Approval\*\*[ ] Investigator’s Brochure\*\* |  11 |
|  |
| [ ] Ethical Considerations and Statement of  Agreement \* | 1 | [ ] Curriculum Vitae of Principal Investigator\* | 1 |
| [ ] **Informed Consent Form**English\*\*  Filipino\*\* Local Dialect\*\* | 111 | [ ] GCP Certificate of Principal Investigator\* | 1 |
| [ ] Curriculum Vitae of Co-investigator/s\* | 1 |
| [ ] **Assent Forms**English\*\*Filipino\*\* | 1 | [ ] GCP Certificate of Co-investigator/s\* | 1 |
| [ ] Case Report Forms (CRF) or Data\*  | 1 | [ ] Protocol Review Fee Receipt  | 1 |
| [ ] Collection Form\* | 1 |  |  |
| **Legend:**\* mandatory \*\* if applicable |

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

After receiving an e-mail notification that your submission is “complete”, submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

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

**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.

**CLINICAL TRIAL AGREEMENT (CTA)**

If applicable, a copy of the CTA may be submitted for parallel review by the Legal Counsel of Makati Medical Center.

Submitted by:

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