Department of Health
**Jose R. Reyes Memorial Medical Center**
Rizal Avenue, Sta. Cruz, Manila
☎732-1071 loc. 296; jrrmmc.irb@gmail.com

# INSTITUTIONAL REVIEW BOARD

## APPLICATION FORM FOR PROTOCOL INITIAL REVIEW

Form 2.1

**IRB Protocol No:**

**Sponsor Protocol Number:**

**Submission Date:**

**Protocol Title:**

**Type of Research:**

- ☐ Clinical Research
- ☐ Clinical Trial
- ☐ Laboratory Research
- ☐ Genetic Research
- ☐ Sociobehavioral
- ☐ Public Health
- ☐ Others

**Study Duration:**

**Principal Investigator:**

**Telephone number:**

**Fax :**

**E-mail:**

**Preferred Contact** ☐ Phone ☐ Fax ☐ Email

**Institution:**

**Sponsor:**

**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 P250,000 or more from the sponsor? | ☐ Yes | ☐ No |

Other ties with the sponsor

_____

_____

**Ethical Responsibility and Conflict of Interest Statement:**
I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

**PI Signature:**

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## DOCUMENT RECEIPT FORM

Form 2.2.

**Basic Documents (must submit):**

- ☐ 1. **Printed Registration and Application Form** (Form 02. Fill-out all items, put N/A if not applicable).
- ☐ 2. **Cover Letter** (request letter for review addressed to the IRB Chair signed by the Principal Investigator and signed by the Department Chairman).
- ☐ 3. **Study Protocol** (attached is the sample content/format).
- ☐ 4. **Curriculum Vitae of PI and study team members** (Updated resume).
- ☐ 5. **Good Clinical Practice (GCP) Training Certificate** of PI, Co-I and the study team.
- ☐ 6. **Research team list**
- ☐ 7. **Study Budget** (include honorarium of the investigators, compensation to subjects, operational expenses & no. of subjects for recruitment).

**Study-specific Documents (submit as needed):**

- ☐ 1. **Data collection forms / Case Report Forms / Questionnaires / Survey Forms** (Any tool (validated) that will be used in the study).
- ☐ 2. **Patient Information Form** (**English and Tagalog**)
- ☐ 3. **Informed Consent Form (ICF) in English and Tagalog** (for studies with human participants). It should conform w/ the guidelines set by the Phil. National Ethical Guidelines on Health Research 2011).
- ☐ 4. **Assent form in English and Tagalog** (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form).
- ☐ 5. **Investigator's Brochure** (for Phase I, II, III) or **Basic Product Information Document** (for clinical trials phase IV); Published literature/medical device information (for Drug Trials only).
- ☐ 6. **Recruitment advertisements and/or other information or documents for participants** (such as diaries, etc. as needed by the study protocol).
- ☐ 7. **Memorandum of Agreement** (for collaborative studies).
- ☐ 8. **List of other sites** (local and international) **& assigned Principal Investigators** (for multicenter global clinical trials (with contact numbers and address).
- ☐ 9. **PFDA Approval Letter** (certification that study has been approved by the Philippine Food & Drug Administration PFDA).
- ☐ 10. **PFDA Certificate of Product Registration** (for use of marketed study drug) or PFDA Import Permit (for use of study drug that is not yet PFDA registered).

**Type of Researcher:** ☐ **JRRMMC Medical Staff**

- ☐ **Clinical Trial – Sponsored**
- ☐ **Outside Research – Student**
- ☐ **JRRMMC Non-medical Employees**

**Received by:** _____
Signature over Printed Name

**Date Received:** _____

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# INSTITUTIONAL REVIEW BOARD

## PROTOCOL SUMMARY SHEET

Form 2.3

| **IRB Protocol No:** | **Title** |
|---|---|
| | |

| **Principal Investigator** | **Sponsor** |
|---|---|
| | N/A |

| | |
|---|---|
| **Rationale** | |
| **Objectives** | |
| **Study Design/ Methodology** | |
| **Inclusion Criteria** | |
| **Exclusion Criteria** | |
| **Data Analysis Plan** | |
| **Ethical Considerations** | |
| **Study Outcomes** | |

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**INSTITUTIONAL REVIEW BOARD**

## PROTOCOL EVALUATION FORM

Form 2.4

| | | | |
|---|---|---|---|
| **IRB Reference No.** | | **Date:** | |
| **Protocol Title:** | | | |
| **Principal Investigator:** | | | |
| **Department** | | **Contact no./ Email** | |
| **Co – investigator(s):** | | **Contact no./ Email** | |
| **Total No. of Participants:** | | **No. of Study Sites:** | |
| **Sponsor** | | **Contact No/ Email** | |
| **Duration of the Study:** | | **Status:** ☐ New ☐ Amended | |

**Type of the Study**

☐ Intervention ☐ Epidemiology ☐ Observational study
☐ Document review ☐ Individual based
☐ Social Survey ☐ Others, specify ☐ Genetic

**Description of the Study in brief**: *(mark whatever applies to the study)*

☐ Randomized ☐ Drug ☐ Use of Genetic Materials
☐ Double blind ☐ Medical Device ☐ Multicenter study
☐ Single blind ☐ Vaccine ☐ Global protocol
☐ Open label ☐ Diagnostics ☐ Sponsor Initiated
☐ Observational ☐ Questionnaire ☐ Investigator Initiated

(to be filled up by the IRB)

| | | | |
|---|---|---|---|
| **Reviewers:** | | | |
| **Review Status** | ☐ Full Board | ☐ Expedited | ☐ Exempted |