Department of Health
Jose R. Reyes Memorial Medical Center
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INSTITUTIONAL REVIEW BOARD

Form 2.2

DOCUMENT RECEIPT FORM

IRB No. _____

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 noted 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. **Electronic copy of study documents**
- ☐ 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 and in 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 Phils. Food & Drug Adm.).
- ☐ 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 Philippines Food & Drug Administration registered).

For IRB use:

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

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

Received by: _____
Signature over Printed Name

Date Received: _____