	Research Institute for Tropical Medicine Institutional Review Board	Form No.	2.1
	REQUEST FOR INITIAL REVIEW OF NEW RESEARCH PROTOCOL	Version No.	4
		Approval Date	31 May 2023
		Effective Date	1 June 2023

INSTRUCTIONS TO INVESTIGATORS: **Please submit the accomplished form together with the protocol and other related documents via email to irb@ritm.gov.ph. Also, please submit 1 hard copy of the documents arranged according to the sequence listed in item 2.17, fastened in an A4 size folder to the IRB Secretariat at Room 205 of the Residence Hall. Kindly FILL OUT THE NECESSARY INFORMATION AT THE FOOTER.**

I. RESEARCH IDENTIFICATION

1.1. **Title of Protocol** _____

1.2. **Name and Signature of Principal Investigator** _____

1.3. **Names of all Co-Investigators** _____

1.4. **Name of Sponsor or Funding Agency** _____

1.5. **Sponsor's Identifier Code (if Applicable)** _____

2 RESEARCH INFORMATION

2.1. **Type of Study:** ☐ Investigator Initiated ☐ Sponsor Initiated

2.2 **Type of Research:** ☐ Interventional ☐ Non-Interventional

CHECK ONLY ONE.

☐ **Clinical Trial**

- ☐ Phase 1 or II
- ☐ Phase III
- ☐ Phase IV (Post marketing)

☐ **Non-Clinical Trial**

- ☐ Biomedical Studies
- ☐ Social Science Research
- ☐ Public Health
- ☐ Health Operations

☐ **Others, specify:**

_____

2.3. **Will a licensed drug, biologic or device be used in this study?**

☐ Yes, a licensed drug, biologic or device will be used.

☐ No, an unlicensed, new investigational new drug/biologic or device will be used

☐ No, no drug, biologic or device will be used

2.4. **To what health/disease category does this research belong (if applicable)?**

☐ ARI ☐ HIV/STD

☐ Dengue ☐ Leprosy

☐ Diarrheal diseases ☐ Malaria

☐ Filariasis ☐ Rabies

☐ Filovirus ☐ Schistosomiasis

☐ Hepatitis ☐ Tuberculosis

☐ Others, please specify:

2.5. **What populations will be involved in this study?**

☐ General population, 18 y/o and above ☐ Infants, children under 5 years old

☐ Children 5- 17 y/o ☐ Elderly 60 years old and above

☐ Pregnant or lactating women, students, prisoners, mentally challenged

☐ Others, specify:

2.6. **How many participants will be enrolled in the study?**

_____

2.7. **What is the duration of the study?**

2.8. **What biological samples will be collected from the study participants for research purposes, if any?**

- ☐ None
- ☐ Blood samples
- ☐ Nasal /throat swabs/ aspirates
- ☐ Others, please specify:
- ☐ Lung aspirates
- ☐ Stool/urine samples
- ☐ Tissues

2.9. **Which of the following data collection methods or procedures will the human participant be subjected to? CHECK AS MANY THAT APPLIES.**

- ☐ Interviews, FGDS
- ☐ Observations
- ☐ Others, specify:
- ☐ Records review and data abstraction
- ☐ Physical assessment and examination

2.10. **Is this a multi-country study?**

- ☐ No, not a multi-country study
- ☐ Yes, multi-country study, with only one RITM Principal Investigator
- ☐ Yes, multi country study, with two or more RITM Principal Investigators

Is this a multi-center study in the Philippines?

- ☐ No, not a multi-center study
- ☐ Yes, multi-center study, with only one RITM Principal Investigator
- ☐ Yes, multi-center study, with two or more RITM Principal Investigators

(PLEASE SUBMIT THE MOTHER PROTOCOL AND THE SITE SPECIFIC PROCEDURES FOR THE RESEARCH SITE(S)

2.11. **What are the study sites?** ***(NOTE:***
If several sites of RITM Investigator/s, mention all these sites.)

2.12. **Has this protocol been reviewed by other ethical review boards prior to its submission to the RITM IRB?**

☐ No ☐ Yes, Name of Ethics Committee: _____

Date of Ethics Approval: Click or tap to enter a date.

Date of Expiry of Approval: Click or tap to enter a date.

2.13. **Will the research use RITM facilities or RITM catchment areas?**

☐ No ☐ Yes

2.14. **Will the research be conducted in collaboration with international or local institutions?**

☐ No ☐ Yes, please specify: _____

2.15. **INVESTIGATOR'S CONFLICT OF INTEREST STATEMENT (All Investigators/Research Staff)**

Is the RITM COI Declaration Form (**RITM-RIO-FM-004**) submitted with this application? ☐ Yes ☐ No

2.16. **How many ongoing researches are you involved in?** _____

ETHICAL RESPONSIBILITY and COI STATEMENT

I hereby pledge to address all forms of Conflict of Interest 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.

Signature of Principal Investigator : _____

2.17. DOCUMENTARY REQUIREMENTS

Check which of the following documentary requirements are submitted together with this application.

2.17.1. Protocol – Related Documents

- ☐ Protocol
- ☐ Investigator's Brochure

2.17.2. Information Sheets for Potential Participants

- ☐ Informed consent, English
- ☐ Informed consent, Tagalog
- ☐ Parental consent, English
- ☐ Parental consent, Tagalog
- ☐ Informed assent, English (for children 12-17 years old)
- ☐ Informed assent, Tagalog (for children 12-17 years old)
- ☐ Verbal Assent Script, English (for children 7-11 years old)
- ☐ Verbal Assent Script, Tagalog (for children 7-11 years old)
- ☐ Other information materials submitted for obtaining consent/parental consent/assent

_____

2.17.3. Recruitment Materials

- ☐ Advertisement, brochure
- ☐ Power-point or other digital platform material for discussion

Other recruitment materials, please specify:

2.17.4. Other materials to be given to participants

- ☐ Diary, English
- ☐ Diary, in Tagalog or in the dialect where it will be used

2.17.5. Data Collection Tools

- ☐ Data Abstraction form
- ☐ Case Report Form
- ☐ Questionnaire (and its translation, as applicable)
- ☐ Focus Group Discussion Question line
- ☐ Others, specify:

2.17.6. ☐ Curriculum vitae (Submit the CVs of **ALL INVESTIGATORS**)

2.17.7. ☐ Conflict of Interest Form (COI) of **ALL INVESTIGATORS/RESEARCH STAFF**

2.17.8. ☐ Site Specific Procedures

2.17.9. ☐ P-FDA Approval to conduct the clinical trial using the product

2.17.10. ☐ GCP Training Certificate of **ALL INVESTIGATORS** (submit the GCP Training Certificate or Ethics Training Certificate with 3 years' validity)

2.17.11. ☐ Materials Transfer Agreement, (if the study will collect human biological samples from participants which will be sent outside RITM.

2.17.12. ☐ Insurance Certificate, required if the study is a clinical trial.

2.17.13. ☐ Biosafety Clearance *(if the research will handle biological materials)*

2.17.14. ☐ National Commission for Indigenous People (NCIP) Clearance, for studies involving indigenous populations, if applicable

2.17.15. Other Documents Submitted

3. IRB Review Fee Information

Payor's Information: _____
(Name that will appear at the Official Receipt for IRB Review Fee)

Will the payment come from the study's fund lodged in RITM? ☐ **YES** ☐ **NO**

Will the payment be directly paid by Principal Investigator/ Sponsor to RITM Cashier? ☐ **YES** ☐ **NO**

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4. Date of Receipt of Application (mm/dd/yyyy) Click or tap to enter a date.

5. Time Received : _____

6. Name and Signature of IRB Staff _____

INSTRUCTIONS TO THE IRB STAFF: Using the Document Receipt Checklist (Form 2.2.), check that all the documents listed above by the investigator are in the documents submitted. Give one copy to the investigator and one copy for the files.