THE MEDICAL CITY
Ortigas Avenue, Pasig City, Philippines

INSTITUTIONAL REVIEW BOARD

REQUIREMENT FOR INITIAL PROTOCOL REVIEW

INITIAL PROTOCOL SUBMISSIONS OF RESIDENTS, FELLOWS AND HOSPITAL STAFF:
Submit via email (irb@themedicalcity.com). The initial study dossier must include the following:

1. Letter of Intent to conduct the study addressed to the Clinical and Translational Research Institute Director, Raul V. Destura, MD, and Institutional Review Board Chair, Carlo Emmanuel J. Sumpaico, M.D.
2. The Principal Investigator, Research Adviser, and Research Coordinator of the department should electronically sign the letter. Incomplete signatures are NOT ACCEPTABLE.
3. Digitally accomplished IRB Forms (TMC-IRB Form 006-2, and 007-1A) as part of the protocol submission. The Principal Investigator must sign and date the said forms. You may get these forms from the IRB Secretariat, and online website of Clinical Trial and Research Institute (CTRI).
4. The study protocol must be formatted using the CTRI Research Protocol Template. Incomplete and unformatted protocols WILL NOT BE ACCEPTED FOR IRB REVIEW.
5. The study protocol MUST have the following sections:
    a. Introduction
    b. Research Question, Objectives, and Hypotheses (as necessary)
    c. Study Significance and Research Utilization
    d. Methodology (including Study Design and Data Collection Plan)
    e. Data Analysis Plan
    f. Administrative, Ethical and Regulatory Considerations
    g. Data Collection Form/s or Questionnaire
    h. Diagrammatic Workflow
    i. Dummy Table/s
    j. Gantt Chart
6. Accomplished line item budget formatted using the CTRI Line Item Budget Template.
7. Accomplished Statistician Consultation Form is REQUIRED to be submitted. The CTRI has an in-house statistician where you can set a consultation appointment. However, if external statistician was consulted, the CTRI Statistician Form should still be accomplished by the assigned statistician. You may get the said form from CTRI.
8. Updated and signed Curriculum Vitae of the study team (i.e. Principal Investigators and Co-investigator/s). Unsigned and undated curriculum vitae are NOT ACCEPTABLE.
9. Valid and updated Good Clinical Practice (GCP) Training Certificate of the entire study team (up to the level of research associates and assistants).

STUDIES INVOLVING HUMAN PARTICIPANTS:
In addition to the basic documents that are required, the following documents must be included for studies involving human participants:

1. Informed Consent Form (English and in the local language). The informed consent form (ICF) must be line numbered. No line number on the ICF is NOT ACCEPTABLE.
2. Assent Form (English and in the local language) for studies involving minors and relevant populations deemed incompetent to sign an informed consent form. The assent form must be line numbered. No line number on the ICF is NOT ACCEPTABLE.

3. Digitally Accomplished Informed Consent Assessment Form (TMC-IRB Form 007-1B). The Principal Investigator must sign and dated the said forms. You may get these forms from the IRB Secretariat, and online website of Clinical Trial and Research Institute (CTRI).
    a. The IRB requires **one witness** to sign the Informed Consent Form whether the study participant is literate or not. Provide a space for the signature of one witness in the English and in the local language version of the ICF. As defined by IRB, *"a witness is any person of legal age and sound mind, and not a party to a contract or to what is being signed."* Study coordinators are not allowed to sign as witnesses.

STUDY-SPECIFIC DOCUMENTS: (Submit as needed)

Study-specific documents are only required if applicable to the study. Examples are the following:

1. Recruitment Advertisements
2. Other information or documents for participants (i.e., Study Diary)
3. Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review).
4. Clearance or permits from regulatory authorities (i.e., FDA approval for Clinical Trials)
5. Clearance from institutions (i.e., TMC) allowing access to any data governed by the Data Privacy Act of 2012

CASE REPORTS AND META-ANALYSIS SUBMISSIONS:

Submit the study dossier via email. The initial study dossier must contain the following:

1. Letter of Intent to conduct the study addressed to the Institutional Review Board Chair, Carlo Emmanuel J. Sumpaico, M.D., The Principal Investigator, Research Adviser, and Research Coordinator of the department should electronically sign the letter. Incomplete signatures are NOT ACCEPTABLE.
2. The study protocol must be formatted using the CTRI Manuscript Template. Incomplete and unformatted protocols are NOT ACCEPTABLE.
3. Updated, signed, and dated Curriculum Vitae of the study team (i.e. Principal Investigators and Co-investigator/s). Unsigned and undated curriculum vitae are NOT ACCEPTABLE.

NOTE:

- Submission of hard copies will only be needed **once recommended by TMC-IRB**.
- Hard copies should be submitted to the IRB Office. The IRB Office is located at 4th Floor, Clinical Services Group, Podium Building, The Medical City.
- The Principal Investigator is responsible for providing hard copies of the study dossier once the IRB recommends the study protocol is for full board review. The hard copies are REQUIRED to be submitted; otherwise, it will not be reviewed.
- Study documents such as amendments, additional study materials, and response to IRB queries should be submitted via email, and/or hard copies, enclosed in an appropriately sized white folder, and fastened on the side. For large documents, submit it on a blue binder. Submission of hard copies will only be needed **once recommended by TMC-IRB**.
- The items above serve to prepare the application for review. Studies with incomplete requirements will not be registered for IRB review. Some requirements may not be applicable for Residents/Students' research paper.