



14 March 2022

TO: All Clinical Departments, CROs, Sponsors and, Principal Investigators
FROM: The Medical City – Institutional Review Board
SUBJECT: TMC-IRB New Forms and Submission Guidelines

Dear All,

Greetings!

This is to inform everyone with regards to the implementation of the **New TMC-IRB Forms** to be used in submitting protocols. These forms can be accessed through the online website of Clinical Trial and Research Institute (CTRI). The new TMC-IRB forms and submission guidelines mentioned below will take effect starting **April 01, 2022**.

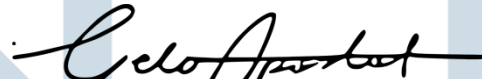
1. All documents must be **submitted electronically** to **irb@themedicalcity.com**. Submission of hard copies will depend once the IRB recommends the study protocol is for full board review. For submission of hard copies, it should be submitted on a white folder, fastened on the side.
2. Submissions will only be accepted and acknowledged during office hours: Monday to Friday, 8:00 AM to 5:00 PM. Any submissions outside office hours will be acknowledged in the following working day.
3. All submitted documents must be in single PDF file format **EXCEPT** for the following forms which must be accomplished digitally and submitted separately as individual files in **EDITABLE WORD** format.
 - **Form 006-2: Application Form for Initial Review**
 - **Form 007-1A: Research Protocol Assessment Form**
 - **Form 007-1B: Informed Consent Assessment Form**
 - **Form 011-3B: Research Completion Report Form**
 - **Form 011-4: Application for Continuing Review/ Renewal of Approval**
4. Electronic signatures for communication letters and forms are acceptable.
5. For protocols for INITIAL REVIEW, all documents must first be submitted to CTRI for verification of completeness.



6. Documents whose file sizes are too large for email attachment can be sent as Google Drive or One Drive links. Kindly assure to give TMC-IRB access to the drive.
7. Communication letters will also be sent via email.

We confirm that we are an Ethics Committee constituted in agreement and accordance with the guidelines of the International Conference on Harmonization of Good Clinical Practice (ICH-GCP).

Sincerely,


Geminn Louis C. Apostol, MD, MBA
Panel Secretary
Institutional Review Board


Carlo Emmanuel J. Sumpaco, MD
Chair
Institutional Review Board