07 September 2017

Re: The Medical City – Institutional Review Board for Review and Approval Documents Submission Guidelines

Dear All:

Please be informed that starting 01 October 2017, the following requirements and timelines must be observed and complied.

➢ CLINICAL DRUG TRIAL/SPONSORED STUDY INITIAL SUBMISSION FOR FULL BOARD REVIEW
  ❖ 11 copies
  • Form 006-1
  • Photocopy of Official Receipt
  • Informed Consent forms
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➢ PROTOCOL, ICF AND OTHER DOCUMENTS WITH AMENDMENT
  ❖ EXPEDITED (4 COPIES)
  ❖ FULL BOARD (11 COPIES)
  • Cover Letter
  • Summary of Changes

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• Track Changes
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• Informed Consent forms
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**Resubmission**
- Cover Letter with answer to the IRB queries:

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<th>IRB Queries</th>
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- Revised documents

**Additional Materials**
- Expedited (4 copies)
- Full Board (11 copies)
- Cover Letter
- Documents

**Case Report Forms**
- 4 copies
- Cover Letter
- Summary of Changes

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**Investigator Brochure**
- 2 copies
- Cover Letter
- Summary of Changes

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*The IRB Chairperson will decide the type of review: FULL BOARD or EXPEDITED once the complete protocol document is submitted and received in the IRB office.

*Once it is for Full Board review 11 copies of the protocol documents should be submitted on or before the deadline of submission for the month of the scheduled meeting. (kindly, refer to released date of deadlines per month of the year)

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

Sincerely,

Carlo Emmanuel J. Sumpaico, MD
Chairperson
Institutional Review Board