01 February 2017

To: All concerned

From: Clinical and Translational Research Institute

Re: Submission of Research Protocols for IRB Review and Approval

Greetings!

The Medical City is committed in producing high quality research proposals that is both scientifically and ethically sound. With the creation of the Clinical and Translational Research Institute (CTRI), the hospital is now entering new age of research governed by a more systematic and efficient research management system. In line with this, the following guidelines shall take effect for ALL the researches to be conducted in the hospital starting 01 February 2017:

For Residents and Fellows:

1. Researchers shall accomplish the following:
   A. Letter of Intent for the Conduct of Research- a template shall be available at the CTRI Office and will be provided as requested
   B. IRB Forms 006-2, 007-1A/007-1B and 007-1C- forms are available at the Institutional Review Board Office
   C. Full Research Protocol- a template shall be available at the CTRI Office and will be provided as requested
   D. Line Item Budget- a template shall be available at the CTRI Office and will be provided as requested
   E. Updated Curriculum Vitae of the Investigator/s

2. For researchers planning to conduct clinical research in the hospital, a certificate on Good Clinical Practice shall be secured beforehand. The researchers shall be responsible for coordinating with CTRI for the schedule of upcoming GCP trainings. A photocopy of the GCP certificate shall be attached together with the accomplished files mentioned above.

3. Four (4) hardcopies of all the accomplished files shall be submitted to the CTRI Office at 17th floor, Nursing Tower.

4. Upon submission, the CTRI shall assign a Research Registry Number (RRN) to the submitted research. This number shall be used by the researchers in tracking the progress of the review of their submitted files and shall be the unique identifier for the research.

5. The CTRI, thru its Technical Review Committee (TRC), shall be responsible in reviewing the scientific and technical aspects of the submitted papers. The expected turnaround time for the technical review is seven working days. Any comments for revisions shall be communicated promptly to the concerned researcher thru email.

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6. The CTRI shall issue a notice of clearance for Institutional Review Board (IRB) review once the research was approved by the TRC. This notice shall be required for the conduct of ethics review by the IRB. Research proposals without a notice of clearance from the CTRI shall NOT be accepted by the IRB for review. A copy of the notice of clearance shall be issued to the researchers upon approval by TRC.

For Industry Initiated Research:

1. The industry sponsor (thru the Principal Investigator, if already available) shall submit the following to the CTRI thru email (ctri@themedicalcity.com):
   A. Letter of Intent
   B. Company Profile
   C. Research Concept Questionnaire- a template shall be available at the CTRI Office and will be provided as requested
   D. Draft of Non-Disclosure Agreement (NDA)

2. The CTRI shall be responsible for coordinating with the different clinical departments for the appropriation of a Principal Investigator if not yet available.

3. The CTRI shall be responsible for the initial review of the company. The NDA shall be reviewed in coordination with the Legal Unit of the hospital.

4. The industry sponsor (thru the Principal Investigator) shall accomplish the following:
   A. Full Research Protocol- a template shall be available at the CTRI Office and will be provided as requested; sections must be properly labeled using tabs
   B. Line Item Budget- a template shall be available at the CTRI Office and will be provided as requested
   C. IRB Forms 006-2, 007-1A/ 007-1B and 007-1C- forms are available at the Institutional Review Board Office
   D. List of Sites and Principal Investigators (for multi-center studies)
   E. Updated Curriculum Vitae of the Investigator/s

5. Eleven (11) hardcopies of all the accomplished files shall be submitted to the CTRI Office at 17th floor, Nursing Tower.

6. Upon submission, the CTRI shall assign a Research Registry Number (RRN) to the submitted research. This number shall be used by the researchers in tracking the progress of the review of their submitted files and shall be the unique identifier for the research.

7. For Principal Investigators conducting clinical research in the hospital, a certificate on Good Clinical Practice shall be secured beforehand. The researchers shall be responsible for coordinating with CTRI for the schedule of upcoming GCP trainings. A photocopy of the GCP certificate shall be attached together with the accomplished files mentioned above.

8. The CTRI shall be responsible for the initial feasibility review of the proposal.

9. Upon approval of the proposal by the CTRI, the industry sponsor is requested to initially pay for the indirect cost for the study (15% of the approved research budget or PhP 150,000, whichever is higher, to be paid on top of the total budget). The payment shall be addressed to the Philip-

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pine Foundation for Health and Development, Inc. Once the indirect cost was already paid, the payment slip shall be submitted to the CTRI for the clearance for IRB review.

10. A notice of clearance for IRB review shall be issued to the industry sponsor (thru the Principal Investigator) once all the required documents are complete and the payment was made. This notice shall be required for the conduct of ethics review by the IRB. Research proposals without a notice of clearance from the CTRI shall NOT be accepted by the IRB for review. A copy of the notice of clearance shall be issued to the industry sponsor upon approval by CTRI.

For any concern, you may contact us at 988-1000 / 988-7000 ext. 7834 or at ctril@themedicalcity.com.

Thank you very much for your continuous support!

Truly Yours,

[Signature]

Raul V. Destine, MD
Director, CTRI
The Medical City