THE MEDICAL CITY
Where Patients are Partners

14 March 2022

TO: **All Clinical Departments, CROs, Sponsors and, Principal Investigators**

FROM: **The Medical City – Institutional Review Board**

SUBJECT: **Guidelines in Submission of SAE, SUSAR, and Protocol Deviation**

Dear All,

Please be informed that starting **01 April 2022**, the following requirements and timelines must be observed and complied. All documents must be submitted via email and/or in one (1) hard copy depending on the IRB recommendation.

1. **Off-Site: Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAE), Adverse Events (AE), Periodic Safety Reports, Investigator Notifications, and CIOMS**

   Requirements:

   - Cover Letter addressed to Dr. Carlo Emmanuel Sumpaico, and signed by the Principal Investigator
   - Incomplete signature will not be considered as complete submission
   - Soft Copy CIOMS Form/s
   - Summary Table

Protocol Title:						
Year _____: ☐ First Quarter ☐ Second Quarter ☐ Third Quarter ☐ Fourth Quarter						
Control number study participant	SAE Reported	Investigation Drug	Country	Reported Date	Report Type	Decision

   Timeline:
   - *Quarterly (Jan-Mar, Apr-Jun, Jul-Sep, and Oct-Dec)*

2. **On-site: Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAE), Adverse Events (AE)**

   Requirements:
   - TMC-IRB Form 011-5 (one form per patient/event)

Ortigas Avenue, Pasig City
Tel. No.: (632) 8-988-1000/8-988-7000
mail@themedicalcity.com

- Cover Letter addressed to Dr. Carlo Emmanuel Sumpaico, and signed by the Principal Investigator
- Incomplete signature will not be considered as complete submission

Timeline:

- Principal Investigator: Initial Report *within 24 hours of SAE event/s*
- Principal Investigator Follow-up: *within 7 calendar days of SAE event/s*
- Study Sponsor final report: *within 7 calendar days of SAE event/s* includes the following content:
  - Assessment of SAE
  - Decision if study drug related or not (is applicable)
  - Decision if the study participant/s will continue or not the study drug

3. On-site: Protocol Deviations

Requirements:

- TMC-IRB Form 011-6 (one form per patient/event)
- Cover Letter addressed to Dr. Carlo Emmanuel Sumpaico, and signed by the Principal Investigator
- Incomplete signature will not be considered as complete submission

Timeline:

- *Weekly*

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,

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

Carlo Emmanuel J. Sumpaico, MD
Chair
Institutional Review Board

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