07 September 2017

Re: The Medical City – Institutional Review Board Post-Approval Documents Submission Guidelines

Dear All:

Please be informed that starting 01 October 2017, the following requirements and timelines must be observed and complied. All documents must be submitted in two (2) copies.

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
   - Hard/Soft copy CIOMS Form/s
   - Summary Table:

<table>
<thead>
<tr>
<th>Protocol Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
</tr>
<tr>
<td>Control number per study participant</td>
</tr>
</tbody>
</table>

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

2. On-site: Suspected Unexpected Serious Adverse Reactions (SUSARs) and Serious Adverse Events (SAEs)
   Requirement:
   - TMC-IRB Form 011-5 (one form per patient/event)
   Timeline:
   - Principal Investigator: Initial report within 24 hours of SAE
   - 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

Requirement:
- TMC-IRB Form 011-6 (one form per patient/event)

Timeline:
- Monthly

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. Sumalco, MD
Chairperson
Institutional Review Board