LCP-IERB Guideline on Reporting Adverse Events

I. Purpose

This guideline is designed for investigators to help comply with the requirement of LCP-IERB for reporting Adverse Events. It provides information on timelines of reporting of on-site and off-site adverse events that occur in the conduct of clinical trials approved by LCP-IERB.

II. Safety Reporting Requirements

1. All on-site unexpected serious adverse events (SAEs) and Suspected unexpected serious adverse reaction (SUSAR) should be reported immediately to the LCP-IERB.
2. Onsite SAEs and SUSARs must be reported using LCPIERB Form 3(A) - 2018: Serious Adverse Event Report Form. The PI should also attach the standard SAE form (CIOMS Form: Suspect Adverse Reaction Report) to this report.
3. For offsite SUSAR, submit report using CIOMS Form: Suspect Adverse Reaction Form.
4. Provide LCP-IERB with a summary report (example line listings) or updates on the safety profile of the investigational new drug (IND), and not individual events.
5. Initial notification of fatal or life-threatening unexpected adverse reactions may be done thru LCP-IERB email address at lcpierb@gmail.com.

III. Reporting Time Frame

The Principal Investigator shall report to LCP-IERB all adverse events according to the following timelines:

1. For onsite fatal or life-threatening unexpected adverse reactions, submit report within seven (7) calendar days after initial knowledge of information together with a written narrative report.
2. For on-site serious adverse events and SUSAR, the report must be submitted within fifteen (15) calendar days after initial knowledge of information.
3. For offsite SUSAR, submit report within thirty (30) calendar days from receipt of the report of the PI from the sponsor.
4. All offsite expected serious adverse events must be reported in the regular annual report.
5. All onsite and offsite not serious adverse events, expected or unexpected, must be reported in the regular annual progress report.
6. Summary reports (line listings) and/or updates on the safety profile of the IND should be submitted every 6 months