



LCP- ETHICS REVIEW COMMITTEE

LUNG CENTER OF THE PHILIPPINES

Quezon Avenue Extension, Quezon City, Philippines 1100

4th Flr. Room 4103 Tel Nos. 9246101 loc 568

E-mail : erc@lcp.gov.ph or www.lcp.gov.ph

LCP-ERC Policies and Guidelines on Local (on-site) Safety Reporting

1. All serious Adverse Events (SAEs) should be reported immediately to the Ethics Review Committee using appropriate LCP-ERC Form
2. If the SAE is fatal or life threatening it should be reported no later than 24 hours of knowledge of the event. This should be reported or notification can be done initially thru LCP-ERC e-mail address at erc@lcp.gov.ph
3. Written report should be submitted within 7 days up to 15 days maximum using the LCP-ERC Serious Adverse Event Report Form 2.9 version 1.2013 which can be downloaded at LCP website (www.lcp.gov.ph). This should accompany the complete narration of the event.
4. All Other Unexpected Serious ADRs

Serious unexpected reaction (ADRs) that are not fatal or life-threatening, whether on-site or off- site, must be filed as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

5. Expected Adverse drug Reactions
 - a. Serious adverse drug reaction which are expected base on information for Investigator's Brochure will be reported in the regular progress report and final report usually submitted annually
 - b. Adverse drug reactions which are not serious will also be reported in the regular progress report and final report usually submitted annually