Guidance on On-Site Serious Adverse Event (SAE) Reporting

The FDA defines a serious adverse event as any experience that suggests a significant hazard, contraindication, side effect or precaution. With respect to human clinical experience, a serious adverse drug or device event includes any experience that is fatal or life-threatening, is permanently disabling, requires or prolongs inpatient hospitalization, results in a congenital anomaly/birth defect, or may be classified as an important medical event (requiring medical or surgical intervention).

Within 10 working days of notification of the event, a detailed written report (IRB Form 3a – Serious Adverse Event Report for SAEs at UNTHSC) must be completed and forwarded, along with supporting documentation, to OPHS.

If the event resulted in death (regardless of whether the event is initially assessed as related to the study), or if the investigator initially assesses the SAE as ***possibly related (or greater causality)*** to the study protocol, an e-mail must also be sent to OPHS within **24 hours** of notification of the event. This e-mail must contain the following information:

IRB Project #
Principal Investigator
Project Title
Subject's Initials, Gender and Age
Date and Time of Event
Brief Description of Event
Investigator's Initial Assessment of Relationship of SAE to the Study
What Event Resulted In: Death
Life-Threatening Situation
Hospitalization or Prolonged Hospitalization
Severe or Permanent Disability
Congenital Anomaly/Birth Defect
Pregnancy*
Other (Important Medical Event)

* Pregnancy does NOT have to be reported if the subject is receiving follow-up only, and conception occurred outside of the time period that the study protocol requires contraception (e.g. contraception is required for 6 months after the last dose of the study drug).

For general guidance regarding SAE reporting, please visit the FDA website by *clicking here*.