North Texas Regional Institutional Review Board

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

Topic: Reporting SAEs

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 (SAE) Report On-Site") must be completed and submitted, along with supporting documentation, via our electronic IRB submission system. You will need to note on the report what the event resulted in:

- Death*
- Life-Threatening Situation
- Hospitalization or Prolonged Hospitalization
- Severe or Permanent Disability
- Congenital Anomaly/Birth Defect Pregnancy**
- Other (Important Medical Event)

*If the event resulted in death (regardless of whether the event is initially assessed as related to the study), a message must be sent in IRBNet (using Project Mail in the electronic submission system) 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 (Death) to the Study

**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).