

## 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 that occur on-site) must be completed and submitted, along with supporting documentation, via IRBNet.

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, a message must be sent in IRBNet (using Project Mail) 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).