

Research Review Board Inc. (RRB)

Serious Adverse Events Reporting System

Investigators are required to report Serious Adverse Events to the Research Review Board that meet at least one of the following criteria:

1. Events that are serious in nature. This includes any event that could result in death, is life-threatening, includes hospitalization periods, or results in diminished health or disability.
2. Events that are unexpected. This includes any event that had not been previously identified in the protocol or consent form.
3. Events that are related to study procedures and/or treatment.

When reporting a Serious Adverse Event, the submission of hospital records, doctor's notes, and any other relevant documentation are accepted. These documents may be submitted in addition to the RRB's Serious Adverse Events Reporting Form. The use of Sponsor SAE Reporting forms is also accepted.

Reports of unexpected, possible or probable drug related, adverse reactions shall be reported by the Investigator to the Board and to the sponsor except for those adverse reactions that the protocol or other document (e.g. Investigator's Brochure) identify as not needing immediate reporting.

Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol. [in accordance to ICH Guidelines 4.11.1 and 4.11.2 (as amended)].

SAE Reports shall be reported to the Board within 15 days of becoming aware of the SAE. The Board may request that the PI provide additional details in relation to any SAE Report.

IND/SUSAR and/or summary reports are not required. The RRB will send an acknowledgement for all SAE Reports received.