Adverse Event Reporting Procedure

Approval Date: 11Nov2013
Revision Date: 28May2015
Revision Date: 9OCT2017 To accommodate eSOURCE implementation.
Revision Date: 31OCT2017 Cosmetic Only
Revision Date: 11DEC2021

1. Enter or update AE during visit while in room with subject.
2. Progress Note at procedure level or in main progress note any special circumstances, discussion regarding AE, meds taken, etc.
3. If AE is serious or unexpected, the sponsor will be notified within 24 hours.
4. Verbally discuss details of AE with Investigator for triage. Investigator determines severity, causality, and any treatment (if deemed necessary by Investigator).
5. Progress Note discussion with Investigator as he determined severity, causality, and any treatment given. This is documented in source by study staff for the Investigator.
6. If PI signoff of the entire visit has already occurred, add internal comment to AE page to remind Investigator to review and approve updated AE documentation.
7. Enter AE into CRF per sponsor's requirements.
8. Update AE as necessary. Follow up with subject until resolved or end of study as determined by sponsor.