Local Adverse Event (AE) Report Form

Use this form to report a local adverse event that is an **unanticipated problem** in accordance with HREBA reporting criteria.

Do not include any individually identifying health information.

Submit the completed form and any supporting documents using the reportable event feature within IRISS.

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| 1. **STUDY INFORMATION** | | | |
| Ethics #: | Protocol #: | | |
| Principal Investigator (of site where event occurred): | | | |
| Study Title: | | | |
| Study Progress:  Recruiting  Participants on study intervention  Follow-up | | | No. subjects enrolled: |
| 1. **REPORTING CRITERIA** *(For details see the* ***Guidance for Submitting a Reportable Event****)* | | | |
| 1. Unexpected 2. Related / Possibly Related / Uncertain / Unknown 3. Suggest greater risk of harm *(includes all events which are serious)*   Only submit events that meet all three reporting criteria (A and B and C).  *Downgrading previous reported event* | | | |
| If submitting a report that does not meet all three criteria, provide justification as to why it is being submitted: (e.g., the event is of medical importance.) | | | |
| 1. **REPORTING TIMELINES** *(within 15 calendar days; 7 if life-threatening or led to death with initial 48hr e-mail notification)* | | | |
| Date study team became aware of the event: | | | |
| If this report was not submitted within reporting timelines, explain the lapse: | | | |
| 1. **AE DESCRIPTION** | | | |
| Report Type: Initial Follow Up *(No.* *, Initial Report Date:* *)* | | | Related to Protocol Deviation |
| Event:  Death  Life-threatening  Hospitalization / Prolonged Hospitalization  Important Medical Event  Persistent or Significant Disability/Incapacity  Congenital Anomaly/Birth Defect  Other | | | |
| SAE Report No. OR Participant No.: | | Event Date: | |
| Case Description Summary: | | | |
| 1. **INVESTIGATOR ACTIONS** | | | |
| Actions taken as a result of the AE:  Change to study treatment  Suspension of study treatment  Study Blind Broken  Discontinuation of study treatment  Hospitalization | | | |
| Additional details of investigator response to the AE: | | | |
| Patient Outcome:  Resolved without sequelae Resolved with sequelae Unresolved  Death Unknown | | | |
| **NOTE**: IF THIS STUDY IS INDUSTRY SOPONSORED OR INVESTIGATOR INITIATED, REPORT EVENT TO REGULATORY AUTHORITIES AS PER PROTOCOL AND / OR REGULATORY REQUIREMENTS. | | | |