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**
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| 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)*
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| Date study team became aware of the event:       |
| If this report was not submitted within reporting timelines, explain the lapse:       |
| 1. **AE DESCRIPTION**
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| 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**
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| 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. |