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 for files within IRISS, or e-mail to the committee for files on paper.

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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. | | | | | | | |
| 1. **SIGN-OFF** *(not required for files within IRISS)* | | | | | | |
| **Person Completing Form** | | | | | | |
| Name: | | E-mail: | | | | Date: |
| **Principal Investigator** | | | | | | |
| Signature: | | | | Name (printed): | | |
| E-mail: | | |
| Date: | | |

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| CHAIR/DESIGNATE USE ONLY | | |
| ⬜ No further action required  ⬜ Request more information  ⬜ Committee discussion required | Comments/Concerns: | |
| Signature: | | Date of Review: |