Non-Local Adverse Event (AE) Report Form

Use this form to report non-local adverse events or periodic safety update/summary reports 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:       |
| 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****)*
 |
| **A.** [ ]  **Is an Unanticipated Problem** (unexpected and related/possibly related and suggests greater risk of harm) **B.** **Requires:**  [ ]  Change to research and/or [ ]  Change to consent form and/or [ ]  Immediate notification to participants for safety\* Only submit events that meet BOTH criteria A and B.  **If you submit a report that does not meet the criteria, you will not receive an acknowledgement from HREBA.** |
| 1. **REPORTING TIMELINES** *(within 15 calendar days)*
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| Date study team became aware of the event/report:       |
| If this report was not submitted within reporting timelines, explain the lapse:       |
| 1. **AE DESCRIPTION**
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| [ ]  Dear Investigator or Other Sponsor Letter [ ]  Periodic Safety Update/Summary Report [ ]  Individual AE  |
| 1. **REQUIRED AE INFORMATION**
 |
| Attached documentation must include **ALL** of the following information:* Description of the event(s)
* All previous safety reports concerning similar adverse events
* Analysis of the significance of the current adverse event(s) in light of previous reports
* Description of proposed research changes, consent form changes, or other corrective actions to be taken

**Note that a change to study materials (e.g. protocol, consent form, documents given to participants) must be submitted as an amendment/modification as soon as available.** |
| Action to be taken by your site:       |
| 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:  |