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 signed completed form and any supporting documents as a modification for files within IRISS, or e-mail to reportable.cancer@hreba.ca for files on paper.

|  |
| --- |
| 1. **STUDY INFORMATION**
 |
| Ethics #:       | Protocol #:       |
| Principal Investigator Name:       |
| 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)*
 |
| Date study team became aware of the event/report:       |
| If this report was not submitted within reporting timelines, explain the lapse:       |
| 1. **AE DESCRIPTION**
 |
| [ ]  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 changes to study materials (i.e. 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**
 |
| **Person Completing Form** |
| Name:       | E-mail:       | Date:       |
| **Principal Investigator** |
| Signature:  | Name (printed):       |
| E-mail:       |
| Date:       |

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