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](mailto:reportable.cancer@hreba.ca) for files on paper.

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| 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: | | |

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