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 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****)* | | | | | | |
| Unexpected  Related/Potentially Related  Suggest greater risk of harm  *Downgrading previous reported event*  \* Only submit events that meet all three reporting criteria.  **If you submit a report that does not meet the criteria, you will not receive an acknowledgement from HREBA.** | | | | | | |
| Justification that the event meets all three criteria: | | | | | | |
| 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:  Hospitalization  Change to study treatment  Suspension of study treatment  Discontinuation of study treatment | | | | | | |
| Additional details of investigator response to the AE: | | | | | | |
| Patient Outcome:  Resolved without sequelae Resolved with sequelae Unresolved Death Unknown | | | | | | |
| 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: |