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 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**
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| 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:  |