Protocol Deviation Report Form

Use this form to report a protocol deviation which meets HREBA reporting criteria (see below).

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**
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| Ethics #:       | Protocol #:       | If multisite study, acknowledgment to:[ ]  This site only [ ]  All sites |
| Principal Investigator (of site where deviation occurred):       |
| Study Title:       |
| Study Progress: [ ]  Recruiting [ ]  Participants on study intervention [ ]  Follow-up  | No. subjects enrolled:       |
| 1. **DEVIATION INFORMATION**
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| **Reporting Criteria** *(For details see the* ***Guidance for Submitting a Reportable Event****)* |
| [ ]  Jeopardizes research participants’ safety [ ]  Jeopardizes research efficacy / data integrity [ ]  Led to a sponsor-approved waiver to participant eligibility criteria *[ ]* Change in the approved process for obtaining consent (i.e. improper translation, current ICF not implemented, etc.)*[ ]* Led to an SAE *(ensure you attach a completed Local SAE report form to this submission )* \* Only submit a deviation if it meets at least one of these reporting criteria. **If you submit a report that does not meet these criteria, you will NOT receive formal acknowledgment from HREBA.** |
| **Reporting Timelines** *(within 15 calendar days; 7 if led to death or life-threatening AE)* |
| Date study team became aware of the deviation:       |
| If the deviation was not submitted to HREBA within reporting timelines, explain the lapse:      |
| **Details** |
| Participant No.:       | Deviation Date:       |
| Detailed Description of Deviation *(Attach copies of any relevant or supporting documentation)*:       |
| Description of Corrective Action:       |
| 1. **SPONSOR NOTIFICATION:**
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| Has the sponsor been notified of this deviation? [ ]  Yes [ ]  No [ ]  N/A |
| If “No” or “N/A”, please explain:       |
| 1. **SIGN-OFF**
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| **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:  |