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

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| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **STUDY INFORMATION** | | | | | | | |
| 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** | | | | | | | |
| **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:** | | | | | | | |
| Has the sponsor been notified of this deviation?  Yes  No  N/A | | | | | | | |
| If “No” or “N/A”, please explain: | | | | | | | |
| 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: |