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 completed form and any supporting documents using the reportable event feature for files within IRISS, or e-mail to the committee for files on paper.

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| --- | --- | --- | --- | --- | --- | --- |
| 1. **STUDY INFORMATION** | | | | | | |
| Ethics #: | Protocol #: | | | | | |
| 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 submitting a report that does not meet at least one of the above criteria, provide justification as to why it is being submitted: | | | | | | |
| **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** *(not required for files within IRISS)* | | | | | | |
| **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: |