**Protocol Violation Log**

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**Visit Month:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Form Completion Date:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | Participant ID:   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Couple I/P Chk* | Protocol Violation Page number:  \_\_\_\_\_\_\_ |

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|  | **Visit Month associated with the violation:** | | | | | | | | |
| 1 | Date event occurred (start date): | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | |
| a | Date of site awareness | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | |
| 2 | Provide a brief description of the protocol violation: | | | | | | | | |
| 3 | Does this event require reporting to the site IRB? | | | | | Yes | | no | |
| a | If no, why not: | | | | | | | | |
| b | If yes, Date reported to site IRB : | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | |
| 4 | Date event ended: | | | |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *dd mm yyyy* | | | | | |
| 5 | Category of event: *(Mark all that apply)* | | | | | | | | |
|  | *breach of confidentiality* |  | *safety related to RAE* | |  | | *informed consent* | |  |
|  | *eligibility criteria* |  | *failure to implement*  *required study procedure* | |  | | *use of non-HREC approved materials and/or performing non-IRB approved procedure* | |  |
|  | *study drug and accountability* |  | *other, specify:* | |  | | | |  |
| 6 | What steps have been taken to address this event? | | | | | | | | |
| 7 | What steps have been taken to prevent future occurrences? | | | | | | | | |
| 8 | Additional comments: | | | | | | | | |

**Completed by:** *(initials/date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**Forms Instruction**

The **Protocol Violation Log** CRF is used to document specific protocol events that have an impact on participant safety. A protocol violation has an impact on participant safety, may substantially alter risks to participants, may have an effect on the integrity of the study data, or may affect the participant's willingness to participate in the study. File **Protocol Violation Logs** in participant binder.

**Item-specific Instructions:**

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| **Participant ID** | Participant IDs are assigned from a list provided by the PROJECT. They are assigned once eligibility has been determined and the subject has been enrolled. The Participant ID should be left blank until the eligibility status of the participant is known. If eligible, the Participant ID should be entered and initialed and dated (if being added on a different date). If the participant is not eligible, then the Participant ID should be left blank. |
| **Page number** | Number the pages sequentially ***by participant***, starting with page 01. Use each page number only once. Do not re-number a page once it has been faxed to DF/Net, unless a correction to the numbering is required. Do not re-use page numbers if a **Protocol Violation Log** is deleted. |
| **Visit Month**  **associated with**  **the violation** | Record the visit month when the violation occurred.  • At Screening, line through the visit month and write “Screening.”  • If the violation spans across several visits, record the first visit month.  • If the violation is not associated with a specific visit, mark “N/A.” |
| **Item 1** | If possible, identify the date the event started and the date the site became aware of the event.  If “day” is not known, draw a line through the “dd” boxes and write “unk” nearby; initial and date, and enter the month and year. |
| **Item 4** | The end date relates to the date the situation ended. This also refers to the date the event resolves, if appropriate.   * The start date and end date should be the same in cases of one-time or single-day events. * Mark “ongoing” if the event is ongoing at the time the PROV is first completed and faxed. * Once the situation resolves, draw a line through the “x” for “ongoing” and complete the end date. * Leave the “ongoing” box marked if the situation is still ongoing at the time the participant exits the study. |
| **Item 5 Category of event:** | * **Breach of Confidentiality:** This should be used to document a breach of confidentiality, be it potential or actual. An example of this may be a staff member putting a participant's PTID (instead of his name) on a referral form used for an evaluation at a local clinic. * **Eligibility criteria:** This should be used to document the enrollment of a participant who does not meet the study inclusion and exclusion criteria. Examples of this may be failure to obtain a urine sample for a pregnancy test at Enrollment but continuing with the visit/enrollment without the test result, or enrollment of an HIV-concordant couple based on local test results. * **Safety related to RAE:** This should be used to document all safety-related violations involving RAEs and protocol-required RAE follow-up procedures and/or laboratory testing not done. * **Failure to implement required study procedure:** An example of this may be failure to draw a chemistry panel from a participant on study drug. * **Informed consent:** Examples of this may be failure to obtain informed consent from the participant, or that the participant signed an expired or outdated consent form at Enrollment. * **Use of non-HREC approved materials and/or performing non-IRB approved procedure**: * Examples of this include performing study or clinic procedures that have not been approved by the HREC, or use of recruitment materials or procedures that have not been approved by the HREC. * • **Study drug and accountability:** This should be used to document errors in study drug management or accountability. |
| **Item 8** | Use this section to clarify the data collected on this form.  • If the violation was associated with a study visit, please provide the visit month. For  Screening, write the visit name. For Enrollment, write “00.0.” |