

Unusual Events

Purpose: To report unusual occurrences or events. Record events that need to be documented but are not captured on other data forms.

When: Whenever a clinical center or the Coordinating Center is aware of an unusual event. Data on subsequent UE forms regarding the same event should be updated if more information becomes available after the first report of the unusual event.

Instructions: Fax both pages of the form to CC (410-955-0932) c/o Milana Isaacson. To update report complete a new form. Make sure that items 8 and 9 are consistent between initial and followup reports. Describe event clearly on page 2.

Definition of unusual event: Examples include a patient having a seizure during a fundus photography session; insufficient lighting in the visual acuity exam room; insufficient lighting on eye charts; visual field not calibrated properly; inadvertent distribution of patient identifiers; and flooding resulting in damage/destruction of study records.

A. Clinic, patient, and visit identification

1. Clinic ID code: _____

2. Is this event about a specific participant:

Yes (1) No (2)
 5.

3. Patient ID#: _____

4. Patient name code: _____

5. Date of report:

_____ day _____ mon _____ year

6. Visit ID code: _____

B. Unusual event

7. Type of report (*check only one*):

New (1)
Recurrent (2)
Followup (3)
Other (*specify*) (4)

specify

8. Was this event reported to the IRB:

Yes (1) No (2)

9. Date of unusual event (*specify*):

_____ day _____ mon _____ year

C. Administrative information

10. Date form reviewed:

_____ day _____ mon _____ year

11. Clinic coordinator PIN: _____

12. Clinic coordinator signature:

13. Describe event (*type or print legibly*):

Signature: _____ **Date:** _____