Reference #: _____

Unusual Event
(UE-1)

Purpose: To report 1) protocol deviations, 2) events that do not rise to the level of a serious adverse event but should be reported, and 3) communications that need to be recorded but are not captured on other data forms. **Do <u>not</u> use this form to report events that should be reported on the Safety Report (SR) form.**

When: Whenever a clinic is aware of an unusual event. Data on the forms should be updated if more information becomes available after the first report of the unusual event.

Completed by: CitAD study coordinator.

Instructions: Complete both pages of the form. Fax form to CC (443-287-5797) within 2 working days. To update the report, complete a new form. Make sure that items 9 and 10 are consistent between initial and follow-up reports. Call CC (443-287-3170) if the event is an emergency.

A. Clinic, patient, and visit identification

1. Clinic ID: ____ ____ ____ ____

2. Patient ID *(If not associated with a particular patient, record as "n".):*
C ____ ____ ____ ____

3. Patient four-letter code *(If not associated with a particular patient, record as "n".):*
____ ____ ____ ____

4. Date form completed:
____ ____ – ____ ____ ____ – ____ ____
day month year

5. Visit ID: ____ ____
(If not associated with a particular visit, record as "n".)

6. Form revision date:
1 1 – a u g – 0 9
day month year

B. Unusual event

7. Type of report *(check only one):*
New . . . . . (1)
Follow-up . . . . . (2)
Other *(specify)* . . . . . (3)

_____
specify

8. Type of unusual event *(check all that apply)*
a. Unusual problem . . . . . (1)
b. Protocol deviation . . . . . (1)

9. Summarize event *(use next page to elaborate if necessary):*

_____
specify

10. Date of event onset:
____ ____ – ____ ____ ____ – ____ ____
day month year

C. Administrative information

11. Date form reviewed:
____ ____ – ____ ____ ____ – ____ ____
day month year

12. Study coordinator ID: ____ ____ ____

13. Study coordinator signature:

_____

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

Signature: _____ ***Date:*** _____