Reference #: _____

Study Participation Closeout
(SC-1)

Purpose: Record information related to study participation closeout.
When: Study participation is completed at week 9 or terminated before week 9.
Completed by: CitAD certified personnel.
Information obtained from: Patient, caregiver, and study staff.
Instructions: Record date and reason(s) for study participation closeout. Study participation completion is defined as completion of week 9 visit. Study participation termination is defined as discontinuing study participation prior to the end of the 9-week follow-up period; no additional information can be obtained after the participant's decision to terminate study participation in CitAD.

A. Clinic, patient, and visit identification

1. Clinic ID: ____ ____ ____ ____

2. Patient ID: C ____ ____ ____ ____

3. Patient four-letter code: ____ ____ ____ ____

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

5. Visit ID: ____ ____

6. Form revision date:
2 7 – o c t – 0 9
day month year

B. Information related to closeout

7. Date of study participation closeout:
____ ____ – ____ ____ ____ – ____ ____
day month year

8. Primary reason for study participation closeout *(check only one):*

- Completion of study (week 9) . . . . . (1)
- Death . . . . . (2)
- Adverse event/health problem . . . . . (3)
- Family pressure to discontinue . . . . . (4)
- Patient is unavailable for future follow-up . . . . . (5)
- Refusal to continue follow-up . . . . . (6)
- Other . . . . . (7)

_____
specify

9. Other reason(s) for study participation closeout *(check all that apply):*

- **a.** No other reason . . . . . (1)
- **b.** Adverse event/health problem . . . . . (1)
- **c.** Family pressure to discontinue . . . . . (1)
- **d.** Patient is unavailable for future follow-up . . . . . (1)
- **e.** Refusal to continue follow-up . . . . . (1)
- **f.** Other . . . . . (1)

_____
specify

C. Patient unmasking

(Unmasking information is obtained from the data system by clicking on "CitAD Treatment Unmasking").

10. Was unmasking performed:
Yes (1) No (2) → **14.**

If no, specify reasons:

_____
specify

_____
specify

11. Drug kit ID: C ____ ____ ____ ____

12. Treatment group *(from data sytem unmasking page):*

_____
specify

13. Treatment group disclosure provided to *(check all that apply):*

- **a.** Participant . . . . . (1)
- **b.** Caregiver . . . . . (1)
- **c.** Other . . . . . (1)

_____
specify

D. Administrative information

14. Date form reviewed by study coordinator:

____ ____–____ ____ ____–____ ____
day month year

15. Study coordinator ID: ____ ____ ____

16. Study coordinator signature:

_____