



NIA/NINR

Resources for Enhancing Alzheimer's Caregiver Health

Off Protocol (OP) form

Completion Log		
	Person	Date
Data collected		____/____/____
Data entered		____/____/____
System ID		
Data verified		____/____/____
Data cleaned		____/____/____
Data transferred		____/____/____
Subject ID		

OFF PROTOCOL FORM

PLEASE USE THIS FORM TO REPORT ANY DEVIATION FROM THE REACH II PROTOCOL

1. Date this form completed ____ / ____ / ____
Month Day Year

2. Interviewer's Name: _____
Last, First

2.1 REACH II certification number _____

I. Protocol Deviations (Check all that apply)

Screening

- () 3. Rescreening occurred after baseline.

3.1 Enter old screening ID: _____

Randomization

- () 4. Ineligible participant randomized.
- () 5. Wrong treatment assigned.
- () 6. Wrong treatment given.
- () 7. Randomization more than 3 days from baseline interview.
- () 8. Randomization completed prior to baseline interview.
- () 9. Eligible participant not randomized.

(9.1 Specify: _____)

- () 10. Participant randomized to wrong stratum. →

10.1 Specify which stratum (*check all that apply*)

() CG relation to CR

Incorrect assignment	Correct assignment
() 1. Non-Spouse	() 1. Non-Spouse
() 2. Spouse	() 2. Spouse

() CG identity

Incorrect assignment	Correct assignment
() 1. Hispanic	() 1. Hispanic
() 2. White	() 2. White
() 3. Black	() 3. Black

Core Battery

- () 11. Interview conducted by non-certified individual.
- () 12. Interview completed over the phone.
- () 13. Follow-up missed.

13.1 Specify which follow-up:

3-month control call	5-month control call	6-month follow-up interview
1 ()	2 ()	3 ()

- () 14. Follow-up completed outside of the window.

14.1 Specify which follow-up:

3-month control call	5-month control call	6-month follow-up interview
1 ()	2 ()	3 ()

- () 15. Project Evaluation not completed.
- () 16. Mini-Mental completed at a different time than core battery.
- () 17. Mini-Mental not completed.
- () 18. Interview required multiple sessions.

18.1 Number of sessions required to complete interview: _____

Intervention

() 19. First intervention session greater than 21 days from randomization

Intervention Refusals

- () 20. CTIS phone.
- () 21. Participation in CTIS support groups.
- () 22. Caregiver notebook.
- () 23. Home visits.
- () 24. Behavioral prescriptions.
- () 25. Stress management module.
- () 26. Further participation in intervention.

Endpoint Data Unavailable

() 27. Interview incomplete - Caregiver withdraws consent after interview started. _____

(27.1 Specify: _____)

() 28. Caregiver withdraws consent.

- () 28.1 Change of caregiver.
- () 28.2 Caregiver felt that the study was too time consuming.
- () 28.3 Caregiver is displeased with randomization.
- () 28.4 Illness. _____

- () 28.4.1 Caregiver.
- () 28.4.2 Care Recipient.

() 28.5 Care Recipient Death.

() 28.6 Other reason. _____

(28.6.1 Specify: _____)

() 29. Caregiver cannot be located / location unknown.

() 30. Caregiver death.

() 31. Caregiver excluded from study. _____

(31.1 Specify: _____)

Other Protocol Deviation

() 32. Other. _____

(32.1 Specify: _____)



NIA/NINR

Resources for Enhancing Alzheimer's Caregiver Health

Care Recipient Tracking (RT)

Completion Log		
	Person	Date
Data collected		____/____/____
Data entered		____/____/____
System ID		
Data verified		____/____/____
Data cleaned		____/____/____
Data transferred		____/____/____
Subject ID		

CARE RECIPIENT TRACKING FORM

PLEASE USE THIS FORM TO REPORT CHANGES IN THE STATUS OF THE CARE RECIPIENT

1. Date of form completion: ___ / ___ / _____

2. Interviewer's name: _____
Last, First

2.1 REACH II certification number: _____

3. Indicate the time period at which the care recipient's status changed.

- 1 () After screening but prior to baseline visit
- 2 () After baseline but prior to randomization
- 3 () After randomization but prior to 6-month follow-up visit
- 4 () Other

3.1 Specify _____

Indicate the care recipient's significant event.

4. () Death of care recipient

<p>4.1 Specify cause of death _____</p> <p>4.2 Specify Date of Death __ / __ / _____</p>
--

5. () Change of caregiver

<p>5.1 Relationship of new caregiver to care recipient</p> <p>() Husband () Son () Son in-law () Brother () Nephew () Grandson () Step son () Wife () Daughter () Daughter in-law () Sister () Niece () Granddaughter () Step daughter () Other (Specify _____)</p> <p>5.2 Specify why there is a change in caregiver _____</p> <p>5.3 Specify date of change __ / __ / _____</p>
--

6. () Institutionalization of care recipient

<p>6.1 Specify Date of institutionalization __ / __ / _____</p> <p>6.2 Specify where the care recipient is living</p> <p>() Personal care home () Rehabilitation facility () Long term care facility (skilled) () Assisted living facility () Long term care facility (intermediate) () Other (Specify _____)</p>
--

7. () Change of institutionalization

<p>7.1 Specify Date of Change __ / __ / _____</p> <p>7.2 Specify where the care recipient is living</p> <p>() Personal care home () Rehabilitation facility () Long term care facility (skilled) () Assisted living facility () Long term care facility (intermediate) () Home () Other (Specify _____)</p>

8. () Other

<p>8.1 Specify _____</p> <p>8.2 Date __ / __ / _____</p>
--



NIA/NINR

Resources for Enhancing Alzheimer's Caregiver Health

Adverse Events (AE)
Caregiver

Completion Log		
	Person	Date
Data collected		/ /
Data entered		/ /
System ID		
Data verified		/ /
Data cleaned		/ /
Data transferred		/ /
Subject ID		

Report Date: ___ / ___ / _____

Subject ID: _____

Reach II Acute Baseline Alerts/ Adverse Events

CAREGIVER

Please complete and fax this form to **Julie Klinger** at the Coordinating Center within 24 hours of learning about a screening alert or an adverse event. **Fax number: 412-624-4810**

1. Form completer's Name: _____
Last First

2. REACH II Certification Number _____

Data Entry codes	Specify acute event <i>(Mark all that apply)</i>	Acute Baseline Alert/Adverse Event	Event Date	Was the event treatment related?				Event Status		Resolution Date <i>(if Applicable)</i>
				No 0	Possibly 1	Probably 2	Definitely 3	Was the event resolved/controlled? No 0 Yes 1		
01	()	1. CES-D score greater than or equal to 15	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
02	()	2. CG Death	__ / __ / ____	()	()	()	()	n/a		n/a
03	()	3. CG Hospitalization	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
04	()	4. CG Institutionalization	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
05	()	5. CG Emergency room visit	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
06	()	6. CG Severe medical problem <i>(Specify _____)</i>	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
07	()	7. CG Abuse	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
08	()	8. CG other event <i>(Specify _____)</i>	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____

Comments *(not entered into PoP)*: _____



NIA/NINR

Resources for Enhancing Alzheimer's Caregiver Health

Adverse Events (AE)
Care Recipient

Completion Log		
	Person	Date
Data collected		/ /
Data entered		/ /
System ID		
Data verified		/ /
Data cleaned		/ /
Data transferred		/ /
Subject ID		

Report Date: ___ / ___ / _____

Subject ID: _____

Reach II Acute Baseline Alerts/ Adverse Events

CARE RECIPIENT

Please complete and fax this form to **Julie Klinger** at the Coordinating Center within 24 hours of learning about a screening alert or an adverse event. **Fax number: 412-624-4810**

1. Form completer's Name: _____
Last First

2. REACH II Certification Number _____

Data entry codes	Specify acute event <small>(Mark all that apply)</small>	Acute Baseline Alert/Adverse Event	Event Date	Was the event treatment related?				Event Status		Resolution Date <small>(if Applicable)</small>
								<small>Was the event resolved/controlled?</small>		
				<small>No 0</small>	<small>Possibly 1</small>	<small>Probably 2</small>	<small>Definitely 3</small>	<small>No 0</small>	<small>Yes 1</small>	
09	()	1. Threatened to hurt him/herself 3 or more times in the past week	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
10	()	2. Commented about the death of him/herself or others 3 or more times in the past week	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
11	()	3. Access to a gun	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
12	()	4. Driving	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
13	()	5. CR Death	__ / __ / ____	()	()	()	()	n/a		n/a
14	()	6. CR Hospitalization	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
15	()	7. CR Institutionalization	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
16	()	8. An event that lead to a CR emergency room visits	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
17	()	9. CR Severe medical problem (Specify _____)	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
18	()	10. CR Abuse	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____
19	()	11. CR Other Event (Specify _____)	__ / __ / ____	()	()	()	()	()	()	__ / __ / ____

Comments (not entered into PoP): _____



NIA/NINR

Resources for Enhancing Alzheimer's Caregiver Health

Adverse Events Follow-up (AF)

Completion Log		
	Person	Date
Data collected		____ / ____ / ____
Data entered		____ / ____ / ____
System ID		
Data verified		____ / ____ / ____
Data cleaned		____ / ____ / ____
Data transferred		____ / ____ / ____
Subject ID		

Report Date: __ / __ / _____

**Reach II
Acute Baseline Alerts/ Adverse Events
Follow-up report**

To be completed only when a participant(s) event status changes to resolved/controlled.

1. Form completer's name: _____
Last First

1.1 Reach II Certification Number: _____

Subject ID	Event Date	Event code	Resolution Date
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____
_____	__/__/____		__/__/____

Event Codes:

- 01 = CES-D score greater than or equal to 15
- 03 = CG Hospitalization
- 04 = CG Institutionalization
- 05 = CG Emergency room visit
- 06 = CG Severe medical problem
- 07 = CG Abuse
- 08 = CG Other
- 09 = Threatened to hurt him/herself 3 or more times in the past week

- 10 = Commented about the death of him/herself or others 3 or more times in the past week
- 11 = Access to a gun
- 12 = Driving
- 14 = CR Hospitalization
- 15 = CR Institutionalization
- 16 = CR Emergency room visit
- 17 = CR Severe medical problem
- 18 = CR Abuse
- 19 = CR other