

REACH II INTERVIEWER INSTRUCTION MANUAL

General guidelines and specific, question-by-question instructions for completing the REACH II battery interviews and forms.

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REACH II INTERVIEWER INSTRUCTION MANUAL

Introduction: The purpose of the following section is to prepare field interviewers for the task of completing the REACH II measures interviews. When completely familiar with the information contained in this section the interviewer should be able to handle all aspects of interaction with the respondent (or caregiver, these terms will be used interchangeably), as well as all aspects of data coding and record-keeping relating to the interview. These instructions assume that the interviewer has already met all of the other interviewer certification criteria. Furthermore, before any interviewer is eligible to conduct an interview in the field, he or she must have logged at least six practice sessions with the full core measures battery. It is the interviewer's job to understand the purpose and intent of each section and each question in the interview. More information about each section can be found in the Rationale and Description of Measures portion of the manual. The procedural guidelines that follow are to be observed after the interviewer has obtained consent from the caregiver to conduct the interview.

GENERAL INSTRUCTIONS:

Before the interview: Interviewers should be completely prepared and have all of the necessary materials on hand. Necessary items: consent forms, questionnaire with subject ID# written in, pen or pencil, three or four sheets of plain blank paper, wristwatch, complete set of response cards, and the address and phone number of the respondent. Mental preparation should include knowing the names of the respondent and care recipient, understanding the purpose of the study, knowing the name of the funding agency, the telephone number of the site and the local Alzheimer's Association, and having some familiarity with the neighborhood in which the interview will take place.

Professionalism: Interviewers should make every effort to speak and behave in a professional manner. This means that the interview should be conducted efficiently, with as little digression as possible. While remaining polite and pleasant, the interviewer should speak clearly and in a neutral tone. When interviewing older respondents, it may be necessary to speak more slowly, at a slightly higher volume, and make additional eye contact if any indication is given that there is difficulty hearing the questions. It is extremely important that the interviewer does not say or do anything that might bias the respondent's answers (see interviewer training materials for more complete description of ways an interviewer can bias an interview).

Difficult situations: In a few cases, you may encounter difficult situations. Perhaps the most common occurrence is when the respondent becomes tired or fatigued. This is especially likely if the respondent is not in good health. If the respondent appears to be having difficulty concentrating or is becoming frustrated with the interview, offer to take a short break and then return to the interview.

Another difficult situation is when the respondent begins to cry or becomes upset. Always attempt to be as empathetic as possible, and ask if a pause or a short break is needed. The interviewer might state, "I know it's very difficult to talk about some of these things. Would you like to take a short break or should we continue with the interview?" If a break is taken, it may be necessary to reinstruct the caregiver on the particular form being administered.

Another difficult situation occurs when the care recipient frequently interrupts or disturbs the interview, because he or she is "acting out" or requires supervision. Always allow the caregiver to take the time to attend to the situation if necessary. By securing a private environment at the start of the interview, this situation may be avoided in some cases. Sometimes the caregiver will indicate that the recipient is having a "bad day" and it will be best to reschedule the appointment.

If possible, it is always best to try to complete the interview in one session, but in cases in which the respondent is very tired, has difficulty concentrating or becomes very upset, or the recipient is in need

of immediate attention, the interviewer may need to offer to complete the interview at another time. In such cases, try to schedule the session at the earliest possible time that is convenient for the participant. All additional sessions should take place within one week of the initial session.

Handling requests from the caregiver: Occasionally a respondent may ask for some type of assistance from the interviewer. These requests may be for support services, adult day care, financial help, medical assistance, help with family issues, help with the care recipient’s behavior problems, or other kinds of help. In general, such requests should be handled by providing the caregiver with the telephone number of the local Alzheimer’s Association, and by suggesting that the caregiver contact a family member to discuss the need.

Emergencies: In the case of a medical or other emergency, the caregiver should be directed to call the local emergency assistance number (“911” or other hotline number). If the caregiver is unable to call, the interviewer should do so. In non-emergency situations, such as when the caregiver asks what he/she should do about a medical condition such as a cold, the interviewer should advise the caregiver to contact his/her family physician, or provide the number of a physician finding service if he/she has no family doctor. For procedures on how to handle other emergency situations such as thoughts or comments about committing suicide, severe depression, or physical abuse, see Section 7 of the Manual of Operations for “Adverse Events/Acute Screening Criteria”.

Data completion cover sheet : All the forms have a data completion cover sheet which appears as the first page of the individual form or the specific battery. Therefore, there is only one data completion cover sheet for all of the forms that make up each battery, including the project evaluation which appears at the end of the follow-up battery, bereavement battery and placement battery. These sheets need to be filled out after the information is gathered or interview is completed. Below is a sample of a form data sheet.

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

The interviewer is responsible for filling out the “data collected” line. Under the person column enter the name of the interviewer. Under date enter the date that the form was completed. In addition the interviewer enters the subject ID at the bottom of the table. The remainder of the form will be filled out by the data entry specialist.

Interview cover page: Each of the batteries (baseline, follow-up, bereavement, placement and discontinued) will have an interview cover page. This page records the time the interview was started and time the interview was completed as well as the interviewer’s name and REACH II certification number. This page also records again the consent of the caregiver and care recipient for the baseline interview only and asks the interviewer to record the alerts that occurred. Only the caregiver CES-D

score alert will be applicable for the placement and bereavement batteries. In this way, the consent and alerts are recorded on the front page of the interview and can be responded to easily by the interviewer, project coordinator and others.

Question wording and question order: It is imperative that the wording of the questions, and the order in which the questions are read, does not vary. The interviewer should simply begin with the introduction, read through the questions in the first form, read the introduction to the second form, read the questions in the second form, and so on, until the entire interview is completed. If a question or several questions have been skipped by accident, the interviewer should return to those questions as soon as the error is noticed, and make note of the occurrence on the form.

Recording responses: The response that the caregiver provides for each question should be recorded immediately, before moving on to the next question. In most cases, recording the response involves simply making a clear mark in the appropriate space on the form. Always record a response, and only one response, for each question. Please make certain that the mark you make stays entirely within the space intended for it. Marks that appear within more than one space will be impossible to enter into the computer. Also, it is important to refrain from making notes in the margins or elsewhere on the forms unless necessary or required.

“Not Applicable”, “Refused” and “Unknown” response options: The table below provides the data code values for not applicable, unknown and refused responses for the different types of variables. The following not applicable, unknown and refused codes refer to all forms (except the MMSE).

| Variable Type | Not Applicable Value | Unknown Value | Refused Value |
|---------------|----------------------|---------------|---------------|
| Number | -2 | -3 | -4 |
| Text | -2 | -3 | -4 |
| Date Code | 02/02/1802 | 03/03/1803 | 04/04/1804 |
| Time Code | 98:00 | 97:00 | 96:00 |

“Not Applicable” – this response is coded “-2”

“Unknown” – this response is coded “-3”

“Refused” – this response is coded “-4”

The number of not applicable, unknown and refused responses should be kept to a minimum.

REFUSED (-4): If the caregiver refuses to answer any particular question, be certain to mark the “refused” response option. The code for “refused” is used when the respondent repeatedly states that he/she does not wish to answer the question. Refusals typically occur on questions that offend or threaten the respondent. For example, when a respondent is asked about helping the CR with bowel or bladder management, the response might be “That’s too personal; I don’t wish to answer that.” The interviewer should not try to force a response in such cases. A simple reminder about confidentiality, such as “I’d like to remind you that this information will be kept strictly confidential,” or about the purpose of the study, such as “This information will only be used to try to improve conditions for in-home caregivers,” may yield a response. If that fails, simply mark the “refused” option, and move on to the next question.

There is an important exception to the above rule: when asking the question about the respondent’s income, interviewers should probe no further than what is provided in the wording of the question. In other words, if the respondent indicates that he/she does not wish to answer this particular question, the interviewer should mark “refused” and move on.

UNKNOWN (-3): The “unknown” code is used when the respondent reports that, after probing, he/she does not know the answer to the question asked. Try to avoid obtaining “unknown” responses. It is important to avoid marking the “unknown” option if possible because these responses cannot be used in later analyses, and in some cases, information from the entire form cannot be used if information is missing for just one of the questions. This option should only be used when the caregiver genuinely does not know the answer. Some respondents will say “I don’t know” even though they are able to choose one of the options when they are prompted. You may need to remind him/her that “Although none of these options may match exactly how you feel, I need you to choose the closest one,” or “Remember there are no right or wrong answers to these questions, we are interested in your opinion.” Again, the respondent should not be pushed to the point of aggravation. If he/she cannot answer the question after prompting, mark the “unknown” response option.

If at any point during the interview, the respondent indicates a prior response was incorrect, make the appropriate change. If the respondent blatantly contradicts a prior response, the interviewer should probe to clarify the discrepancy.

Frequency responses: The following should be applied to all frequency responses for all forms. Every day of the month is equal to 30 days. Once a week is equal to four times per month. Every other week is twice per month. Only weekdays is 20 days per month. Only weekends is eight times per month.

Time estimates: The following are some general guidelines that will help the interviewer obtain time estimates: In administering these types of questions, respondents frequently find it difficult to provide answers without extensive probing. The reasons for these difficulties can be categorized as:

1. Variation in frequency and amount of care, making it difficult to arrive at an average.
2. Unfamiliarity of the process, i.e. caregivers are often not used to counting or timing instances of care.
3. Distinguishing between different types of care, i.e. a caregiver may know that during a 3-hour visit she cleaned the kitchen, prepared a meal, helped the care recipient take a bath, changed the bedding, and called the VNA to find out why an appointment had been missed, but thinks of these things as having been done together, not separately.
4. Undue concern with the precision of a numeric answer, the caregiver may believe that “don’t know” is a more accurate answer than “15 minutes” when she is unsure where in the range of 10-20 minutes the answer falls.

To overcome these difficulties and collect the most accurate data possible, the following probing instructions for administering questions about frequency and amount of help given to care recipients should be followed. These instructions were originally developed by the New England Research Institute (NERI).

- 1) When the respondent indicates that the answer varies from time to time depending on a number of factors, remind the respondent of the time frame of the question (e.g. the last week) to make sure variations before and after that time are excluded, and probe for an estimate or best guess for the average frequency or amount of time spent during that period. If the question is phrased in terms of the number of “times” a particular type of care was provided during the period, you do not need to probe for the meaning the respondent is attaching to “times.” If the respondent says help is given every day of the week, the answer “7” is acceptable. If the respondent says, on the other hand, that help is given three times a day, each day of the week, the answer “21” is also acceptable. What is necessary is that in the follow-up question about the amount of time each “time” the care is provided, the same definition of “time” is maintained. For example, if the respondent says help is given preparing meals every day (answer 7), the number of minutes each time refers to the total time in the average day the respondent prepared meals for the care recipient. On the other hand, if the number of times has been recorded as 3 times per day = 21 times, then the question about amount of time needs to be the

average time for preparing one meal. Assuming, for example, 1 hour is spent in preparing each meal, the same measure of 21 hours/week will be arrived at either as 7x3 or 21x1.

It is often helpful to record the respondent's verbatim responses in the margin of the question and then convert into our measures after the interview, as long as you are sure all needed information to make the conversion has been obtained. For example, an answer of 2 hours a day can be converted into 120 minutes by the interviewer. On the other hand, an answer of "I've helped obtain social services for him twice this year" would require the probe: "Have either of those times been during the last week?"

2) When the caregiver becomes irritated by asking for numeric measure of things they do not count or time, explain the importance of these measures for yielding valuable information relating to the cost of care and the possible burden on caregivers which are needed to better understand and improve the care required by recipients.

3) When the caregiver is having difficulty dividing time between multiple tasks, probe by asking for "just a best guess" as to how much of the total time is spent on average with each activity.

4) When the caregiver is very concerned about giving a "wrong" answer in the sense of being imprecise or not 100% certain, be prepared to explain how much more valuable the answer is when, for example, the caregiver knows that help is given with shopping at least once a week but not every day. The following dialogue between an interviewer and a caregiver illustrates possible probes. "How many times during the last week did you help your wife shop?" "I don't know. I don't count how often we shop." "Just as a rough estimate, how many times in the last week would you say you helped her shop?" "I told you, I don't know. It was at least once a week." "Is it every day?" "Of course it's not every day. Don't be silly." "OK, that means it was somewhere between 1 and 6 times last week. Given that, do you think you might be able to guess any closer to the number of times you helped shop during the last week?" "I guess 2 or 3 times would be right." "Great, which should I put down, 2 or 3?" "Well, if you have to have one number, I guess it's more often twice a week than three times." "Thanks very much. I know making estimates is always difficult, but it really helps us."

5) Some respondents quickly figure out the kinds of answers you need and train themselves to respond helpfully. Others may be more resistant and require extensive probing with each question. A few may be wholly unwilling to do what we want. Your job is to get the best answers possible, without leading the respondent. This requires probing that is unbiased, tactful, sympathetic to the respondent's difficulty, but committed to getting an answer. A "don't know" answer to frequency items really means "I am either unwilling or incapable of making a guess about the frequency or amount of care I give." Usually, respondents will work with you to come up with a "best guess" about frequency items.

Errors in recording: Sometimes the interviewer might make a mistake in recording the answer. If it is necessary to change an answer, be sure to give the reason. Never erase if you marked the answer by mistake; scratch out the wrong answer and mark (M.E.), meaning "my error", next to the error. If the respondent changes his/her mind after you have already marked the answer in a pre-coded question, scratch out the wrong answer and note next to it (R.E.) meaning "respondent error." Remember to initial and date all changes.

What to read aloud: The individual forms contain instructions to the interviewer regarding questions which must be included, or should be skipped, contingent upon the response of the caregiver. Instructions to the interviewer and other information which should **NOT** be read aloud during the interview are always printed in standard unbolded font. In other words, while conducting the interview, read aloud all of the text which appears in *italic bold* font, but do not read aloud anything in standard unbolded font. For some questions, the interviewer must read aloud all of the response options, in

other cases this is not called for. Throughout the interview, the same rule applies: Read aloud only the text that appears in *italic bold font*. In situations where the same set of response options are used for three or more consecutive questions, it may not be necessary to repeat the response options. Read through them the first two times, and then use your judgment as to whether further readings are necessary.

Throughout the interview, the abbreviation "(CR)" appears quite frequently. CR stands for care recipient, but that is NOT what should be read. Prior to conducting the interview, find out the name of the care recipient, and substitute it whenever "(CR)" appears. If the care recipient is the mother or father of the caregiver, it may be more natural to replace "(CR)" with "your mother" or "your father" rather than the recipient's name. Please note, however, that for other relationships, such as siblings, aunts, uncles, or grandparents, substituting the relationship (e.g., "your aunt") may be confusing if there is more than one sibling, aunt, uncle, or grandparent. Using the name of the recipient will help to personalize the interview.

About response cards: Some of the forms contain a large number of questions that all have the same set of response options. The directions for these forms will contain instructions to the interviewer to provide a card to the caregiver which lists the response options. In these cases, the interviewer should read through the response options after the first and second questions to ensure that the caregiver understands them. From then on, it should no longer be necessary to read the response options aloud for that set of questions. Before moving on to the next set of questions, remember to remove the response card that is no longer pertinent.

Additional response cards have been prepared, and interviewers may wish to use response cards for additional scales or items. Response cards are required, however, whenever instructions at the beginning of the form refer the interviewer to a response card.

Some respondents may tell you that they cannot read or that they are unable to see the information on the response card. If this happens, you should continue repeating the response options as often as necessary.

Recording the Subject ID and completing the Interview Cover Page: The Subject ID number is recorded at the top right hand corner of each page. This number should be obtained from the participant list at your site, and recorded on all pages *prior to conducting the interview*. The reason this should be written on every page is to avoid any lost data in case any of the pages become detached.

The Interview Cover Page contains a number of items, and not all are completed prior to the interview. It is recommended that the interview date not be recorded until after the interview has taken place, because missed appointments are possible, or the interview might have to take place over two sessions. Remember, the baseline interview must be completed within 30 days of screening or the individual needs to be screened again. Other items include the visit time point at which the interview is taking place (baseline or 6 months), the name of the person completing the form, and certification number. To save time, do not record the date, ID number, your name or the certification number *during* the interview.

Using Auto-Subject ID

All forms and batteries {except the Screening form (SC), SPMSQ (SP), and Participant Information (PI)} now have the web based "Auto-Subject ID" feature. In order to take advantage of the Auto-Subject ID feature, prior to printing, enter the Subject ID on the first page of the battery/form and the ID will automatically be entered on every subsequent page.

*Note that because of some web browser default settings, once a Subject ID is entered on to a battery/form, it will NOT automatically be removed unless the entire web browser is closed. Prior to printing any batteries/forms from the REACH II website, **ALWAYS REMEMBER TO CHECK THAT***

THE APPROPRIATE ID HAS BEEN ENTERED ONTO THE FORM.

After the interview: After concluding the interview, it is important that you go through the questionnaire page by page, to check for missing data, or items you need to code or record more completely. It is best to do this as soon as possible after the interview while your memory is still fresh. This is also a good time to record the date, session, and other required information on the form cover pages. If you discover that you skipped any items during the interview, call the respondent and administer these items over the telephone.

Subject identification numbers: In the REACH II project there is one subject identification number assigned to the participant after screening (see the screening Q X Q for more details). It is used for all participants that are screened regardless of whether they were eligible or not. It is made up of four digits and three characters. The first digit is the site number. The next three digits are the sequential numeric numbers, and the last three characters are the name code (the first three letters of the last name). Below is an example:

| | | |
|-----------|-------------------|-----------|
| 3 | 001 | SCH |
| Site Code | Sequential number | Name Code |

Key values are used to uniquely identify records within the database. The ID is comprised of a combination of subject identifiers to uniquely identify a participant (site, a 3-digit sequential number, and 3-letter name code). For report formatting purposes, the editing system combines these key values and displays them as one number.

Eligibility determination and assignment of REACH II Identification Number:

The flow charts on the next 4 pages demonstrate the process of enrolling and randomizing participants. It consists of Initial Eligibility Assessment, Screen Completion, Baseline Assessment, and Randomization Process.

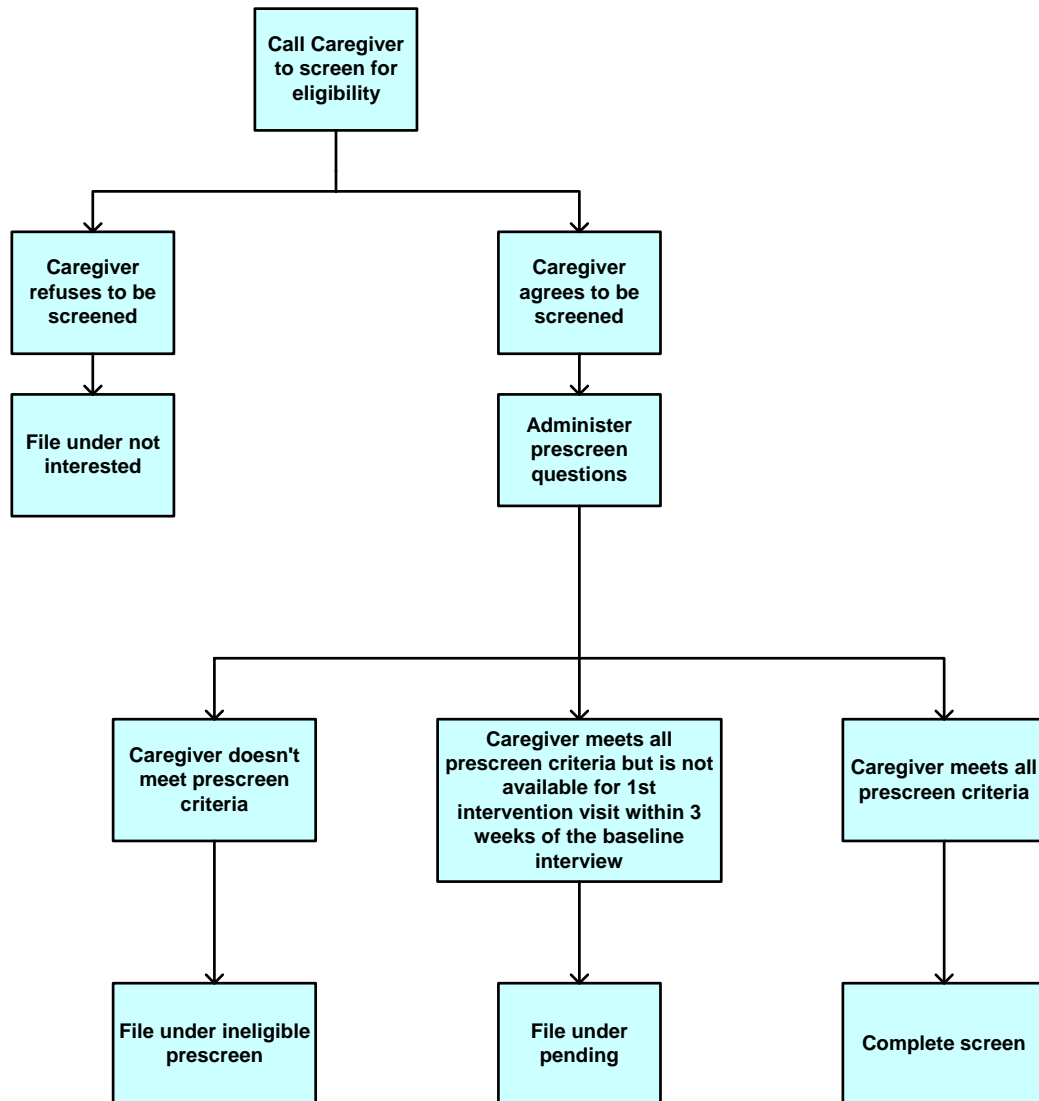
When the participant is first contacted the screening process is started. If the participant refuses to be screened, then the participant's flow through the REACH II project ends. If the participant agrees to be screened the pre-screening section of the screening form is administered (see screening form Q x Q for more details). If the participant is ineligible for the project based on the pre-screen questions, then the participant's flow through the REACH II project ends. If the participant is eligible based on the pre-screen questions, then the screening form is administered. At this point there are three possible eligibility states; **ineligible**, **eligible**, and **maybe**.

Ineligible, Eligible: If after administering the screening form, it is determined that the participant is either ineligible or eligible, the screening form is entered into pop and the Study ID is generated and assigned (see screening form Q X Q for more details). Ineligible participants' flow through the REACH II project ends.

Maybe: If after administration of the screening form the participant's eligibility status is "maybe," the PI or Study Coordinator must be consulted and an additional assessment may be administered to determine the participant's eligibility status. *Note that the screening form should not be entered into PoP until the maybe status has been changed to either ineligible or eligible.*

REACH II Detailed Project Flowchart

A. Initial Eligibility Assessment

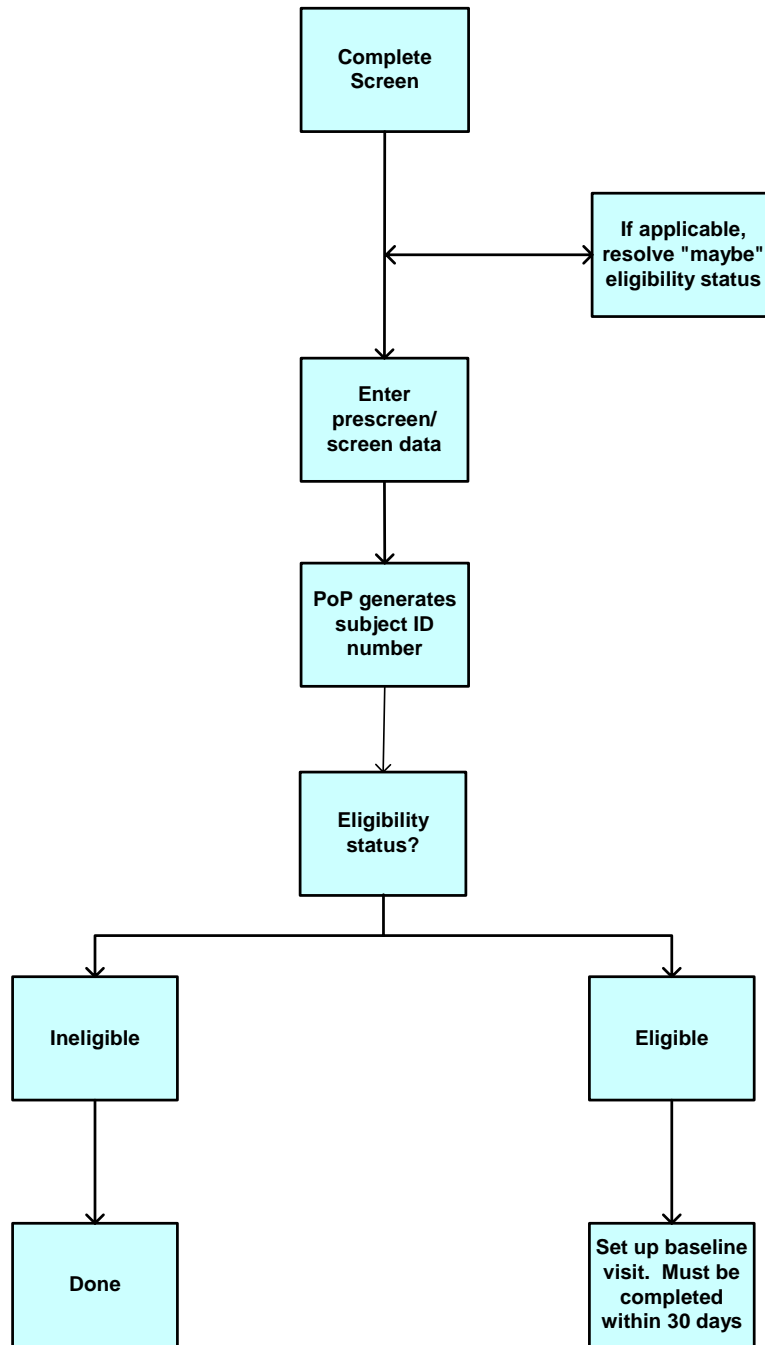


Windows:
 Screen to Baseline - 30 days
 Baseline to Randomization - 3 days
 Baseline to 1st intervention visit - 21 days (goal 1 - 10 days)
 6-month assessment - 7 days prior and 30 days after due date
 Two week turnaround from form completion to data entry

Off Protocol Events:
 Baseline interview occurs > 30 days after screen
 Caregiver randomized > 3 days after baseline interview
 First intervention visit outside of 21 day window
 Six month interview completed outside of -7/+ 30 day window

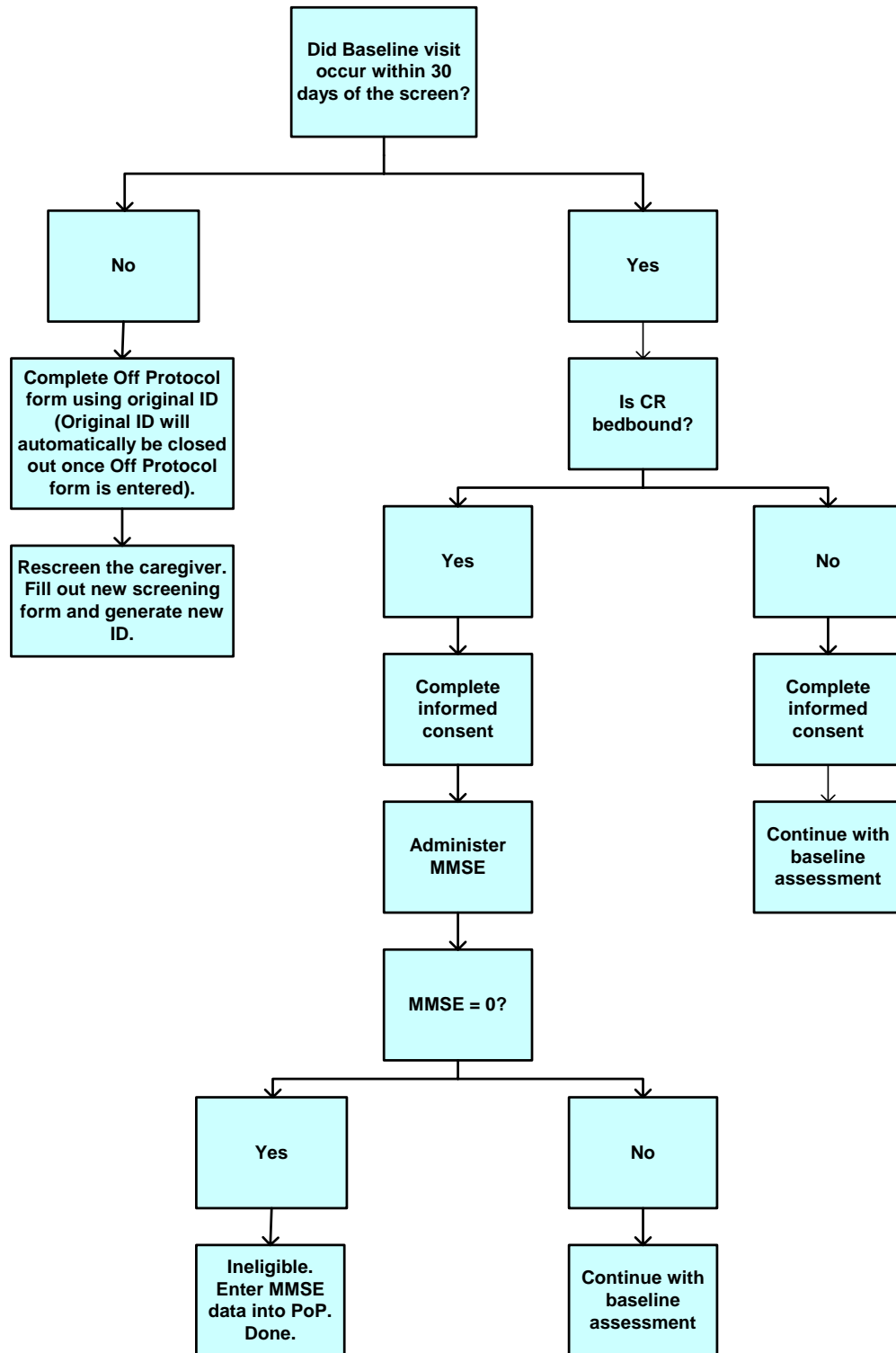
REACH II Detailed Project Flowchart

B. Screen Completion



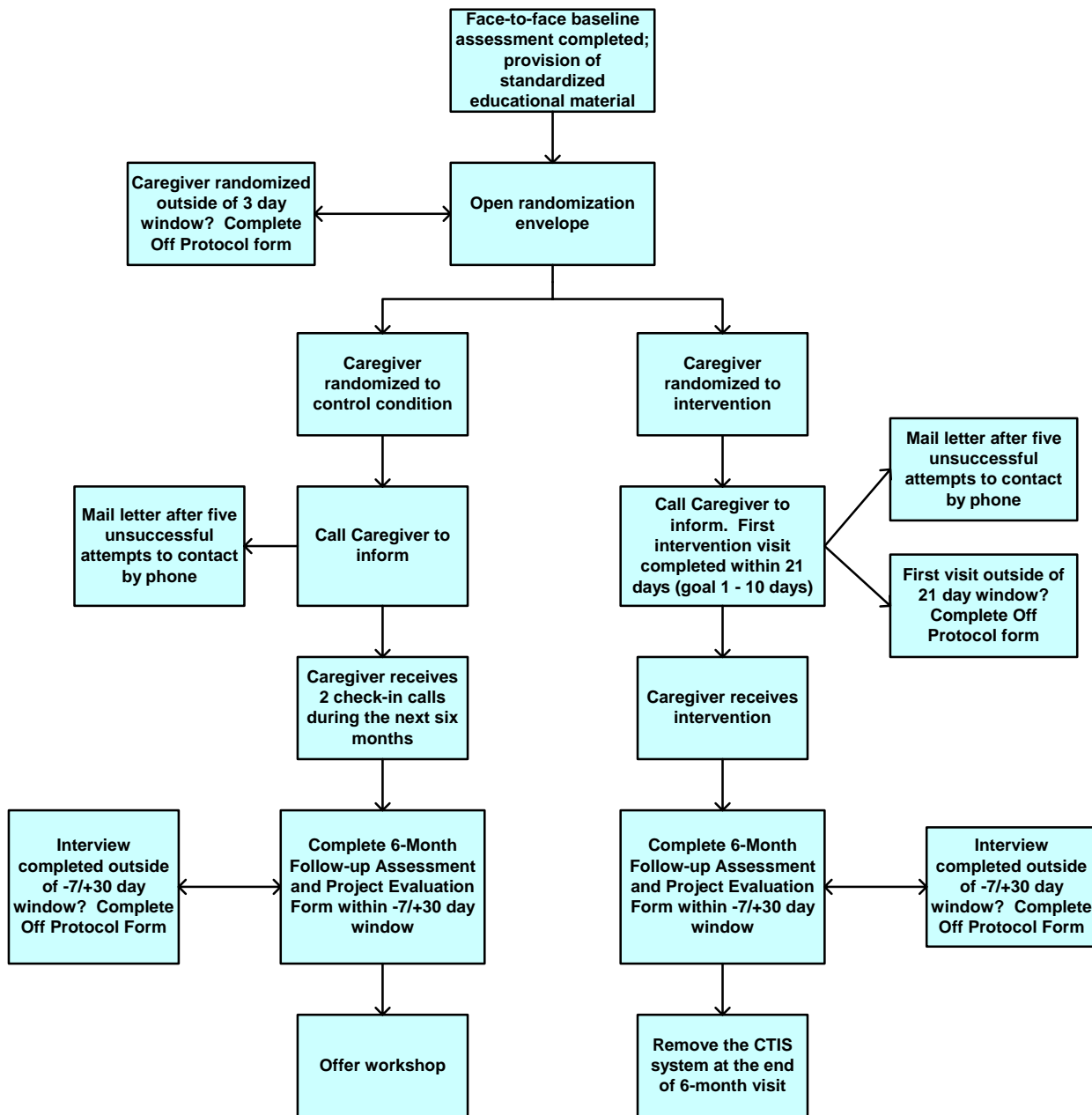
REACH II Detailed Project Flowchart

C. Baseline Assessment



REACH II Detailed Project Flowchart

D. Randomization through 6 Month Follow-up



Transition Batteries

In the event that there is a transition of the (CG) out of the mainstream of continuing participants, there are transition batteries that should be administered. There are four possible ways for the (CG) to undergo transition: the (CR) dies, the (CR) is placed in a long-term care facility, (CG) relinquishes caregiver responsibilities to someone else or the (CG) elects to discontinue (or drop out) of the study. When a transition occurs, the following procedures should be followed.

A bereavement battery should be completed at the six-month follow-up visit when the care recipient has died between the baseline and follow-up time points.

A placement battery should be completed when the care recipient has been placed in a long-term care facility, such as a personal care home or an assisted living facility. The placement battery should not be administered for temporary situations, such as an acute hospitalization or a stay at a short-term rehabilitation facility. If when attempting to schedule the follow-up interview the care recipient is in a short-term care facility, every attempt, within protocol, should be made to wait to schedule the interview when the care recipient's place of residence has stabilized, that is the care recipient returned home or is admitted to a long-term care facility. However, it is possible that the care recipient's status may not stabilize within the interview window. If this occurs, the interview should be attempted, using the placement battery, with the knowledge that the caregiver will not know the answer to some questions. Under these conditions, an "unknown" should be recorded.

In the case of bereavement or placement, the Recipient Tracking (RT) form and the Adverse Event (AE) form should be filled out as soon as the site learns of the changed status of the (CR).

If the caregiver relinquishes caregiving duties to someone else (e.g. another family member) either in the same home or because the CR has changed residence to live with another family member, it is essential to continue collecting data from the original caregiver. The standard follow-up battery should be administered. Please note that under this circumstance, the caregiver may not be able to answer some of the questions regarding the CR's status and an unknown response may be applicable.

In the case of a drop-out, the Off-Protocol (OP) form should be filled out immediately. If the participant drops out after the baseline interview is complete and before the 30-day window for the six month follow-up interview, the caregiver should be told "I am sorry to hear you do not wish to participate any longer. Is it alright if I contact you in (number of months until six month follow-up time point) and check in?" Every attempt should be made to have the caregiver agree to allow you to contact them at that time. At the six month follow up time point, the caregiver should be contacted and asked whether they would consider completing the entire follow-up battery at this time. Every attempt should be made to complete the entire follow-up battery, even if they have moved and the follow-up battery must be administered over the phone. If the caregiver is not willing to complete the entire follow-up battery, then every attempt should be made to have the caregiver complete the Discontinued Battery at this time.

If the caregiver does not want to be contacted, he or she is considered "inactivated" and is no longer contacted for REACH II related visits.

RANDOMIZATION FORM (RF)

PURPOSE: This form is used to randomize eligible participants either to an intervention or a control arm.

TIME OF DATA COLLECTION: Within 3 days of the baseline interview.

REQUIRED RESPONSE CARD(S): None required.

GENERAL INSTRUCTIONS:

The Randomization Form consists of three parts: Part I contains information needed to request randomization be completed for a participant; Part II consists of the response to Part I (***this is the information used to notify sites how participants are randomized – to intervention or control***); Part III is completed to confirm that the site received the randomization.

Completion Instructions:

Part I

Sites are required to complete Part I of the Randomization Form to request randomization and fax it to the Coordinating Center, **Fax 412-624-3775**. At the same time, the sites are required to enter the subject ID and Participant Name on the randomization log sheet provided by the coordinating center. *This process must be completed within 3 days after the baseline interview is completed.*

Part II

The Coordinating Center will complete Part II of the form, to reveal the randomization arm (intervention or control) and fax it back to the sites. At this time, the sites are required to enter the randomization number, the treatment arm and the randomization date on the randomization log sheet. *This process will occur during the day of request, provided that the request occurs during prime time working hours (8 AM – 4 PM eastern time).*

In cases where requests for randomization occur during non-prime time working hours (4 PM – 8 AM eastern time) the Coordinating Center will return the randomization response the following morning.

Example 1: If a site faxes a request for randomization at 10 AM EST during a week day, the Coordinating Center will return the randomization response prior to 4 PM EST during that day.

Example 2: If a site faxes a request for randomization at 6 PM (or after) EST Monday through Thursday evening, the Coordinating Center will return the randomization response the next morning.

Example 3: For cases where requests for randomization occur during non-prime time working hours on Friday, Saturday, or Sunday, the Coordinating Center will return the randomization response the following Monday Morning.

Part III

Upon receipt for randomization, Part III of the Randomization Form must be completed to confirm receipt of randomization and faxed back to the Coordinating Center. *This process must be completed within 24 hours after receipt of randomization response.*

After completion of the three part process, the form should be entered into PoP.

SPECIFIC INSTRUCTIONS:

1. All time fields should be entered as local (and military) time.
2. Question 1 of Part II – Randomization Response, the “Date of randomization” is the date used for all data management and analysis activities.
3. This form is to be completed only by specified site coordinators who have been trained and certified in this randomization process. This number is assigned to each coordinator by the Coordinating Center.
4. The numerical code for Intervention = 1, the numerical code for control = 0.

OFF PROTOCOL (OP)

- PURPOSE:** This form is used to document any occurrences which are protocol variations (do not adhere to standards established in the protocol).
- TIME OF DATA COLLECTION:** At the time of awareness of any occurrences which are protocol variations.
- REQUIRED RESPONSE CARD(S):** None.

GENERAL INSTRUCTIONS:

Protocol deviations can occur at different time points or can be initiated by a caregiver who chooses to discontinue in the study. This form should be filled out for any variation, unless it is clear that the variation is still within the protocol. Most notably, if there is a change in status of the care recipient such as items 25.4.2 and 25.5 but the caregiver does not discontinue participation in the REACH II project, then this information is *not* recorded on this form but is recorded on the Care Recipient Tracking (RT) form and, if appropriate, on the Adverse Events (AE) form as well.

SPECIFIC INSTRUCTIONS:

Subject ID: Enter the subject ID that is generated by the active/correct screening form. In the case where a subject ID was generated and that screening becomes invalid, the off protocol will have the new screening number entered in the subject ID space, and the old screening ID will be entered in the space provided in question 4.1.

Question 1: Enter the date that this form was completed, in the form two digits for month (e.g. 01 for January, 12 for December), two digits for day (e.g. 01, 02, 03...., 31), and four digits for the year. August 14, 2002 would be recorded as 08/14/2002. This is not necessarily the date that the off-protocol event occurred but the date that this form was completed. If the caregiver is off-protocol because the caregiver has discontinued participating in the REACH project and a discontinued interview (DI) has been administered, this date should be the same as the date of the discontinued interview (DI).

Question 2: After entering the name of the interviewer, enter the certification number of the person conducting the interview. This number is assigned to each interviewer by the Coordinating Center. Completion of this form should only be done by individuals certified for the tracking forms. If for some reason this form was completed by a non-certified individual leave this space blank.

PROTOCOL DEVIATIONS (please check all that apply)

SCREENING

3. Rescreening occurred after baseline.

Check this item if the baseline interview was conducted more than 30 days after the initial screening **and** the rescreening did not occur before the baseline interview. *The new screening needs to be done at the same time as this Off Protocol (OP) form is completed.* The subject ID generated from the new screen is entered in the space on the top right hand corner of this form. The subject ID from the first screen will be entered in item 3.1. If the baseline battery has not been entered into PoP, the subject ID on the baseline battery needs to be changed to match the new screen. If the baseline battery has been entered into PoP already, contact the data center to change the ID for the entered baseline battery.

RANDOMIZATION

4. Ineligible participant randomized.

Check this item if a caregiver was admitted to the study but was later found out to be ineligible when randomized.

5. Wrong treatment assigned.

Check this item if the treatment was wrongly assigned by the coordinating center.

6. Wrong treatment given.

Check this item if the caregiver was randomized to a group and then received the other group treatment, control person receives intervention or intervention person receives control condition.

7. Randomization more than 3 days from baseline interview.

Check this item if the randomization was conducted more than 3 days from the baseline interview.

8. Randomization completed prior to baseline interview.

Check this item if the participant was randomized before the baseline interview was completed.

9. Eligible participant not randomized; specify: _____

Check this item if the participant was not randomized but was eligible for the study.

CORE BATTERY

10. Interview conducted by non-certified individual.

Check this item if an interview was done by someone who has not been certified. If the entire interview was conducted by a non-certified interviewer, it is not to be entered into the database. If this occurred at baseline, the caregiver is not eligible for the study and an Off-Protocol form does not need to be filled out. If this occurred at a follow-up assessment, an Off-Protocol form is completed indicating that the entire interview was conducted by a non-certified interviewer.

11. Interview completed over the phone.

Check this item if the interview was completed over the phone instead of in person. The one exception is the discontinued battery which is designed to be conducted over the phone and would not be off protocol.

12. Follow-up missed.

Check this item if one of the three follow-up contacts is missed: 3-month control call, 5-month control call or six month follow-up visit. In question 12.1 check the specific follow-up contact that is missed.

Special notes regarding the 3- & 5-month control calls:

- *If 4 weeks has passed from the actual due date of the 3-month control call, the call is considered as missed - no further attempt should be made to complete the call.*
- *If 4 weeks has passed from the actual due date of the 5-month control call, the call is considered as missed – no further attempt should be made to complete the call.*
- *A 5-month control call must be made prior to a 6-month follow-up interview.*

13. Follow-up completed outside of the window.

Check this item if one of the three follow-up contacts is outside the window: 3-month control call, 5-month control call or six month follow-up visit. In question 13.1 check the specific follow-up contact that is outside the window. The 3-month control call and the 5-month control call must take place within

the window prescribed (two weeks prior through two weeks past the due date for the 3-month or 5-month call). Check the remaining option if the caregiver's follow-up visit was not conducted within the six month follow-up window (7 days prior + 30 days past six month time point) but the caregiver remains active in the study.

14. Project Evaluation not completed.

Check if the project evaluation was not completed at the end of the follow-up, bereavement or placement battery interview.

15. Mini-Mental completed at a different time than core battery.

Check this item if interviewer needed to complete the mini- mental at a different time than the battery. A baseline battery may not be completed at the same time as the mini-mental, due to a score of greater than 23 on the MMSE and a need to get a MD diagnosis of dementia. But if a baseline battery or follow-up battery is completed, the mini- mental should be completed at the same time.

16. Mini-Mental not completed.

Check this item if the mini-mental is never completed on the care recipient.

17. Interview required multiple sessions.

Check this item if the interview was stopped before it was completed and required more than one visit to complete the interview.

INTERVENTION REFUSALS

18. CTIS phone.

Check this item if the caregiver refuses to have the CTIS phone system installed in his or her home.

19. Participation in CTIS support groups.

Check this item if the caregiver refuses to join a CTIS support group.

20. Caregiver notebook.

Check this item if the caregiver does not accept the caregiver notebook from the interventionist.

21. Home visits.

Check this item if the caregiver refuses to have the interventionist come to his or her home.

22. Behavioral prescriptions.

Check this item if the caregiver refuses to participate in the behavioral prescriptions developed for his or her intervention.

23. Stress management module.

Check this item if the caregiver refuses to participate in the stress management module presented by the interventionist.

24. Further participation in intervention.

Check this item if the caregiver refuses to participate in the intervention entirely.

ENDPOINT DATA UNAVAILABLE (Check all that apply)

25. Caregiver withdraws consent.

25.1 Change of caregiver.

Check this item if the primary caregiver has changed and the original caregiver no longer wishes to participate in the REACH II project. If there is a change of caregiver but the original

caregiver continues to participate in REACH II this information should not be recorded here but should be recorded on the Care Recipient Tracking (RT) form. Do not check this item if the reason for the change of caregiver is death of the caregiver. That information should be recorded in item 27.

25.2. Caregiver felt that the study was too time consuming

Check this item if the caregiver states that they will no longer participate in the REACH II project because the REACH II project is taking up too much of their time.

25.3. Caregiver is displeased with randomization

Caregiver has been assigned to either the intervention group or control group and they decide they are unhappy with this assignment and withdraw consent to participate.

25.4. Illness

Check this item if the caregiver states that he or she will no longer continue in the REACH II project secondary to any illness of either the caregiver or the care recipient. This item will include situations where the caregiver or care recipient has been institutionalized in a long term care facility and chooses not to continue participation in the project.

25.5 Care Recipient Death

Check this item if the caregiver states that he or she will no longer continue in the REACH II project due to the care recipient's death.

25.6 Other reason; specify: _____

Specify another reason not listed that the caregiver chooses to discontinue in the study.

26. Caregiver cannot be located / location unknown

27. Caregiver Death

Check this item if there is a death of the caregiver.

OTHER PROTOCOL DEVIATION

28. Other: Specify: _____

Specify another reason not listed that the subject is off protocol.

CARE RECIPIENT TRACKING (RT)

PURPOSE: This form is used to record any significant event that changes the status of the care recipient.

TIME OF DATA COLLECTION: At the time of awareness of any significant event that changes the status of the care recipient.

REQUIRED RESPONSE CARD(S): None required.

GENERAL INSTRUCTIONS:

This form is completed if the care recipient (CR)'s status has changed permanently, meaning no further change is anticipated. Some of the changes that are recorded on this form are also reported on the Adverse Events (AE) form. Be sure to check if both a Care Recipient Tracking (RT) form and an Adverse Events (AE) form need to be completed. If the caregiver's participation in the REACH project discontinues due to any reason, the appropriate information is also recorded on the Off-Protocol (OP) form.

This form may be completed multiple times during the course of the study. For example, a care recipient may be institutionalized for several months and then returned to their original home. This would be recorded as two transitions: the first move would be indicated as an institutionalization (#6) and the second move (return to home) would be categorized as a change of institutionalization (#7).

Record all dates using two digits for the month (e.g. 01 for January, 12 for December), two digits for the day (e.g. 01, 02, 03...31) and four digits for the year (e.g. 2002, 2003).

SPECIFIC INSTRUCTIONS:

Question 6 & 7: The institutionalization of a care recipient or a change of the institutional status of a care recipient is to be indicated on this form only for long-term changes, such as placement in a personal care home or an assisted living facility. If the care recipient living arrangements are temporary, such as an acute hospitalization, then the care recipient tracking form is not completed. In these questions you will indicate (6.2, 7.2) the care recipient's new living situation.

CAREGIVER ACUTE BASELINE ALERTS/ ADVERSE EVENTS (AG)

PURPOSE: To quickly collect vital information about an acute baseline alert or an adverse event.

TIME OF DATA COLLECTION: At the time of awareness.

REQUIRED RESPONSE CARD(S): None.

GENERAL INSTRUCTIONS:

This form is to be completed, for the caregiver only, and given to the site Project Coordinator to be faxed to the REACH II project coordinator at the Data Coordinating Center within 24 hours of learning about the event. It should then be entered into PoP at the site level. *Note that if an event outcome has NOT been reported as resolved/controlled, a Follow-up Report will need to be completed when this event is resolved/controlled. (See the Acute Baseline Alerts/Adverse Events Follow-up (AF) Report QxQ's and the Acute Baseline Alerts/Adverse Events Procedures in Section 7 of the MOP.)*

SPECIFIC INSTRUCTIONS:

1. Date descriptions:

- **Report Date** – this is the date in which the acute screening/adverse event is being reported.
- **Event Date** – this is the date in which the acute screening/adverse event occurred. If the caregiver can not identify the exact date, then try to identify the month and year, and enter an “unknown (-3)” as the date. For example, the event occurred in May of 2002, the appropriate response is 05/-3/2002. For ongoing events, such as some severe medical problems, use the report date.
- **Resolution Date** – this is the date in which the acute screening/adverse event was resolved or controlled. Note that if the event is being reported as ‘continuing,’ the corresponding resolution date should be marked as “n/a” (not applicable).

2. Type of Events:

- **CES-D score greater than or equal to 15** – Mark this item if the CG has a total score of 15 or greater on the CES-D scale. (*Acute Baseline Alert only*)
- **CG Death** – Mark this item if the CG has died.
- **CG Hospitalization** – Mark this item if the CG has been hospitalized.
- **CG Institutionalization** – Mark this item if the CG has been institutionalized.
- **CG Emergency room visit** – Mark this item if the CG has had an emergency room visit.
- **CG Severe medical problem** – Mark this item if the CG has had a severe medical problem.
- **CG Abuse** – Mark this item if the CG has been abused.
- **CG Other** – Mark this item if an event has occurred that is not listed on the AG form.

3. Relationship to Treatment:

- It is up to the discretion of the research staff at the site to determine the relationship of the event to treatment. There is one exception- in the case of acute baseline alerts (*CES-D score greater than or equal to 15*), the event is **NOT** treatment related and should be marked “no”.

4. Outcomes

- For each event, determine the outcome of the discrete occurrence identified. Some events may be resolved while others may be controlled, indicating the underlying problem may still exist but

the acute event has passed. It is at the discretion of each site to determine the outcome of each acute baseline alert/adverse event. Some of these events may occur together, such as an emergency room visit leading to a hospitalization for a severe medical problem. The following guidelines should be followed:

- **CES-D Score greater than or equal to 15-** Determine whether the depression is controlled following the baseline interview.
- **CG Death-** For a death there is no resolution it is a not applicable (N/A) item.
- **CG Hospitalization-** Resolution would be indicated by the caregiver being released from the hospital.
- **CG Institutionalization-** Resolution would be indicated by the caregiver returning to a private residence.
- **CG Emergency room visit-** For this item, determine whether the event that lead to the emergency room visit has been resolved or controlled. In this case, an acute episode of an illness may be resolved and the individual may be sent home. Or an individual can be hospitalized after an emergency room visit. It will be at the site's discretion to report and code these events as they are uncovered and understood by the site.
- **CG Severe medical problem-** Determine whether the medical problem is being controlled.
- **CG Abuse-** For this item, determination of resolution is at the discretion of the site. An abusive event may have occurred and ended but the situation leading to the abuse needs to be controlled in order to consider the abuse not continuing.

4. Comments:

- Record any comments necessary to further explain any events. **Do not include the participant name, randomization assignment or any other participant identifying information.**

CARE RECIPIENT ACUTE BASELINE ALERTS/ ADVERSE EVENTS (AR)

PURPOSE: To quickly collect vital information about a serious adverse event.

TIME OF DATA COLLECTION: At the time of awareness.

REQUIRED RESPONSE CARD(S): None.

GENERAL INSTRUCTIONS:

This form is to be completed, for the care recipient only, and given to the site Project Coordinator to be faxed to the REACH II project coordinator at the Data Coordinating Center within 24 hours of learning about the event. It should then be entered into PoP at the site level. *Note that if an event outcome has NOT been reported as resolved/controlled, a Follow-up Report will need to be completed when this event is resolved/controlled. (See the Acute Baseline Alerts/Adverse Events Follow-up (AF) Report QxQ's and the Acute Baseline Alerts/Adverse Events Procedures in Section 7 of the MOP.)*

SPECIFIC INSTRUCTIONS:

1. Date descriptions:

- **Report Date** – this is the date in which the acute screening/adverse event is being reported.
- **Event Date** – this is the date in which the acute screening/adverse event occurred. If the caregiver can not identify the exact date, then try to identify the month and year, and enter an “unknown (-3)” as the date. For example, the event occurred in May of 2002, the appropriate response is 05/-3/2002. For ongoing events, such as driving that occurs regularly, use the report date.
- **Resolution Date** – this is the date in which the acute screening/adverse event was resolved or controlled. Note that if the event is being reported as ‘continuing,’ the corresponding resolution date should be marked as “n/a” (not applicable).

2. Type of Events:

- **Threatened to hurt him/herself 3 or more times in the past week** – Mark this item if the CR has threatened to hurt him/herself 3 or more times in the past week. (*Acute Baseline Alert only*)
- **Commented about the death of him/herself or others 3 or more times in the past week** – Mark this item if the CR has commented about the death of him/herself or others 3 or more times in the past week. (*Acute Baseline Alert only*)
- **Access to a gun** – Mark this item if the CR has/had access to a gun. (*Acute Baseline Alert only*)
- **Driving** – Mark this item if the CR has/had access to driving a car. (*Acute Baseline Alert only*)
- **CR Death** – Mark this item if the CR has died.
- **CR Hospitalization** – Mark this item if the CR has been hospitalized.
- **CR Institutionalization** – Mark this item if the CR has been institutionalized.
- **CR Emergency room visit** – Mark this item if the CR has had an emergency room visit.
- **CR Severe medical problem** – Mark this item if the CR has had a severe medical problem.
- **CR Abuse** – Mark this item if the CR has been abused.
- **CR Other** – Mark this item if an event has occurred that is not listed on the AR form.

3. Relationship to Treatment:

- It is up to the discretion of the research staff at the site to determine the relationship of the event to treatment. There is one exception- in the case of acute baseline alerts (*threatened to hurt*

*him/herself 3 or more times in the past week, commented about the death of him/herself or others 3 or more times in the past week, access to a gun, driving), the event is **NOT** treatment related and should be marked “no”.*

4. Outcomes:

- For each event, determine the outcome of the discrete occurrence identified. Some events may be resolved while others may be controlled, indicating the underlying problem may still exist but the acute event has passed. It is at the discretion of each site to determine the outcome of each acute baseline alert/adverse event. Some of these events may occur together, such as an emergency room visit leading to a hospitalization for a severe medical problem. The following guidelines should be followed:
 - **(CR)Threatened to hurt him/herself 3 or more times in the past week** - Determine whether the threatening to hurt him/herself is controlled following the baseline interview.
 - **(CR)Commented about the death of him/herself or others 3 or more times in the past week**- Determine whether the commenting about him/herself or others is controlled following the baseline interview.
 - **CR Death**- For a death there is no resolution it is a not applicable (N/A) item.
 - **CR Hospitalization**- Resolution would be indicated by the CR being released from the hospital.
 - **CR Institutionalization**- Resolution would be indicated by the CR returning to a private residence.
 - **CR Emergency room visit**- For this item, determine whether the event that lead to the emergency room visit has been resolved or controlled. In this case, an acute episode of an illness may be resolved and the individual may be sent home. Or an individual can be hospitalized after an emergency room visit. It will be at the site’s discretion to report and code these events as they are uncovered and understood by the site.
 - **CR Severe medical problem**- Determine whether the medical problem is being controlled.
 - **CR Abuse**- For this item, determination of resolution is at the discretion of the site. An abusive event may have occurred and ended but the situation leading to the abuse needs to be controlled in order to consider the abuse not continuing.

5. Comments:

- Record any comments necessary to further explain any events. **Do not include the participant name, randomization assignment or any other participant identifying information.**

ACUTE SCREENING/ ADVERSE EVENTS FOLLOW UP REPORT (AF)

PURPOSE: To report resolution or control of all acute baseline alerts or adverse events previously stated as continuing events.

TIME OF DATA COLLECTION: Within a week of determining a continuing event has been controlled or resolved.

REQUIRED RESPONSE CARD(S): None.

GENERAL INSTRUCTIONS:

This form is to be completed for the care giver and/or the care recipient and entered into PoP at the site level. One form can be used for multiple study participants.

SPECIFIC INSTRUCTIONS:

1. Date descriptions:

- **Form Completion Date** – this is the day in which the form is completed.
- **Event Date** – this is the date in which the acute screening/adverse event occurred initially. (*This date is taken from the AG or AR form completed previously for the individual*).
- **Resolution Date** – this is the date in which the acute baseline alert/adverse event was resolved or controlled.

2. Event Code:

- Enter the event code as listed in the table on the bottom of the form. Note: CG death (02) and CR death (13) are omitted since resolution is not applicable.

PARTICIPANT INFORMATION (PI)

PURPOSE:

To collect personal information on each participant that can be used to locate the participant for follow-up. This form is a tool for site specific management of participants. **DO NOT SEND THIS FORM TO THE COORDINATING CENTER.**

TIME OF DATA COLLECTION:

At time of entrance into the study, but should be reviewed periodically with the participant to update any changes.

REQUIRED RESPONSE CARD(S):

None.

GENERAL INSTRUCTIONS:

This form is not to be entered into the REACH database (PoP). It is intended solely as a source of information for contacting study participants. Do not send this form to the Coordinating Center. This form should be reviewed periodically with caregiver in order to make updates and maintain current accurate information on study participants.

SCREENING (SC)

| | |
|-----------------------------------|--|
| PURPOSE: | To screen prospective REACH II participants and determine their suitability for the study. |
| TIME OF DATA COLLECTION: | The first study contact with the participant. |
| REQUIRED RESPONSE CARD(S): | None required. |

GENERAL INSTRUCTIONS:

The screening questionnaire incorporates two types of questions; questions that assist in answering eligibility determining questions; and the eligibility determining questions. All eligibility determining questions are yes/no questions and have responses in “boxes” to the immediate right of the questions. If a response is recorded in one of the shaded boxes on any of the eligibility determining questions, the respondent is determined ineligible, and the script for an ineligible caregiver is read at the conclusion of the form.

Generating the ID

This number is entered on every sheet at the top right hand corner. It is automatically generated by PoP during data entry. The data entry specialist, not the interviewer, is responsible for recording this number on the screening form since the number is not generated until after the screening interview. Therefore, during the screening interview this space is left blank.

Pre-screen

If the respondent answers “no” to any of the eligibility determining questions, he/she is ineligible for REACH II. The interviewer should read subscript A to the respondent and then terminate the call. Data collected for respondents who do not meet the pre-screen eligibility criteria should **NOT** be entered in PoP, but rather placed in an “ineligible prescreen” file at the site.

Screen

If a participant qualifies for the screen based on the pre-screen questions, all screening questions are required to be administered regardless of the respondent meeting inclusion or exclusion criteria.

The screening portion of the questionnaire asks questions about the CG and CR. An additional section, Risk Assessment – Part I & II, collects information about how the CG and CR have been doing within the past month. The final section is the Eligibility Determination section. This sections reports whether the participant is “not eligible”, “eligible”, or “maybe” eligible.

Questions 21.1.1, 33 – 35, and 41 require special consideration regarding whether to determine the CG as eligible for the study or not. If the response to any of these questions is “Yes”, *and no other exclusion criteria are met*, the respondent should be classified as a “maybe” on the eligibility section of the form (question 50) and referred to the site Principal Investigator for resolution of the “maybe” status. *The remainder of the Screening form must be completed.* If the participant is excluded because of other criteria, the case is not referred to the site Principal Investigator. Note that if a “Yes” is recorded for any of these questions, the interview should probe and record details in the box at the bottom of this page to assist the Principal Investigator in resolving the “maybe” status. Once the interviewer consults with the site Principal Investigator and the eligibility status of the respondent is determined, the interviewer should go back to question 50 and enter “yes” or “no” regarding eligibility determination. Question 52 should then be completed.

SPECIFIC INSTRUCTIONS:

Question 6.1 is bolded which instructs the screener to read all the racial categories. If the respondent

answers before you read them, fill the answer in and continue onto the next question. If the respondent states he or she is biracial, ask the respondent “which group do you most identify with?” or would feel more comfortable being categorized as “no primary group”. Screeners need to be careful to probe the respondent in this situation without forcing a response. If the respondent asks why there is no biracial category, the screener can explain that the study is looking at certain groups, but the respondent has the option to choose to identify with a group, choose “no primary group” or choose “other” and specify his or her response. If the respondent has already identified him or herself as Hispanic or Latino/a in Question 6, this question must still be asked. Some people of Hispanic or Latino/a background will also identify a racial category, while others will choose other or no primary group.

Question 7.1 is where the screener places the respondent in one of the three groups identified for the study. In cases, where a respondent has identified him or herself as Hispanic or Latino/a and also chooses either White, Caucasian or Black, African-American as his or her primary racial group, the screener will mark Hispanic/Latino/a in this questions. For the purposes of this study, anyone who identifies as Hispanic/Latino/a will be placed in that category regardless of the other responses. Identification as Hispanic/Latino/a supercedes any other group identification.

Question 11 may be filled in without asking the caregiver if the caregiver’s relationship to the care recipient has been positively determined during the introduction to the screening form.

Question 12 of the pre-screen asks to record the number of years and months the CG has taken care of this particular CR. Do not include time taking care of other CRs. Include in the response any time spent caregiving prior to the CRs development of Alzheimer’s disease. If a CG has been taking care of the CR for 8 years, of which the CR has had Alzheimer’s disease of only the past 2 years, the correct response is 8 years, 0 months. If the number of years is less than ten, insert a leading zero in the first digit for both the year and the month (e.g. 3 years = “03”, 7 months = “07”). If a fraction of a year is given, the interviewer must convert the fraction to number of months (E.G. 1 and ½ years = “01 years” and “06 months”). If the amount of time is less than six months (a response of “00” years and “05 months” or less) the participant is not eligible for the study. Even though the CG is not eligible for the study, the remainder of the Screening form must be completed.

Question 17 may be filled in without asking the caregiver if the care recipient’s sex has been reported to the screener during the introduction to the screening form.

Question 20 records the caregiver’s relationship to the care recipient. If this information has already been determined earlier in the screening, simply confirm the answer to this question. Responses are bolded but if the respondent gives an answer after the question is read, it is not necessary to read all the responses.

Question 21 requires special consideration regarding whether to determine the CG as eligible or not. If the response to question 21 is “no” AND the response to question 21.1 is “no” AND the response to 21.1.1 is “Yes,” AND *no other exclusion criteria are met*, this respondent should be classified as a “maybe” and referred to the site Principal Investigator for resolution of the “maybe” status. This question is asked to ensure that if the CG is randomized to the intervention, the CTIS system can be installed. If the CG does not have the equipment necessary to install the CTIS, it may be available at a minimal cost. It is up to the discretion of the site Principal Investigator to offer this service.

Question 25 asks the number of hours the caregiver spends taking care of the CR. If the number of hours is less than ten, insert a leading zero digit on the data collection form (e.g. 5 hours = "05"). If a fraction of an hour is given, round to the nearest hour (e.g. 4 hours and 30 minutes = "05", 3 hours and 15 minutes = "03"). The CG is excluded if less than four hours per day is spent caring for the CR. If the CG is not eligible for the study, the remainder of the Screening form must be completed.

Question 30 is not an eligibility determining question in itself. If no exclusion criteria are met but the CR

is reported to be bedbound, the interviewer should administer the MMSE to the CR at the beginning of the baseline interview to determine eligibility. If the MMSE score is 0 and the CR is bedbound, then he/she is ineligible for the study.

Question 32 asks about the number of times the care recipient has been hospitalized in the past year. If the respondent answers that the care recipient has been hospitalized more than three times in the past year, the screener needs to probe to determine if these hospitalizations were for illnesses other than psychiatric or Alzheimer's disease related illnesses.

Questions 33 and 34 require special consideration regarding whether to determine the CG as eligible or not. If the response is "Yes," *and no other exclusion criteria are met*, this respondent should be classified as a "maybe" and referred to the site Principal Investigator for resolution of the "maybe" status. CRs may have memory problems for reasons other than Alzheimer's disease or related disorders (ADRD). These individuals should not be included in the study. The Principal Investigator should attempt to verify a clinical diagnosis of dementia not due to memory problems because of a severe mental illness or past head injury respectively, by asking permission to contact the care recipient's primary care physician.

Question 35 requires special consideration regarding whether to determine the CG as eligible or not. If the response is "Yes," *and no other exclusion criteria are met*, this respondent should be classified as a "maybe" and referred to the site Principal Investigator for resolution of the "maybe" status. If a CR is blind or deaf and either disability prohibits him/her from completion of data collection or participation in the intervention, the CG/CR dyad should not be included in the study.

Question 37 -40: These questions assume that the caregiver has been told by a health professional that the care recipient has one or more of these diseases. If the caregiver asks 'have I been told by whom?' the screener can clarify.

Question 41 also requires special consideration regarding whether to determine the CG as eligible or not. If the response is "Yes," *and no other exclusion criteria are met*, this respondent should be classified as a "maybe" and referred to the site Principal Investigator for resolution of the "maybe" status. This question refers to the CR exclusion criteria of "history of Parkinson's Disease or a stroke with no reported decline in memory over the past year". Because REACH II is a study about Alzheimer's disease or related disorders (ADRD), it is essential that individuals with ADRD make up the study cohort. Some CRs may have multiple diseases. This is acceptable as long as the CR is also exhibiting deteriorating memory problems due to Alzheimer's disease.

Question 49: In cases where the interviewer suspects that the respondent may be cognitively impaired, the SPMSQ should be administered, at the discretion of the interviewer. The cut off point for the SPMSQ is a total score of 4. If the caregiver scores 4 or more, he or she is NOT eligible for inclusion in REACH II. A score of 3 and less would allow the caregiver to participate in REACH II.

SPMSQ (SP)

PURPOSE:

To determine mental status of the participant (CG) to determine eligibility.

TIME OF DATA COLLECTION:

The administration of this form is at the discretion of the Screener. It is administered immediately after the Screening form if the Screener feels that it is necessary to determine mental status.

REQUIRED RESPONSE CARD(S):

None.

GENERAL INSTRUCTIONS:

For each question, check wrong or correct.

If the participant fails to answer any of the questions record a "-3" in the margin and check "Wrong" for that question.

Ask questions 4 to 13 and 15, and record all answers.

Question 14: This question is the subtotal score. Add up the number of **wrong answers** recorded in questions 4-13 and enter here. If the number of wrong answers were less than ten, place a leading zero in the response field (e.g. 5 errors, enter 05).

Question 15: This question asks the caregiver for his or her highest level of formal education. This response is used in determining the final score. If the participant had no grade school education, you will allow one more error, which results in subtracting one from their subtotal score. If the participant had education beyond high school, you will allow one fewer error, which results in adding one to their subtotal score. After reviewing the response to this question, you will then subtract one, add one or maintain the score in the subtotal (Question 14).

Question 16: Record total number of wrong answers based on the ten questions, 4-13 plus the possible adjustment made in question 15. If the number of wrong answers were less than ten, place a leading zero in the response field (e.g. 5 errors, enter 05).

The cut off score for inclusion in REACH II is 4. If the total score entered in question 16 is 3 or less, the caregiver can be included in REACH II. If the total score is 4 or more, the caregiver is NOT eligible to participate in REACH II.

MINI-MENTAL STATE EXAMINATION (MM)

PURPOSE: To assess the level of cognitive functioning of the CR.

TIME OF DATA COLLECTION: At the baseline visit and six month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC2, RC3

GENERAL INSTRUCTIONS:

The MMSE is administered to the CR at the beginning of the interview, and should not interrupt the interview of the caregiver. The care recipient proxy must be obtained before completing this form.

The following are the original instructions (quoted from Folstein, Folstein, & McHugh, 1975) for administering the MMSE.

“Questions are asked in the order listed and scored immediately. The tester (psychiatric resident, nurse, or volunteer) is instructed first to make the patient comfortable, to establish rapport, to praise successes, and to avoid pressing on items which the patient finds difficult. In this setting most patients cooperate, and catastrophic reactions are avoided.

The MMSE is divided into two sections, the first of which requires vocal responses only and covers orientation, memory, and attention; the maximum score is 21. The second part tests ability to name, follow verbal and written commands, write a sentence spontaneously, and copy a complex polygon similar to a Bender-Gestalt Figure; the maximum score is nine. Because of the reading and writing involved in Part II, patients with severely impaired vision may have some extra difficulty that can usually be eased by large writing and allowed for in the scoring. Maximum total score is 30. The test is not timed.” (Folstein, et al., pp. 189-190).

The interviewer will need to compute the total MMSE score in the presence of the CR or CG in some cases when eligibility is at question. When it appears the MMSE score will be over 23 or if the CR is bedbound and the MMSE score appears to be zero, then the score must be tallied before continuing with the baseline battery. If the interviewer is familiar with the MMSE and is sure the score will not be in either of these categories then the score can be tallied after the baseline battery is completed.

Make sure a score *is* recorded for each item. It is very important that the interviewer delivers the instructions exactly the same way for each respondent in order to ensure that the test is fair. Pay careful attention to the specific instructions below. The test should be given in exactly the same manner at both the baseline and follow-up interview.

Note that when determining a MMSE score:

- **All items will receive a numerical value when calculating a score. Correct answers will receive points as described below, and all missing values, refusals, don't know, or incorrect answers will receive a “0” (zero).**
- **If the respondent exhibits any signs of physical impairment or illiteracy that would impair performance on any item(s), mark the item(s) on the form so when recording this information in question 16, details and item numbers can be provided.**

When a subject gives more than one response he/she should be encouraged to choose one of the responses, although no cueing for a specific choice should be provided. “Which one is it?” or “Choose one” can be used as prompts. Subjects should be encouraged to give an answer even if they are unsure. “What’s your best answer?” or “try” can be used as prompts in these situations. An incorrect response can give some evidence that the subject understood the question.

The following specific instructions are adapted from the original.

1. Please tell me today's date.

Read the question. Record the response in the spaces provided for 1.1, 1.2, and 1.3, if the respondent answers correctly. Each scoreable item may be queried separately if the answer is incorrect or the respondent does not answer.

1.1 Can you tell me what month it is?

Read only if respondent does not provide this in response to question 1. Record the month numerically, i.e., January = "01", February = "02", etc.

1.2 Can you tell me what date it is?

Read only if respondent does not provide this in response to question 1. Record the date numerically, i.e., the seventh = "07". The date can be prompted with "what day of the month is it?"

1.3 Can you tell me what year it is?

Read only if respondent does not provide this in response to question 1. Record the year numerically, i.e., 2002 = "2002". The year can be prompted with "two thousand..."

1.4 Can you tell me what day it is?

Record the day of the week (e.g., "FRIDAY") in all capital letters in the space provided. The day can be prompted with "what day of the week is it?"

1.5 Can you tell me what season it is?

Record the season (e.g., "FALL") in all capital letters in the space provided. When a season is near transition, the correct answer can be prompted with "are you sure?" If seasons are in transition, either season is acceptable as correct as long as the season change has occurred or will occur within two weeks of the interview.

Score

Record the number correct on items 1.1 through 1.5 in the space provided.

2. Can you tell me what building we are in right now?

Record the response in the space provided for 2.1. Use capital letters. For questions 2.2 through 2.5, use the same question, but insert the specific location and appropriate preposition.

Please note: interview will take place in the person's home and the correct answer referring to that should be recorded appropriately.

2.1 building

Repeat question 2 only if response is inadequate.

2.2 floor(street address)

Ask "Can you tell me what floor we are on right now?" Record the response numerically. If the care recipient doesn't respond to "floor" (most likely they will be in a home), ask "can you tell me the street address here". A street name without number is an acceptable response.

2.3 city

Ask "Can you tell me what city we are in right now?" Record the response in capital letters.

2.4 **county**

Ask "Can you tell me what county we are in right now?" Record the response in capital letters.

2.5 **state**

Ask "Can you tell me what state we are in right now?" Record the response in capital letters.

Score

Record the number correct for items 7.1 through 7.5 in the space provided.

3. I'm going to name three objects and I'd like you to repeat them after me, ok?

(Name three objects, allotting one second to say each).

Say "APPLE...TABLE...PENNY", allowing one second to say each word. Allow the respondent to repeat the three words, and record the number repeated correctly in the space provided for item 3.2 (Score). If the score is less than "3", repeat the objects until the respondent can name them all - maximum of 6 trials. Stop after 6 unsuccessful trials and enter a "7" in the space provided for item 3.1 ("number of trials") to indicate that they never learned the succession. If 6 or fewer trials were required for the respondent to learn all 3 words, record the number of trials required in the space provided for item 3.1("number of trials").

Give 1 point for each correct answer on the first trial only. Repeat the objects until the respondent can name them all - maximum of 6 trials. Stop after 6 unsuccessful trials and enter a 7 for number of trials to indicate that they never learned the succession.

3.1 **Number of trials:**

Record the number of times it took for the respondent to name the three objects. If after six trials the respondent was unable to successfully name the three objects enter a 7.

Score:

Record the number correct for each object for the first trial only.

4. I'm going to ask you to do some subtraction. Think of the number 7. I want you to subtract 7 from 100. Now subtract 7 from that and keep going until I stop you. (Enter numbers given by respondent below)

Enter the first 5 responses in the spaces provided for items 4.1 through 4.5. Stop the respondent after 5 subtractions. The score on this section is the number of times 7 was correctly subtracted from the number provided previously (regardless of whether or not that number was correct). For example, "93, 88, 81, 74, 67" would receive a score of 4. Pause after asking the respondent to subtract 7 from 100 in order to give the respondent time to do the calculation.

4.1

Record the first number. If a response greater than 99 is given, record a 99.

4.2

Record the second number. If a response greater than 99 is given, record a 99.

4.3

Record the third number. If a response greater than 99 is given, record a 99.

4.4

Record the fourth number. If a response greater than 99 is given, record a 99.

4.5

Record the fifth number. If a response greater than 99 is given, record a 99.

Score:

This question should be scored after the interview. Enter the number of correct answers. Allow for previous mistakes with subsequent subtraction. For instance, if the respondent gets the first subtraction wrong but all subsequent ones correct the correct score would be four.

5. I want you to spell a word forward and then backward. The word is 'WORLD.'

Read the question as worded. No points are scored for spelling the item forward. Up to five points can be scored for spelling the item backward.

5.1 Spell it forward.

Read this statement if the respondent has not responded to 5. If response is incorrect, correct the respondent and allow him/her to respell it until he/she spells it correctly. The respondent gets no points for a correct spelling.

5.2 Spell it backward.

Read the statement and record the response in the spaces provided. As explanation, you may also say, "start from the end and go to the beginning". Score 1 point for each properly placed letter in the sequence. For example, DLORW = "3". The maximum score is five.

Score:

This question should be scored after the interview.

6. Do you remember a few minutes ago I had you repeat some words after me? Can you tell me what they were?(Give 1 point or each correct answer)

Prompting is not allowed. Record the words given by the respondent. Print legibly (no script) in all capital letters.

Score:

Give 1 point for each correct answer, and record the score in the space provided.

7. Please name these for me. (Show the participant a wooden pencil and a watch, preferably worn on the wrist. Score 1 point for each correct answer).

Show the respondent a wooden pencil and a watch, preferably worn on the wrist. If respondent gives a function say, "yes, but what is this called?" or "what is its name?" No other clues should be provided.

Score:

Score 1 point for each correct answer, and write the score in the space provided.

8. I'm going to read a sentence and I want you to repeat it after me. Say exactly what I say, ok?

NO IFS, ANDS, OR BUTS.

Read the phrase out loud once.

Score:

Score 1 point if and only if the entire sentence is repeated exactly as stated. Failure to pluralize counts as a mistake. Record the score in the space provided.

9. **Now I'm going to ask you to do something for me. I'm only going to say it once, so listen carefully. Take this paper in your right hand; Fold the paper in half with both hands; and put the paper in your lap.**

Read the commands out loud once. One repetition is permitted as the respondent's request, but the entire command must be repeated.

Score:

Score 1 point for each stage correctly completed, and record the score in the space provided.

10. **Read this card, and do what the card tells you to do. (Show the card (RC2) with "close your eyes" on it. One prompt allowed after initial instructions. Score 1 point.)**

Show the respondent the response card (RC2) with "Close your eyes" written on it. You may prompt the respondent once after the initial instructions. You may remind the respondent not to just read the sentence, but to obey it. If the subject is unable to read, read the sentence out loud to them.

Score:

Score 1 point if and only if respondent closes his/her eyes. Record the score in the space provided.

11. **Now please write a sentence for me on this blank piece of paper. (Do not dictate a sentence or provide a subject; it must be written spontaneously. Prompt as often as you like. The sentence must contain a subject and a verb and be sensible. Correct grammar and punctuation are not necessary. Score 1 point).**

Give respondent the page provided, and read the item. Do not dictate a sentence or provide a subject; it must be written spontaneously. Prompt as often as you like. The sentence must contain a subject and a verb and be sensible. Correct grammar and punctuation are not necessary.

Score:

Score 1 point for an acceptable sentence, and record the score in the space provided.

12. **Please copy this design exactly as it is for me. (Hold the card (RC3) with the design on it in front of the participant; do not let the participant trace the design. All 10 angles must be present and 2 must intersect to score 1 point. Tremor and rotation are ignored).**

Give the page provided to the respondent. Hold the response card (RC3) with the intersecting pentagons on it in front of the respondent; do not let the respondent trace the design. It is better to avoid erasing and allow a second try, if necessary.

Score:

All 10 angles must be present and 2 must intersect to score 1 point. Tremor and rotation are ignored. Record the score in the space provided.

13. **Total score**

This should NOT be calculated in the presence of the CR or CG. First, go to items 4 and 5. The higher of these should be included in the calculation of the total score. The total score is the sum of the scores for items 1, 2, 3, 4 or 5, 6, 7, 8, 9, 10, 11, and 12.

14. **Is the MMSE Total Score = 0?**

Check “yes” if the total score in question 13 is equal to zero, otherwise check “no”.

15. **Does (CR) spend at least 22 hours a day in a bed or chair?**

Check “yes” if the respondent is confined to a bed or chair for at least 22 hours a day, otherwise check “no”. All time out of bed or chair is counted as non-bedbound time.

15.1 **Has this occurred for at least 4 of the past 7 days?**

Check “yes” if the respondent is confined to a bed or chair for at least 22 hours a day for at least 4 of the past 7 days, otherwise check “no”.

16. **Is the MMSE Total Score greater than 23?**

Record whether or not the MMSE Total Score is greater than 23. If yes, then the interviewer must ask for written permission (release of information form) to contact the care recipient’s doctor to obtain a diagnosis of dementia. The baseline battery must not be completed at this time. Another appointment is to be scheduled once a diagnosis of dementia is obtained.

16.1 **Was an MD diagnosis of dementia obtained?**

This question is completed when the MD diagnosis of dementia is obtained, or when the diagnosis of dementia can not be obtained.

17. **Did the participant exhibit any signs of illiteracy, or of physical impairments that would hinder performance on any of the items in this test?**

Record whether or not physical impairments or illiteracy were evident. If yes, briefly explain what they were and how you noticed them. Record the question numbers that were affected by this impairment.

17.1 **Specify:**

Record signs of illiteracy or signs of physical impairment.

18. **Is the respondent eligible to participate in the REACH project?**

This question is answered only at the baseline assessment. There are two ways in which the answer to this question can be “no”.

In the first case, the respondent is ineligible if both the respondent’s MMSE Total Score is equal to 0 and the respondent is bedbound. If questions 14, 15, and 15.1 are checked “yes”, check “no” for question 17. The interviewer will not complete the baseline battery with the caregiver but will use the Bedbound & MMSE=0 script to explain that the caregiver is not eligible for the study.

In the second case, the respondent is ineligible if the respondent’s MMSE Total Score is greater than 23 and there is no doctor diagnosis of dementia. The interviewer will only check “no” when the answer to question 16.1 is ‘no’ indicating that the diagnosis has been confirmed as NOT to be dementia or the caregiver refuses to grant permission to contact the care recipient’s doctor for this information.

If “yes” is checked, the caregiver and care recipient are eligible for the REACH project. The interview should proceed as normal. If “no” is checked, the caregiver and care recipient are ineligible for the REACH project.

PERSONAL APPEARANCE (PA)

PURPOSE: This form helps us to get a picture of the personal appearance of the care recipient. Through this information, it suggests an aspect of the quality of care given by the caregiver.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This information is observed and collected while administering the MMSE. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1

GENERAL INSTRUCTIONS:

These questions are not asked of the caregiver or care recipient, they are **strictly observational**.

The behavioral definitions included in this form must be memorized by the interviewer before doing the interview. The interviewer will observe these aspects of the care recipient's appearance while administering the MMSE to the care recipient. Therefore, the interviewer can either take notes regarding the care recipient's appearance while administering the MMSE and then fill out this form later or can find a way to take a few minutes before or after the MMSE to look over this form and fill in.

There will likely be missing data for individuals as you will not be requesting information from individuals, just observing. If you are unable to determine any of the items by observation under normal circumstances, then a (-3) Unknown is entered. Enter a "N/A" response if the item is not applicable for the individual.

This information is solely informational and not a value judgment; therefore, **if the item meets the definition, record it so. Do *not* take any other factors into consideration when recording data. For example, even if the CR just got in from gardening, if fingernails are dirty, record them as dirty.

SPECIFIC INSTRUCTIONS:

Question 9: This questions goal is mainly to gain information about incontinence care. If wetness is notices on an individual's shirt most likely from drinking and it is not excessively wet, the individual's clothes can be considered dry.

Question 10: Untorn clothing should be carefully considered. Many people will not have the means to provide new clothes for the care recipient, especially when the care recipient begins to lose weight due to illness. Caregivers also have challenges making clothing easy for care recipient to manage by themselves. Minor wear in the form of tears, fabric pulls etc. should not be considered torn clothing.

CAREGIVER AND CARE RECIPIENT SOCIODEMOGRAPHICS (SO)

PURPOSE: This form is included in order to obtain descriptive information about the caregiver and care recipient.

TIME OF DATA COLLECTION: It is asked only at the baseline visit.

REQUIRED RESPONSE CARD(S): RC1, RC4, RC5, RC6, RC7, RC8, RC9, RC10, RC11, RC12, RC13, RC14, RC15.

GENERAL INSTRUCTIONS:

This questionnaire begins with three literacy questions. The respondent is given a response card (RC4) and is asked to read the items on the card. This will give the research staff information about how to present the remaining materials in the interview and later in the intervention.

This questionnaire asks certain questions about both the caregiver and care recipient (marital status, education, ethnicity, race, country of birth, years lived in the United States). The remaining questions are for the caregiver to answer about themselves only.

Respondents are asked first to identify their ethnicity (and care recipient's), only in terms of identifying as Hispanic/Latino/a or not. Next they are asked to identify their race (and care recipient's). In this manner, Hispanic/Latino/a respondents are able to first affiliate as Hispanic/Latino/a and then identify their primary race, which will vary. These ethnicity/race items are based on the 2000 Census and appear to gain a more accurate picture of the population.

SPECIFIC INSTRUCTIONS:

Questions 1-3: These questions are answered by the interviewer, while the respondent is reading Response Card (RC4). If the caregiver struggles with the set of words and/or the boxes (CTIS screens), encourage them to move on. The caregiver should attempt all three literacy items.

Question 5: If the caregiver or care recipient never attended school or did not complete one year of formal education, the response "No formal education" should be checked. If the caregiver or care recipient stopped attending school during an academic year, the year completed is recorded. For example, if the caregiver stated "I dropped out of high school in eleventh grade", then the response would be "10" since the eleventh grade was not completed.

The question may require some additional prompting. For instance, if the respondent has received a high school diploma, the interviewer should ask "Did you attend any vocational or training school after high school?" If the respondent says "I went to college", it is up to the interviewer to ask "How long were you in college?" or "Did you finish college?" If the participant responds with a range it is important for the interviewer to first try to encourage the participant to give an explicit answer. If the participant is still unable to give an explicit answer, record the minimum of the range.

Question 6: The purpose of this question is to allow the caregiver to identify him/herself and the care recipient as "Hispanic/Latino/a". If the response is "yes", question 6.1 allows the caregiver to identify his/her ethnic group and the ethnic group of the care recipient. If the caregiver states that they describe themselves as "Hispanic/Latino/a" and also another ethnic group, record this as a "yes" response and ask of what Hispanic/Latino/a origin they (or care recipient) are.

Question 7: The purpose of this question is to capture the primary racial group of the caregiver and care recipient. If the response is "no primary group", record the racial groups identified with in the space provided (specify). If the caregiver or care recipient's racial group is not provided for in the list of

responses, then "Other" is checked and the name of the racial group is recorded in the allocated space.

Question 9: Indicate the number of years the caregiver has lived in the United States. The response to this question should be recorded in whole numbers. When recording the value, if the number of years is less than ten (e.g. "8"), a zero is placed in first integer field (e.g. "08"). If the caregiver responds in fractions of numbers (e.g. "three and a half years" or "5 years and two months") then the answer would be rounded to the nearest whole number (e.g. "04" or "05"). Round up when the response is half way between two years, such as "three and a half years."

Question 10: If the caregiver states that he or she is not currently employed, a probe will need to be given to determine if the caregiver has retired. If the caregiver has not retired, the response "Not currently employed, not retired" is checked regardless of whether or not the caregiver is currently looking for employment. A probe may need to be given to determine if the employment is full-time or part-time. Full-time is defined as 35 or more hours per week. If the respondent is not currently employed and not looking for a job (for example, an AFDC recipient, a seasonal worker, not currently working, or disabled not currently working), code as "Not currently employed, not retired." In other cases that may arise in which it is difficult to decide how the employment situation should be coded, it should be up to the respondent to decide which category best describes his/her situation.

Question 10.3.1: Indicate the amount of time in hours and minutes, that the caregiver has reduced his or her work load. If the caregiver indicates a fraction of an hour, the fraction must be converted to minutes (e.g. twenty and three quarters of an hour = "20:45").

Question 12: Keep in mind that many people do not like to reveal information about their income, and may have a negative reaction to this question. Although every effort has been made to ask this question in the most unintrusive manner possible, respondents may still resist answering it. The introduction to the question reminds the respondent that all the information is kept strictly confidential, it will not be associated with their name in any way, the information is very important for the study, and that they only need to indicate the number of the category on the card, not the dollar amount.

Because the assurances about confidentiality are provided at the beginning of the question and because it is a sensitive question, an initial refusal by the respondent to answer the question should be acknowledged and the interviewer should mark "Refused" and go on to the next item.

If the respondent seems unsure, but does not explicitly refuse to answer the question, you may need to remind the respondent that "because this information is kept confidential, it will in no way jeopardize your eligibility to receive services from any agency." Also, a reminder of the importance of the study might help. Of course, if the respondent refuses to answer the question, we must respect his or her privacy.

Question 14: Single-story single family homes and multiple-story single family homes will include row houses, duplexes, and other variations of residential structures. Single-story and multiple-story homes are separate categories in order to capture information about who needs to climb stairs during their daily routines.

Question 15: This question refers to persons having permanent living arrangements, i.e., persons who have been residing in the dwelling for at least 6 months. If an individual lives in the house less than 6 months out of the year, they should not be included in the count. If they live in the house more than 6 months out of the year, they should be counted. A permanent resident of the home that has been living in the home less than six months is not counted in the census.

Question 16: If the response is stated in time units other than years, the interviewer must convert it to years. It is quite likely that a response like "18 months" will be obtained. In this instance, the response is round to the nearest year. If the response is on the half-year mark, round up. Thus if the respondent

states "18 months," this response should be recorded as "2." If the response is something like "as long as we've been married" or "all my life", then the number of years married or the age of the respondent will need to be recorded. If the caregiver is a child and has lived apart from the care recipient during his/her lifetime, record only the length of the current living arrangement, do not include the caregiver's childhood.

Question 18 & 20: Medicare numbers consist of a social security number and a letter code of either A, B or AB. The social security number portion of the Medicare number can be the individual's social security number or the social security number of his or her spouse. Therefore, in some cases, the Medicare number will duplicate the social security number recorded. If the caregiver refuses to report his or her Medicare number or the care recipient's Medicare number, do not pressure them for a response. Record a "-4" for refused in the two far right spaces. If the caregiver does not know the Medicare number(s), ask them if he or she can find out what it is and if it is okay for you to call them at a later time. It is the interviewer's responsibility to follow-up with this phone call. If the caregiver is unable to acquire the Medicare number(s), record a "-3" for unknown in the two far right spaces. If the caregiver or care recipient does not have a Medicare number, record a "-2" for Not Applicable in the two far right spaces.

Questions 19 & 21: As in the previous question, if the caregiver seems concerned about reporting this number, you should remind the caregiver that it will not be given to anyone outside of the project and it will only be used for research. If the caregiver refuses to report his or her social security number or the care recipient's social security number to you do not pressure them for a response, record a "-4" for refused in the two far right spaces. If the caregiver does not know the social security number(s) ask them if they can find out what it is and if it is okay for you to call them at a later time. It is the interviewer's responsibility to follow-up with this phone call. If the caregiver is unable to acquire the social security number(s) record a "-3" for unknown in the two far right spaces. If the caregiver or care recipient does not have a social security number, record a "-2" for Not Applicable in the two far right spaces.

ADL/IADL AND COST (AD)

| | |
|-----------------------------------|---|
| PURPOSE: | This form helps us to get a picture of the level of functioning of the care recipient. It also assesses the amount of time spent by the caregiver providing specific kinds of help. The amount of time spent caring for the recipient provides information on how much care is provided and allows for an approximate estimate of the cost of care provision if a professional was paid to provide assistance to the recipient. |
| TIME OF DATA COLLECTION: | At the baseline visit and six month follow-up visit. This form appears in the baseline and follow-up batteries. |
| REQUIRED RESPONSE CARD(S): | RC1, RC16, RC17, RC18, RC19, RC20, RC21, RC22. |

GENERAL INSTRUCTIONS:

The form is divided up into two general types of daily activities. The first are the Instrumental Activities of Daily Living (IADL) items. These items ask the caregiver whether or not care recipient has needed help with daily activities that are required to maintain living independently in the community. The second are the Activities of Daily Living (ADL) items. These items concern the basic activities that one needs to perform to care for oneself.

For each item, the form asks (1) whether (CR) needed help, (2) whether the respondent helped with the particular activity, and (3) how much helping with this activity bothers or upsets the caregiver. The second question (did you help with this?) is only asked if the caregiver answers "yes" to the first question (during the past week, has CR needed any kind of help...). The third question (how much does helping with this bother or upset you?) is only asked if the caregiver answers "yes" to the second question (did you help with this?).

The IADL items are followed by one question that asks the caregiver to rate their impression of (CR)'s overall improvement in IADL's over the past six months.

The ADL items are followed by one question that asks caregiver to rate their impression of (CR)'s overall improvement in ADL's over the past six months.

One final question asks about the amount of time other family members and friend have provided unpaid help.

Throughout the form, "Help" is defined as supervision, direction, or personal assistance. This definition also includes totally performing the task for the CR. If the respondent indicates a misunderstanding or the interviewer perceives a misunderstanding of the definition of help, clarification should be provided by reiterating the instruction that "help means supervision, direction or personal assistance."

Many of the questions on this form ask if the CR needs any kind of help with a certain "activity". A respondent may answer that the CR "has never done that activity". The interviewer should probe to find out if the caregiver performed this activity for the CR **during the past week**. If the caregiver did not do the activity in the past week, a no response should be marked. If the caregiver did the task during the past week even though the CR was never responsible for that task, then a yes response should be marked. Caregivers often assume that because the CR was never responsible for the task prior to his/her illness it should not be included as a part of the present burden of caregiving. You should interpret this type of response as CR needs help with that activity and is dependent. These questions

are asked to determine the **current** sense of burden the caregiver feels and therefore should include all of the assistive tasks the caregiver provides **during the past week**.

Some questions ask about more than one related tasks, such as question 16 (...*grooming, such as brushing teeth, combing or brushing hair, washing hands, washing face, and either shaving or applying makeup*). It is not necessary to differentiate these tasks, needing help in one is sufficient to complete the question and if the CR needs help in more than one, it is not necessary to probe and describe each. Complete question the same way in both situations.

Be aware of shifting time frames. All questions are in the past week except for the perception questions (9 & 17) which refer to the past six months.

SPECIFIC INSTRUCTIONS:

Question 2: “Going to a store for light groceries” is not read aloud, but is provided as a definition of shopping if the term “shopping” is not clear to the respondent.

Question 3: “Making lunch or a light meal” is not read aloud, but is provided as a definition of food preparation if the term “food preparation” is not clear to the respondent.

Question 4: “Making bed, vacuuming, dusting” is not read aloud, but is provided as a definition of housekeeping if the term is not clear to the respondent.

Question 7: Medications are self defined by the caregiver.

Question 9: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes” response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

Question 12: This question includes help with getting in and out of the bathtub.

Question 13& 14: Dressing includes both dressing and undressing. Be aware that some caregivers and care recipients will have made adaptations to their dressing routine (e.g. wear a hospital gown instead of a blouse) or the care recipient may have an amputation that requires no specific dressing. Take these adaptations/situations at face value and evaluate whether they need any help. If an adaptation is made so the care recipient does not need help, then the answer should reflect this- no, they do not need help.

Question 17: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes” response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

Question 18: If more than one family member or friend helps, the answer should reflect the combined amount of days help was received in the past week.

VIGILANCE (VG)

PURPOSE:

This form enables us to assess the amount of time the caregiver spends just “being around” for the care recipient. These questions will also help us to estimate the cost of caregiving at home.

TIME OF DATA COLLECTION:

At the baseline visit and six month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S):

RC1.

GENERAL INSTRUCTIONS:

No response cards are required. However, optional response card (RC1- yes, no) may be used if the interviewer wishes.

SPECIFIC INSTRUCTIONS:

Question 1: “Family emergency” has no fixed meaning and depends on the definition of the respondent. Examples might include visiting a sick friend, death of a family member, etc. If the answer is “Yes”, go to question 1.1. The answer to question 1.1 is recorded in the number of hours and minutes. For this question “24 hours a day” is an acceptable answer.

Question 2: This refers to only waking hours, so hours sleeping should not be counted. Be aware that some care recipients and caregivers sleep on and off throughout the day and night so any number of hours can be recorded, but should reflect their waking hours due to the care recipient’s needs. Some caregivers may respond that the care recipient can be left alone “indefinitely”, please record this response as “24:00” hours.

Questions 1 & 2: The following directions apply to recording amount of time for these questions:

- **Less than One Hour:** If the length of time is less than one hour, only the number of minutes should be recorded, with zero placed in the hours field (e.g. forth five minutes = 00:45).
- **Full hour:** If the amount of time is expressed as a full hour, there should be two zeros placed in the minute fields (e.g. 10 hours = 10:00).
- **Less than Ten:** If the number of hours or number of minutes is less than ten, then a leading zero should be placed in the first field. (e.g. two hours and five minutes = 02:05).

Question 3: The answer is recorded in the number of hours. Some caregivers will state that they must supervise the care recipient “24 hours a day.” This is an acceptable answer to this question.

Question 4: “Doing things for” should be defined as actively doing something to assist the care recipient. The answer is recorded in the number of hours. Some caregivers may indicate that they are doing things for the care recipient “all day long.” If this response is given, the interviewer should probe to see how many hours that is. “24 hours a day” is **not** an acceptable answer for this question, because the response should only include waking hours.

- **Time Spent per Day Differs:** Respondent may state that the amount of time spent per day differs, for instance on weekdays and weekends. To arrive at a daily average, first probe the respondent for “time spent doing things for (CR) on a typical day.” If a clear response is not given, ask how much time is spent on a typical weekday, and then ask how much time is spent on a typical weekend day. Given these two figures, the interviewer should calculate

the time spent on a *typical* day by multiplying the weekday figure by five, and the weekend day figure by two; add these two products together, and divide by seven. A similar procedure should be used if the respondent indicates that he/she spends an uneven amount of time per day on some other patterned basis, such as "I spend about 3 hours on Tuesdays, Thursdays, and Saturdays, and about 6 hours each day the rest of the week." The calculation in this case would be: $((3 \times 3) + (6 \times 4)) / 7$. It may be necessary to perform these calculations at a later time. Write down the responses in the margin of the form, and make a note to return to this item after the interview.

Questions 3 & 4: The following directions apply to recording amount of time for these questions:

- **Less than Ten:** If the number of hours is less than ten, the first digit should be a leading zero (e.g. 9 hours = "09").
- **Fraction of an Hour:** If the caregiver includes a fraction of an hour, the time should be rounded to the nearest hour (e.g. 1 hour, 45 minutes = "02", 2 hours, 15 minutes = "02", 3 hours and 30 minutes = "04").

REVISED MEMORY AND BEHAVIOR PROBLEM CHECKLIST (MB)

PURPOSE: This form asks about the memory, behavioral and emotional problems that the care recipient has been having. Each question lists a particular problem, and the caregiver must respond as to whether the problem has occurred during the past week.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1, RC16, RC18, RC19, RC23.

GENERAL INSTRUCTIONS:

This form contains two possible adverse event/acute screening criteria alerts.

For most of the questions, there is one primary question, which asks about a memory or behavioral problem. If the response to a primary question is one of the three options stating the problem occurred this past week, then the two other questions, "How bothered or upset were you by this?" and "How confident do you feel about handling this behavior?" must be read.

There are three questions that asks caregiver to rate their impression of (CR)'s overall improvement in cognition, behavior and mood over the past six months. These questions appear after the set of questions which ask about the particular area: memory, behavior, mood.

Three final questions give the caregiver the opportunity to indicate other memory, behavioral or emotional problems that the care recipient may have displayed in the last week, not already covered by the specific questions asked. The first of these questions is asked to everyone. If the caregiver does not have any other problems to report, the remaining questions do not need to be asked. The caregiver can list up to three additional problems, only. "Other problem" is whatever the caregiver defines for him/herself as a problem.

If at any point during the interview, the respondent indicates a prior response was incorrect, make the appropriate change. If the respondent blatantly contradicts a prior response, the interviewer should probe to clarify the discrepancy. Be sure to follow all standards covered in the GENERAL INSTRUCTIONS section of this manual about recording errors. Changes to previous questions should only be made if respondent initiates the change.

Be aware of shifting time frames. All questions are in the past week except for the perception questions (9, 19 & 28) which refer to the past six months.

SPECIFIC INSTRUCTIONS:

Question 4: Significant past events include marriages, births, deaths; possibly important birthdays and anniversaries etc.

Question 7: Record whether or not (CR) has failed to finish any tasks that he/she set out to do during the past week. These tasks are self defined by the caregiver. In some rare instances, the respondent may volunteer the information that (CR) has not started anything, and hence could not possibly have started but not finished something. If this occurs, the "No" response should be checked.

Question 9: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes’ response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline. Cognitive can be defined as thinking ability, knowledge.

Question 19: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes’ response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

Question 21: If caregiver indicates that the care recipient expressed feelings of hopelessness or sadness nonverbally, the "yes" response should be marked.

Question 28: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes’ response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

Questions 29-31: If the response to question 29 is "no", leave the rest of the items blank and go to the next form. If response is "yes", ask the caregiver to specify the problem that (CR) had during the past week. In most cases, if there were other problems, the caregiver will tell the interviewer what they were. However, it may require some probing on the part of the interviewer to get the caregiver to be specific about the problems. For instance, the respondent may say something such as "Jane has also been acting strangely lately." A suggested text for probing would be: "Can you tell me what those problems were?" or "Could you please be more specific?" Record the response and proceed to the other questions (29.2, 29.3, 29.4) as described for the previous problems asked about in this questionnaire. Continue on with the next questions (30 & 31) in the same manner. Note: This form is designed to record only the first three “other” memory problems. If there are more than three record only the first three mentioned by the participant.

Question 32: *If the answer to **question 16** “Within the past week, has (CR) threatened to hurt him/herself?” is either 3 () “3 to 6 times in the past week” or 4 () “Daily or more often” is “yes”, the PI or PI designate should be contacted and then the caregiver must be contacted by a REACH team member (e.g., interviewer, interventionist, PC, or PI), who will follow the established alert process. After the initial contact, the REACH site is expected to monitor the caregiver, but no other action is required. This protocol applies to all assessment points (baseline and 6 months). Thus, a caregiver triggering this alert at Baseline and the 6-month follow-up would be contacted after Baseline and again after the 6-month battery.*

Question 33: *If the answer to **question 23** “Within the past week, has (CR) been commenting about the death of him/herself or others” is either 3 () “3 to 6 times in the past week” or 4 () “Daily or more often” is “yes”, the PI or PI designate should be contacted and then the caregiver must be contacted by a REACH team member (e.g., interviewer, interventionist, PC, or PI), who will follow the established alert process. After the initial contact, the REACH site is expected to monitor the caregiver, but no other action is required. This protocol applies to all assessment points (baseline and 6 months). Thus, a caregiver triggering this alert at Baseline and the 6-month follow-up would be contacted after Baseline and again after the 6-month battery.*

BURDEN INTERVIEW (BI)

PURPOSE: To record information regarding the caregiver's burden in caring for the care recipient.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up, batteries.

REQUIRED RESPONSE CARD(S): RC24.

GENERAL INSTRUCTIONS:

These questions all begin with the stem, "Do you feel..." and ask the caregiver about the personal strain and role strain they experience from caregiving. The response options range from "never" to "nearly always."

These questions are to be considered presently, so the caregiver should respond how they feel right now.

You may need to remind the respondent that "Although none of these options may match exactly how you feel, I need you to choose the closest one," or "Remember there are no right or wrong answers to these questions, we are interested in your opinion." Again, the respondent should not be pushed to the point of aggravation. If he/she cannot answer the question after prompting, mark the "unknown" response option.

In some instances, others might be present during the interview. If caregiver is uncomfortable answering these questions out loud, use the response card and have the caregiver point out his or her answer to each question, to maintain his or her confidentiality.

FORMAL CARE AND SERVICES (FC)

PURPOSE: To record information regarding the variety and frequency of usage of community-based medical and other care services. This form asks what kinds of community-based services that the caregiver and/or the care recipient have been using. The questions essentially list the services available to in-home caregivers.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1, RC25, RC26

GENERAL INSTRUCTIONS:

The time frame for most items in this form is within the past month. "The past month" refers to the 30 days falling immediately prior to the day of the interview. Interviewers will ask about a service and if a "yes" response is given, will then ask two follow up questions, (1) for whom (CG, CR, or both) this service is provided and (2) how often you/CR make use of/receive this service.

For all follow up questions, the number of times the service was used refers to the number of days the service was used in the last month. If, for example, the caregiver has a homemaker who prepares two meals every day, the response for the last month would be 30, not 60 (2 meals a day times 30 days).

The following conversions should be applied:

1. Every day of the month is equal to 30 days
2. Once a week is equal to 4 times per month
3. Every other week is twice per month
4. Only weekdays is 20 days per month
5. Only weekends is 8 times per month

On some rare occasions, the respondent may not be aware that some of those options exist. As a result, he/she may ask how and where to obtain those services. In these instances, the interviewer should provide the respondent with the telephone number of the local Alzheimer's Association. Previous studies using a similar questionnaire have encountered few respondents that ask these questions, but it is best to be prepared.

SPECIFIC INSTRUCTIONS:

Question 1: For this question, homemaker is defined as someone who is paid for services that they provide, or a volunteer affiliated with a formal organization, such as a church.

Questions 3 and 4 are to determine whether the same person is providing two different types of services. The cost of these services will differ depending on whether it is one person or more. This will be considered in the analysis of cost.

Question 5: Deliveries from businesses not catering specifically to the elderly, such as pizza shops and other non-discounted restaurants are excluded. Any other retail-priced prepared food is also excluded.

Question 6: This includes a formalized agreement with a taxi service, but exclude public mass transportation services (e.g. bus service, subways), which are available to people of all ages.

Question 10: A "physician" can be defined as a medical doctor or a general practitioner.

Question 14: Record the total number of days that (CG) spent in the hospital during the past month. Portions of a day are counted as a full day.

Questions 15 -20: These questions serve as a "catch-all" for services that either (CG) or (CR) have utilized during the past month that were not listed among the previous items in this form. These questions are unlike the others in that #15- #17 ask specifically about the other services the caregiver receives; while #18- #20 ask about the other services (CR) receives. As with the other questions, a "yes" response only, will lead to the follow- up questions about specifying the service and asking about the frequency. With each additional service listed, you will ask again, if there are any other services, up until 3 additional services have been identified. The caregiver will determine each discrete service as they interpret it. In some places, some services will be combined whereas in other places, the services are not combined. For some services it will appear that both the caregiver and care recipient are the beneficiaries of the service. In these cases, if it is possible to attribute a service to either the caregiver or care recipient, it should be recorded for only one. One example, respite care, should be recorded as a caregiver service only. Record as understood by the caregiver being careful to understand the service and describe it accurately. The term "agency" refers to any unpaid organization, such as a church. Use memory aid (RC25) to help caregiver identify possible services more easily. It is not necessary to read RC25 out loud (although do read if it appears necessary), but be sure the caregiver has read or understands the types of services captured in this question.

Question 21: Some people will be receiving services because they qualify as low income and receive services for free. In this case, "not at all difficult" is an appropriate response, since they do not have any financial burden due to these services.

Question 23: This question refers to any studies relating to Alzheimer's Disease or dementia, such as pharmaceutical testing studies or other intervention studies.

POSITIVE ASPECTS OF CAREGIVING (PC)

PURPOSE: To capture information that will characterize the positive aspects of caring for the care recipient that the caregiver has experienced. This form asks the respondents about possible good feelings they may get from the experience of caregiving.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC27.

GENERAL INSTRUCTIONS:

It is important to emphasize the instructions for this form. Piloting experience has pointed out the difficulties that some caregivers have with mentally “shifting” from questions about their negative experiences to questions about feelings of self-worth and fulfillment.

In the past, some respondents have become annoyed with these questions, since they did not see anything good coming out of the caregiving experience. Again, placing emphasis on the instructions should help to head off this type of problem. If the respondent does become annoyed, remind him/her that: “Some caregivers have reported positive experiences as a result of caregiving, and we are just trying to find out if you have had any similar experiences,” “I know some of these questions may not seem relevant to you, but I am required to ask everyone all of the questions,” “which of these options is closest to how you feel?,” or “Although none of these options may match exactly how you feel, I need you to choose the closest one.” If the respondent is still annoyed, do not try to force responses, mark “refused” and proceed.

For each question read the initial part (Providing help to (CR) has.....) followed by the remainder of the question-specific text. If the respondent feels that it is not necessary to hear the entire question each time the interviewer should read only the question-specific text.

When asking the questions on this form, the interviewer may find it helpful to change the wording of the questions from “your mother/father/etc.” to “my mother/father/etc.”

SPECIFIC INSTRUCTIONS:

Question 11: This question states “providing help to (CR) has strengthened my relationships with others”. CR is included in others for this question.

DESIRE TO INSTITUTIONALIZE (DI)

PURPOSE: To record information regarding the caregiver's plans regarding institutionalization of care recipient.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up, batteries.

REQUIRED RESPONSE CARD(S): RC1.

GENERAL INSTRUCTIONS:

The timeframe for these questions is the past six months.

SPECIFIC INSTRUCTIONS:

Question 1: Boarding home is defined as "a home in which accommodation and meals are provided to one or several unrelated individuals".

Questions 1-3: Any kind of sheltered care can be included in these questions.

Question 5: Visiting placement options or making calls to inquire about options would constitute a "yes" response.

CAREGIVER HEALTH AND HEALTH BEHAVIORS (CH)

PURPOSE: To collect basic information concerning the physical health status, symptoms, conditions and health-related behaviors of the respondent.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline, follow-up, bereavement, and placement batteries.

REQUIRED RESPONSE CARD(S): RC1, RC18, RC19, RC28, RC29, RC30, RC31.

GENERAL INSTRUCTIONS:

The first section of this questionnaire asks about the general health of the respondent. The next section asks about the health conditions of the respondent. The third section collects information on symptoms experienced. Lastly, there are a few questions about the impact of illness on daily routine and the respondent's perception of their health.

Be aware of shifting time frames. Questions shift from past month to past six months in the first section. The section about health conditions asks about the condition currently, meaning right now. The symptoms section asks about the past month, while the perception question (48) refers again to the past six months.

Questions 9 through 21: These questions (self-reported health problems) will require special attention. Most respondents should answer these questions without any problem. Sometimes, however, respondents may say they don't know whether or not they have a particular health problem. In this case, mark "unknown" and go on to the next question. In other cases, however, the respondent may say he/she doesn't know, and then volunteer some particular information. This information is critical for the interviewer to use in determining which response to choose. The question-specific instructions contain some guidelines to use if "yes" or "no" is not given immediately. If a condition is reported and the caregiver is unsure of whether it fits into any of the specific areas asked in these questions, report that condition in question 20 (other). Record as much information about the condition as you are given, which can later be verified and recoded in the appropriate category if it then appears to fit one of the listed categories.

Questions 24-44: These questions ask about symptoms. Any symptoms reported should be recorded even if they appear to be connected to one of the previously self-reported health problems. This will not result in double coding; rather it will capture a different element of the illness, that of how often the respondent experiences certain particular symptoms.

SPECIFIC INSTRUCTIONS:

Question 5 & 6: If the caregiver is not a smoker or does not drink alcohol, the N/A response should be checked.

Question 9: Arthritis. A doctor's diagnosis of arthritis is not necessary for a positive response to this question. The respondent may also mention that they take medication for pain in the joints. If the respondent mentions taking medications for this reason, mark "yes".

Question 10: High Blood Pressure. If the response is something like: "I don't know; the last time my blood pressure was checked it was 150 over 80", the interviewer must interpret that response. In order to do so, the interviewer needs to know that there are two types of blood pressure measurements. Systolic blood pressure is the higher of the two. A systolic blood pressure reading of 160 or greater is

considered high. Diastolic blood pressure (the lower of the two) is considered high if it is 90 or greater. Thus, the response above (i.e., 150 over 80) should be marked as “no”. If, however, either figure is higher than the cutoff, mark the “yes” response. If the respondent indicates only that his/her blood pressure is considered “borderline,” mark “no” and proceed to the next question.

Another indicator of high blood pressure is the use of medication. If the respondent says something like “I don’t know, my blood pressure is under control now,” the interviewer should find out if the respondent’s blood pressure is being controlled by medication. A suitable prompt would be: “Are you taking medication to control your blood pressure?” Any indication that the respondent is taking medication for high blood pressure or hypertension should be marked as a “yes” response.

The interviewer should not ask about the use of medication or the exact blood pressure, but these guidelines should be used if either are mentioned.

Question 11: Heart Condition (specifically heart disease, heart attack, chest pain due to your heart, congestive heart failure, angina, MI). Again, if the respondent does not know, then mark “unknown”, unless he/she volunteers further information specifying one or more of the following: heart disease, heart attack, chest pain due to the heart, congestive heart failure, angina, or myocardial infarction. Mark the “yes” response if any of these conditions are volunteered.

Question 12: Chronic Lung Disease such as chronic bronchitis or emphysema (not asthma). This question should be marked “yes” only if the respondent reports having a chronic lung disease other than asthma. If the response is “I have bronchitis”, or “I have a respiratory infection”, the interviewer should ask: “Is it a temporary condition?” If the respondent is suffering from a temporary condition, and has no chronic condition, mark the “no” response. Another indicator of lung disease is use of oxygen, although oxygen is sometimes given to asthma sufferers. If the respondent reports he/she is taking oxygen, or if he/she is obviously taking oxygen, the interviewer should find out if it is for asthma, and if not, mark the “yes” response.

Question 13: Diabetes. This question should be marked as “no” unless the respondent either answers “yes” or mentions “problems with my sugar.” In addition, if the respondent is on insulin or oral hypoglycemics (“sugar pills”) mark “yes”.

Question 14: Stroke. If the respondent reports receiving treatment or medication to prevent a stroke, mark “no” unless he/she reports having had a prior stroke. If he/she reports having had a “TIA”, but not a stroke, the “no” response should be marked as well. If the response is a “small stroke” mark “yes”. Mark “yes” if he/she responds that they had any kind of “stroke”.

Question 15: Stomach ulcers, irritable bowel syndrome, etc. Not simple indigestion- this is intended to reflect a condition that needs monitoring by a health professional.

Question 16: Kidney problems. This should be a condition that is being treated through medication or dialysis.

Question 17: Cirrhosis or other serious liver problem. This is intended to reflect a condition that needs monitoring by a health professional.

Question 18: Cancer. If the respondent mentions having had cancer that was “cured” or successfully treated, mark the “no” response. If the respondent is currently undergoing treatment for cancer, mark the “yes” response. The same rule holds true for skin cancers: if the respondent reports having had a skin cancer that was removed/treated, mark the “no” response; if the respondent is currently undergoing treatment for skin cancer, mark “yes”.

Question 19: Vision or hearing problems. If the respondent states he/she wears glasses only, and can see fine with glasses, mark the “no” response. The response should be yes for anything other than glasses and a standard hearing aid.

Question 22 & 23: These questions also refer to currently, therefore if the respondent has a short term health problem or a long term health problem that requires them to have help at the time of the interview, mark the “yes” response. If the respondent, has had help in the past, but not currently, mark the “no” response.

Questions 24-44: These questions might require some prompting to help the respondent recall the symptom and length of time symptom lasted. If they give a vague amount of time, such as “a few days”, “a couple of days” etc., ask them to give a number of days. If the respondent is unable to recall having the symptom, mark the “no” response. If the respondent states they have had the symptom but is unsure of the length of time it lasted, you may need to probe further. “Did you have it a long time or short time?, “Can you remember things you did this past month, visiting, shopping, etc.- did you alter your routine because of this symptom?”

Question 29: Toothache. Include bleeding and or swollen gums as symptom.

Question 32: Dry Cough. A dry cough is a condition that does not produce phlegm and is not due to temporary irritation such as swallowing food/drink improperly.

Question 34: Wheezing. Wheezing is defined as difficulty maintaining normal air flow resulting from respiratory inflammation such as asthma or allergic reactions.

Question 35: Unusual shortness of breath. This refers to difficulty breathing after normal physical exertion, inability to regain normal breathing pattern after brief period of excitement.

Question 36: Unplanned loss of weight. This refers to weight loss that does not occur due to conscious effort through diet and/or exercise.

Question 39: Heartburn. This category should include simple/chronic indigestion.

Question 43: Bloody or black stools. The color and condition of the stool is due to an underlying health condition, not medication or diet.

Questions 45-47: These questions ask about the number of days lost of different activities due to illness. Enter the number of days reported. If the caregiver does not work, the response for question 45 is N/A, written in the space provided.

Question 48: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes” response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

CES-D (SD)

PURPOSE: To record information regarding the affective state of the respondent. The CES-D is a widely-used instrument for the measurement of depression and for the identification of individuals who are prone to depression.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline, follow-up, bereavement, placement, and discontinued batteries.

REQUIRED RESPONSE CARD(S): RC1, RC18, RC19, RC32.

GENERAL INSTRUCTIONS:

This form contains a possible alert.

This form contains 12 statements describing different feelings and emotional states. The caregiver is asked to indicate how often she or he felt that way during the past week.

These mood items are followed by one final question that asks the caregiver to rate their impression of the overall improvement in their mood or emotional well-being over the past six months.

The phrases used in this questionnaire are subjective and definitions should be left up to the respondent. If a respondent asks what a particular phrase means, you should simply state "whatever it means to you" and repeat the question.

If the respondent has difficulty with the items in this form, it may be necessary to reread the question and/or response options, or state "remember there are no right or wrong answers to these questions, we are interested in your opinion", or "these possible responses may not fit exactly how you feel, but please choose the option that is closest to how you feel."

SPECIFIC INSTRUCTIONS:

Question 10: If respondent asks what does "get going" means, state it means "get started".

Question 13: This is a perception question. The caregiver is to answer yes or no to the main question. A "yes" response is followed by asking whether the caregiver sees minimal or substantial improvement. A "no" response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

Question 14: CES-D Score: The CES-D score should be calculated only when there are 2 or less missing responses on **questions #1-10 only** (questions 11 & 12 are additional items not used to score the 10 item CES-D). If more than 2 questions are missing, the total CES-D score should be given a missing value. *If there is any indication based on the non-missing responses and the interviewer's impression that the caregiver may have depressive symptomatology, the PI or PI designate should be shown the non-missing responses.*

To compute the CES-D score, first reverse code the responses for* items #5 and #8 so that all the questions which comprise the CES-D score are in the same direction (i.e., higher scores for all questions are worse, indicative of greater duration of depressive symptomatology). Thus, for questions #5 and #8, a zero should be scored as a three, a one as a two, a two as a one and a three as a zero.

Do NOT reverse the codes on the form; PoP will automatically reverse, so data entry personnel will enter items as they appear on the form.

Then to compute the score:

- 1) First add the scores for questions #1 through #10 (using the values from questions #5 and #8 after reverse coding their responses in the manner described above).
- 2) Take the total score and divide by the number of non-missing items.
- 3) Multiply the value from step 2 by 10 (the total number of questions in the scale).

For example, if a participant answered 8 questions and had a score of 16 on these 8 questions (after doing reverse scoring, where appropriate), the CES-D score is:

$$16 / 8 = 2$$

then multiply by 10

$$2 \times 10 = 20. \text{ Thus the CES-D score is 20.}$$

Question 15: Is the CES-D score greater than or equal to 15?

Indicate if the CES-D score is greater than or equal to 15. If “yes”, indicate whether the Principal Investigator at the site or the appropriate personnel were notified about the depression level of the caregiver. If the PI or appropriate personnel were not notified, then do so immediately and indicate that they were informed.

If the CES-D score is 15 or greater, the PI or PI designate should be contacted and then the caregiver must be contacted by a REACH team member (e.g., interviewer, interventionist, PC, or PI), who will follow the established alert process. After the initial contact, the REACH site is expected to monitor the caregiver, but no other action is required. This protocol applies to all assessment points (baseline and 6 months). Thus, a caregiver scoring 15 or higher on the CES-D at Baseline and the 6-month follow-up would be contacted after Baseline and again after the 6-month battery.

SOCIAL SUPPORT (SS)

PURPOSE: To record information regarding the kinds and amount of support that the caregiver receives from friends, neighbors, or family members.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline, follow-up and placement batteries.

REQUIRED RESPONSE CARD(S): RC1, RC18, RC19, RC33, RC34, RC35, RC36.

GENERAL INSTRUCTIONS:

Most of the questions ask about the support received in the past month. When there is no time frame given, the question should be understood as asking about right now.

The questions throughout this form refer to persons outside the home. This means other people living in the same home and the care recipient are excluded from the questions. The interviewer should always ensure that the respondent's answer excludes these individuals. You may need to probe to obtain this information when necessary.

The social support items are followed by one final question that asks the caregiver to rate their impression over the past six months of the overall improvement in the social support they have received.

The response options throughout this form must be read aloud, since they vary from question to question. It may be necessary to make a statement like "I know this may seem repetitious, but I am required to read all of the possible responses."

Many of the questions use the terms "someone" or "others." By "someone" or "others," we mean friends, neighbors, or family members. . Some of the questions, mostly in the beginning of the questionnaire, explain who someone/others are. Occasionally however, a respondent may want to know who is meant by the term "someone" or "others". If this information is requested, the interviewer should respond, "By someone (or others), we mean friends, neighbors, or family members." Again, the care recipient should always be excluded from these responses.

"Relatives" include both blood relatives and relatives by marriage.

Throughout the form, the term "help" refers to aid, assistance or lending a hand with the actual performance of the activity/task (e.g., actually does the grocery shopping or bill paying) or some aspect of the task (e.g., drives to the grocery store or provides care to the care recipient so that you are able to go to the grocery store)

SPECIFIC INSTRUCTIONS:

Questions 1, 7, 9, 11: These questions are designed to probe satisfaction with received support. These questions ask the caregiver how satisfied they are with... If the caregiver states they do not receive the type of help or support asked about in the question, then probe to determine how satisfied the respondent is with not receiving any help. An example probe would be, "I understand that you did not receive any help with _____. Were you not at all, a little, moderately, or very satisfied with that?"

Question 2: "See or hear" includes visits in person or by telephone, as well as letters received.

Questions 6 & 7: The term “transportation” refers to driving the participant somewhere.

Question 8: For someone to “be there” in this question the person needs to be in the same place with the caregiver. If a person is with the participant but only by phone and is not there physically with the participant this would not count. Providing comfort is a subjective term and the definition should be left up to the participant. If the participant asks what “providing comfort” means, tell them that it means providing comfort to them in any way. Expressed concern is a subjective term and the definition should be left up to the participant. If the participant asks what “expressed interest or concern” means tell them that it means expressing any type of interest or concern.

Question 12: “Demands” is a subjective term and the definition should be left up to the respondent. If the participant asks what “demands” means tell them that it can mean anything that others ask them to do that they feel is a demand.

Question 13: Being critical is a subjective term and the definition should be left up to the respondent. If the participant asks what is meant by “being critical” tell them that it can mean anything that they feel is a criticism from someone else.

Question 14: The definition of “pried into your affairs” should be left up to the respondent. If the participant asks what is meant by “pried into your affairs” tell them that it can mean anything that they feel others have done to find out things that they feel are private.

Question 15: The definition of “taken advantage of” is subjective and should be left up to the respondent. If the participant asks what we mean tell them that it can mean anything that they feel others have done to take advantage of them.

Question 16: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes” response is followed by asking whether the caregiver sees minimal or substantial improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

RELIGIOUS/SPIRITUAL COPING (RG)

- PURPOSE:** To record information regarding spiritual coping and religion in the caregiver's life.
- TIME OF DATA COLLECTION:** At the baseline visit only. This form appears in the baseline battery only.
- REQUIRED RESPONSE CARD(S):** RC37, RC38

GENERAL INSTRUCTIONS:

The first section of this form asks about spiritual coping. If a caregiver states they do not believe in God, but in some other higher force or a polytheistic faiths (e.g., "gods"), please ask the questions referring to a higher force or gods. If referring to God is appropriate, it is also sufficient to mention only God after establishing this preference in the remaining questions.

The second section asks the caregiver for their religious preference as well as about their attendance at religious activities and frequency of praying.

SPECIFIC INSTRUCTIONS:

Question 7: Do not read the list of responses to the caregiver. If the religion preference specified is not on the list, check "other" and indicate preference stated by the caregiver. If the caregiver indicates no religious preference, but considers himself or herself spiritual, Agnostic or Atheist, also check "other" and indicate preference stated by the caregiver. If the caregiver indicates no religious preference, check "None". If the caregiver refuses to answer this question check "Refused".

Question 8: Examples of religious activities include services (e.g. Mass), meetings (e.g. Bible study groups) or activities (e.g. church socials). A response of "every day", or "daily" should be coded as "Nearly every day".

Question 9: A response of "every day" or "daily" should be coded as "Nearly every day".

SOCIAL ACTIVITIES (SA)

PURPOSE: To record information regarding how satisfied the caregiver is with the amount of time spent on activities that he/she might engage in for enjoyment.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline, follow-up, bereavement, and placement batteries.

REQUIRED RESPONSE CARD(S): RC39.

GENERAL INSTRUCTIONS:

These questions contain two parts to each question. The first part of the question asks how often the caregiver engaged in the activity. The second part of the question asks the caregiver how satisfied he/she is with the amount of time spent doing the particular activity. All the questions refer to the past month.

In some cases, the interviewer may encounter a situation in which the caregiver responds “No, I didn’t do that at all” to the second part of the question. You should first repeat the question, emphasizing the phrase “How satisfied are you”. If that fails, probe to find out if that amount of activity was satisfactory with a question such as “I understand that you did not ____ during the past month. Would you say you were not at all, a little, or a lot satisfied with that?”

You may need to remind the respondent that “Although none of these options may match exactly how you feel, I need you to choose the closest one,” or “Remember there are no right or wrong answers to these questions, we are interested in your opinion.” Again, the respondent should not be pushed to the point of aggravation. If he/she cannot answer the question after prompting, mark the “unknown” response option.

SPECIFIC INSTRUCTIONS:

Question 1: “Activities” refer to any activities that the participant enjoys doing.

Question 3: This includes any type of organized group that meets on a regular basis.

Question 4: This includes anything that the participant considers a hobby or other interest.

Question 6: “Fun things” are self defined by the respondent.

QUALITY OF CARE (QC)

PURPOSE: This form helps us to get a picture of the living environment of the caregiver and care recipient, as well as abusive and exemplary behavior towards the care recipient. Through this information, aspects of the quality of care given by the caregiver are obtained.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1, RC40.

GENERAL INSTRUCTIONS:

Living Environment:

This first section contains questions that are both asked of the caregiver and observational. The interviewer will ask the questions directly of the caregiver where indicated and then observe themselves other aspects that are specified on the form. This section involves a tour of the rooms that the care recipient uses. The interviewer will explain to the caregiver that “the purpose of the tour is not to judge the home (as to its cleanliness or orderliness) or inspect it. Rather, we are interested in the many ways people change or do not change their home in response to caregiving. This information will enable us to help other people.” It is important that the caregiver accompanies you on the home tour since probes and questions will be required to clarify your observations.

In a few cases, you may encounter reluctance from a participant to observe one or all of the rooms you request to see. This may be likely if the caregiver is fatigued from the interview, does not feel comfortable with the interview and/or if someone else is using one of the rooms and its observation would be intrusive. In these cases, ask caregiver “would it be ok to try and view the rooms when the interview is complete before we leave today?” If the caregiver still resists, then thank them, move onto the next section and mark as “refused”. Some caregivers may express embarrassment about the appearance of their home or become defensive as a consequence of this aspect of the assessment. It may become necessary to periodically reassure the participant that the purpose of this part of the interview is merely to ascertain information about the home environment of people with dementia.

Frustrations in Caregiving:

In this section, you will be asking questions that may be uncomfortable to the caregiver, as they ask about negative feelings and actions towards the care recipient. Be sure to read the instructions for this section clearly and completely. Remind the caregiver there is no right or wrong answer, just his or her own feelings.

If the respondent does become annoyed, remind him/her that: “Some caregivers have reported feeling frustrated and using these types of methods to get care recipients to do what you need them to do, and we are just trying to find out if you have had any similar experiences,” “I know some of these questions may not seem relevant to you, but I am required to ask everyone all of the questions,” “which of these options is closest to how you feel?” If the respondent is still annoyed, do not try to force responses, mark “refused” and proceed.

If the caregiver states they do these things, not just think about it, mark the frequency that they engage in the behavior. **If the responses to these questions describe a situation that has the care recipient in an abusive environment, report this information to the project coordinator or principal investigator.**

Exemplary Caregiving:

These questions ask about ways caregivers continue to involve the care recipient in positive social, emotional and physical interactions and environments. Again, you might have some caregivers who have difficulty answering these and will need to encourage them to respond however they feel.

SPECIFIC INSTRUCTIONS:

Question 1-5: For this set of questions, the N/A option should NOT be used. The rationale for this is that the caregiver should not be determining if these adjustments to the physical environment are necessary or not. For the study, it is only important to record whether these items are being done/used or if they are not being done/used.

Question 1: Materials refers to games, magazines, photos, stuffed animals or other items that the care recipient finds comforting and interesting to him or her.

Question 3: Some caregivers may be unaware that they have made modifications in response to the situation. Examples like taking up area rugs, moving the television, removing plants can be given to help probe.

Question 5: This question will capture all devices except a grab bar in the bathroom which is asked separately in question 9. Do not include a bathroom grab bar in this question. Examples of assisted devices or special equipment are canes, walkers, built-up utensils, tub seats, elevated toilet seat, communication boards, transfer boards, pill splitters, adapted faucets, commodes, long-handled items such as reachers, lift cushion, stocking donner, telephone with large button, etc.

Question 9: A grab bar is different than a banister or handrail, as it is a specifically installed item which is installed so an individual can steady themselves and assist in tasks such as raising or lowering at the toilet area. Towel racks and safety bars on windows are NOT considered grab bars even if they are used for that purpose.

Question 16: Physical restraint should be considered something that keeps care recipient confined for more than a few minutes. Therefore, holding a person's hands together or keeping them in a chair with your own body in front of them for a few minutes would not be restraint.

Question 22: This question asks about telling CR to stop doing things that caused worry. If the caregiver asks for clarification, a statement such as "these things are things that are potentially dangerous to you (CG), (CR), or others."

Questions 23-40 Exemplary Caregiving questions. Some of these questions, (34 & 39 particularly) may evoke a response from the caregiver that the CR doesn't enjoy anything or never gets upset. There is no N/A (not applicable) option in this section, therefore use a (-3) "unknown" response for situations where the caregiver states this item is not applicable to him or her.

RISK APPRAISAL (RA)

PURPOSE: This form asks general questions in the areas of education; safety; caregiving skills; social support; and caregiver emotional and physical well-being to identify risk for the caregiver.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1, RC41.

GENERAL INSTRUCTIONS:

This form contains two possible adverse events/acute screening criteria alerts.

Be aware of shifting time frames. Some questions refer to the present, while others ask about the past month, past six months or past year depending on the issue involved.

If the caregiver responds that the care recipient did do a certain behavior but is not currently doing it, then the “never” response is appropriate.

The questions asked require either a yes/no response or a response of never, sometimes, or often.

These questions are somewhat repetitive with questions asked previously throughout the battery. If the respondent becomes annoyed with these questions try to repeat the instructions and remind him/her that “Some of these questions are repetitive but it will not take long to answer and I am required to ask everyone all of the questions.”

SPECIFIC INSTRUCTIONS:

Question 3: Living will can be defined as a type of advance directive which allows a person to give instructions about future medical care and appoint another person to make health care decisions if he or she is unable to make them him/herself.

Question 5: Both a working smoke detector and a fire extinguisher are needed by caregiver. If caregiver replies they have one of the two, mark the “no” response.

Question 7: If the caregiver answers yes to this question, (the care recipient has access to dangerous objects), probe to identify what the object is/are that the care recipient is able to get. In question 52.1 it is recorded whether this object is a gun. A response of a gun will trigger the adverse event/acute screening criteria alert.

Question 9: If caregiver is unsure, since they are out of the house. Ask “do you think, or have any reason to believe this is happening”. Caregiver should answer how they feel most comfortable. If caregiver can not answer, mark “unknown”.

Question 10: The stove does not have to be turned on. It is only necessary that the care recipient has a habit of leaving things on or in the stove, in an inappropriate manner.

Question 23: This question refers to an extended period of time, more than a few days at a time. For example, if the caregiver became ill.

Question 38: This question asks whether a female caregiver has had a mammogram in the past two years. This question should be asked of all female caregivers. If the caregiver is <40 years old, N/A (not applicable) will most likely be the appropriate response. Women under the age of 40 with high risk, such as family history of breast cancer may report they have had a mammogram.

Question 39: This question asks whether a female caregiver has had a pap smear in the past two years. This question should be asked of all female caregivers. If the caregiver has had a hysterectomy, it is up to her physician to determine whether she needs to have additional pap smear tests and the frequency of these tests. If the caregiver reports her doctor has said it is not necessary or not necessary in the past two years (i.e. she needs the test only once every 5 years and hasn't had it in the past two years) then N/A (not applicable) will be the appropriate response.

Question 40: This question asks whether a male caregiver has had a prostate examination in the past year. This question should be asked of all male caregivers. If the caregiver is <50 years old, N/A (not applicable) will most likely be the appropriate response. Men under the age of 50 with high risk, such as family history of prostate cancer may report they have had a prostate examination.

Question 52 & 52.1: *If the answer to **question 7** "Can (CR) get to a dangerous object" is "yes", and the object identified is a gun, the PI or PI designate should be contacted and then the caregiver must be contacted by a REACH team member (e.g., interviewer, interventionist, PC, or PI), who will follow the established alert process. After the initial contact, the REACH site is expected to monitor the caregiver, but no other action is required. This protocol applies to all assessment points (baseline and 6 months). Thus, a caregiver triggering this alert at Baseline and the 6-month follow-up would be contacted after Baseline and again after the 6-month battery.*

Question 52: *If the answer to **question 14** "Does (CR) drive" is "yes", the PI or PI designate should be contacted and then the caregiver must be contacted by a REACH team member (e.g., interviewer, interventionist, PC, or PI), who will follow the established alert process. After the initial contact, the REACH site is expected to monitor the caregiver, but no other action is required. This protocol applies to all assessment points (baseline and 6 months). Thus, a caregiver triggering this alert at Baseline and the 6-month follow-up would be contacted after Baseline and again after the 6-month battery.*

CAREGIVER MEDICATIONS (GM)

PURPOSE: To record information regarding all of the medications (prescription and non-prescription, including herbal and vitamins) currently being taken by the caregiver.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline, follow-up, bereavement, and placement batteries.

REQUIRED RESPONSE CARD(S): RC1.

GENERAL INSTRUCTIONS:

This form asks the interviewer to list all of the medications currently being taken by the caregiver. The respondent should have been instructed prior to the interview to gather all his/her medications and all of the care recipient's medications (into two separate bags) to expedite filling out this form. Read the instructions on the form, and clearly print the names of the medications onto the appropriate form.

Drug codes are available by accessing the REACH II website – call the Coordinating Center for a username and password to access the document sharing area. More detailed instructions are provided in the instructions for question 1.1 of this form.

Medications encountered in interviews that are not currently on the list will be assigned to the appropriate category by the Coordinating Center. If this is encountered please notify the Coordinating Center immediately. Be sure to obtain the entire name of the medication(s) before contacting the Coordinating Center. Medications codes should be temporarily coded as 9999. Once the code for the medication is received from the Coordinating Center, the pending code should be updated to the correct code.

On some rare occasions, the respondent may not have prepared the bag of medication, for whatever reason. In this situation, the interviewer should patiently ask the respondent to gather the medications, and wait until this task is complete.

In a number of instances, participants may have difficulty separating their own medications from those of the care recipient because they both take the same drug. In this case, be sure to record that medication on both the CG Medications form and the CR Medications form.

IMPORTANT NOTE: Do not offer any advice to the respondent on medications. This includes advice on the medications currently taken by the caregiver, other medications which the interviewer may know about, compliance, dosage instructions, or any other advice. If the respondent asks any questions relating to medications, the interviewer should respond: "I really don't know anything about any medicines--the best thing I could tell you is to ask your physician or pharmacist."

If the caregiver is taking medication as part of a trial **and is masked or blinded to the name of the drug** that he or she is taking, record "BLINDED STUDY DRUG" in the space allocated for the medication name and record a code of 8888 for the medication code.

If a participant is taking more than 30 medications, call the Coordinating Center for further details.

Specific Instructions:

Question 1: The interviewer should first record whether or not the caregiver is taking any medication. If the caregiver is not taking any medications enter the word "NONE" in all capital letters in the allocated

space. If the caregiver is unable to report the medications enter the word "UNKNOWN" in all capital letters. If the caregiver refuses to report the medications enter the word "REFUSED" in all capital letters.

If the caregiver is taking medication, record the name of the first medication using all capital letters. The name of the medication should be copied as it appears on the label. Record only the first twenty letters of the name. The response begins at the left most space. Record only one letter per space. If the name of the medication is less than twenty letters, leave the remaining spaces blank. If the name is longer than 20 letters, also record the entire name in the margin of the form. The interviewer should continue this until all of the medication, that the CG takes, has been recorded. After recording all the medications, leave the remaining lines, if applicable, blank.

The interviewer should then record the 4-digit code associated with the medication listed in 1.1.1. This is available on the Medication Code Table listed on the REACH II web site (or by printing this listing) and entering the 4-digit code number assigned to the drug. Herbal medications and vitamins have been included in this master list. Combination drugs (more than one drug combined in one tablet) should be recorded and coded separately.

If a medication is encountered that is not currently on the list, contact the Coordinating Center and the drug will be assigned to the appropriate category.

Question 2: After all of the medication, that the caregiver takes, has been recorded, the interviewer should ask if any of the medication is being taken for anxiety, depression, or stress. If the answer is "Yes", the interviewer should prompt the caregiver to identify which medication is being taken for anxiety, depression, or stress and then check the appropriate column to the right of the medication name. This question is asking for the caregiver's opinion. This question is to determine what the caregiver believes he or she is taking for anxiety, depression or stress. It is not important whether the medication(s) selected are actually used for those purposes or if a known medication to treat anxiety, depression or stress is not indicated.

CARE RECIPIENT MEDICATIONS (RM)

PURPOSE: To record information regarding all of the medications (prescription and non-prescription including herbal and vitamins) currently being taken by the caregiver.

TIME OF DATA COLLECTION: At the baseline visit and six-month follow-up visit. This form appears in the baseline and follow-up batteries.

REQUIRED RESPONSE CARD(S): RC1.

GENERAL INSTRUCTIONS:

This form asks the interviewer to list all of the medications currently being taken by the care recipient. The respondent should have been instructed prior to the interview to gather all his/her medications and all of the care recipient's medications (into two separate bags) to expedite filling out this form. Read the instructions on the form, and clearly print the names of the medications onto the appropriate form.

Drug codes are available by accessing the REACH II website – call the Coordinating Center for a username and password to access the document sharing area. More detailed instructions are provided in the instructions for question 1.1 of this form.

Medications encountered in interviews that are not currently on the list will be assigned to the appropriate category by the Coordinating Center. If this is encountered please notify the Coordinating Center immediately. Be sure to obtain the entire name of the medication(s) before contacting the Coordinating Center. Medications codes should be temporarily coded as 9999. Once the code for the medication is received from the Coordinating Center, the pending code should be updated to the correct code.

On some rare occasions, the respondent may not have prepared the bag of medication, for whatever reason. In this situation, the interviewer should patiently ask the respondent to gather the medications, and wait until this task is complete.

In a number of instances, participants may have difficulty separating their own medications from those of the care recipient because they both take the same drug. In this case, be sure to record that medication on both the CG Medications form and the CR Medications form.

IMPORTANT NOTE: Do not offer any advice to the respondent on medications. This includes advice on the medications currently taken by the caregiver, other medications which the interviewer may know about, compliance, dosage instructions, or any other advice. If the respondent asks any questions relating to medications, the interviewer should respond: "I really don't know anything about any medicines--the best thing I could tell you is to ask your physician or pharmacist.

If the care recipient is taking medication as part of a trial **and is masked or blinded to the name of the drug** that he or she is taking, record "BLINDED STUDY DRUG" in the space allocated for the medication name and record a code of 8888 for the medication code.

If a participant is taking more than 30 medications, call the Coordinating Center for further details.

Specific Instructions:

Question 1: The interviewer should first record whether or not the care recipient is taking any medication. If the care recipient is not taking any medications enter the word "NONE" in all capital letters in the allocated space. If the caregiver is unable to report the medications enter the word

“UNKNOWN” in all capital letters. If the caregiver refuses to report the medications enter the word “REFUSED” in all capital letters.

If the care recipient is taking medication, record the name of the first medication using all capital letters. The name of the medication should be copied as it appears on the label. Record only the first twenty letters of the name. The response begins at the left most space. Record only one letter per space. If the name of the medication is less than twenty letters, leave the remaining spaces blank. If the name is longer than 20 letters, also record the entire name in the margin of the form. The interviewer should continue this until all of the medication, that the CG takes, has been recorded. After recording all the medications, leave the remaining lines, if applicable, blank.

The interviewer should then record the 4-digit code associated with the medication listed in 1.1.1. This is available on the Medication Code Table listed on the REACH II web site (or by printing this listing) and entering the 4-digit code number assigned to the drug. Herbal medications and vitamins have been included in this master list. Combination drugs (more than one drug combined in one tablet) should be recorded and coded separately.

If a medication is encountered that is not currently on the list, contact the Coordinating Center and the drug will be assigned to the appropriate category.

Question 2: After all of the medication, that the CR takes, has been recorded, the interviewer should ask if any of the medication is being taken for anxiety, depression, or stress. If the answer is “Yes”, the interviewer should prompt the caregiver to identify which medication is being taken for anxiety, depression, or stress and then check the appropriate column to the right of the medication name. This question is asking for the caregiver’s opinion. This question is to determine what the caregiver believes the care recipient is taking for anxiety, depression or stress. It is not important whether the medication(s) selected are actually used for those purposes or if a known medication to treat anxiety, depression or stress is not indicated.

FOLLOW-UP SOCIODEMOGRAPHICS (FS)

PURPOSE: This form is included in order to obtain descriptive information about the caregiver and care recipient. This follow-up form is an abbreviated version of the baseline form. It focuses on sociodemographic characteristics that can change during the course of the study.

TIME OF DATA COLLECTION: At the six-month follow-up visit. It appears only in the follow-up battery.

REQUIRED RESPONSE CARD(S): RC1, RC5, RC10, RC11, RC12, RC13, RC14, RC15.

GENERAL INSTRUCTIONS:

This questionnaire asks one question (marital status) about both the caregiver and care recipient that may have changed in the past six months. The remaining questions are for the caregiver to answer about themselves only.

SPECIFIC INSTRUCTIONS:

Question 2: If the caregiver states that he or she is not currently employed, a probe will need to be given to determine if the caregiver has retired. If the caregiver has not retired, the response "Not currently employed, not retired" is checked regardless of whether or not the caregiver is currently looking for employment. A probe may need to be given to determine if the employment is full-time or part-time. Full-time is defined as 35 or more hours per week. If the respondent is not currently employed and not looking for a job (for example, an AFDC recipient, a seasonal worker, not currently working, or disabled not currently working), code as "Not currently employed, not retired." In other cases that may arise in which it is difficult to decide how the employment situation should be coded, it should be up to the respondent to decide which category best describes his/her situation.

Question 2.3.1: Indicate the amount of time in hours and minutes, that the caregiver has reduced his or her work load. If the caregiver indicates a fraction of an hour, the fraction must be converted to minutes (e.g. twenty and three quarters of an hour = "20:45").

Question 4: Keep in mind that many people do not like to reveal information about their income, and may have a negative reaction to this question. Although every effort has been made to ask this question in the most unintrusive manner possible, respondents may still resist answering it. The introduction to the question reminds the respondent that all the information is kept strictly confidential, it will not be associated with their name in any way, the information is very important for the study, and that they only need to indicate the number of the category on the card, not the dollar amount.

Because the assurances about confidentiality are provided at the beginning of the question and because it is a sensitive question, an initial refusal by the respondent to answer the question should be acknowledged and the interviewer should mark "Refused" and go on to the next item.

If the respondent seems unsure, but does not explicitly refuse to answer the question, you may need to remind the respondent that "because this information is kept confidential, it will in no way jeopardize your eligibility to receive services from any agency." Also, a reminder of the importance of the study might help. Of course, if the respondent refuses to answer the question, we must respect his or her privacy.

Question 7: This question refers to persons having permanent living arrangements, i.e., persons who have been residing in the dwelling for at least 6 months. If an individual lives in the house less than 6 months out of the year, they should not be included in the count. If they live in the house more than 6 months out of the year, they should be counted. A permanent resident of the home that has been living in the home less six months is not counted in the census.

TRANSITION FORMAL CARE AND SERVICES (TF)

PURPOSE: To record information regarding the variety and frequency of usage of community-based medical and other care services. This form asks what kinds of community-based services that the caregiver and/or the care recipient have been using. The questions essentially list the services available to in-home caregivers.

TIME OF DATA COLLECTION: At the six-month follow-up visit. This form appears in the bereavement and placement batteries.

REQUIRED RESPONSE CARD(S): RC1, RC25, RC26.

GENERAL INSTRUCTIONS:

The time frame for most items in this form is within the past month. "The past month" refers to the 30 days falling immediately prior to the day of the interview. Interviewers will ask about a service and if a "yes" response is given, will then ask one follow up questions, (1) how often you make use of/receive this service.

For all follow up questions, the number of times the service was used refers to the number of days the service was used in the last month. If, for example, the caregiver has a homemaker who prepares two meals every day, the response for the last month would be 30, not 60 (2 meals a day times 30 days).

The following conversions should be applied:

1. Every day of the month is equal to 30 days
2. Once a week is equal to 4 times per month
3. Every other week is twice per month
4. Only weekdays is 20 days per month
5. Only weekends is 8 times per month

On some rare occasions, the respondent may not be aware that some of those options exist. As a result, he/she may ask how and where to obtain those services. In these instances, the interviewer should provide the respondent with the telephone number of the local Alzheimer's Association. Previous studies using a similar questionnaire have encountered few respondents that ask these questions, but it is best to be prepared.

SPECIFIC INSTRUCTIONS:

Question 1: For this question, homemaker is defined as someone who is paid for services that they provide, or a volunteer affiliated with a formal organization, such as a church.

Questions 3: This question is to determine whether the same person is providing two different types of services. The cost of these services will differ depending on whether it is one person or more. This will be considered in the analysis of cost.

Question 4: Deliveries from businesses not catering specifically to the elderly, such as pizza shops and other non-discounted restaurants are excluded. Any other retail-priced prepared food is also excluded.

Question 5: This includes a formalized agreement with a taxi service, but exclude public mass transportation services (e.g. bus service, subways), which are available to people of all ages.

Question 9: A "physician" can be defined as a medical doctor or a general practitioner.

Question 12: Record the total number of days that (CG) spent in the hospital during the past month. Portions of a day are counted as a full day.

Questions 13: This question serves as a "catch-all" for services that the caregiver (CG) has utilized during the past month that were not listed among the previous items in this form. As with the other questions, a "yes" response only, will lead to the follow- up question asking about the frequency. With each additional service listed, you will ask again, if there are any other services, up until 3 additional services have been identified. The term "agency" refers to any unpaid organization, such as a church. Use memory aid (RC24) to help caregiver identify possible services more easily.

TRANSITION RELIGIOUS/SPIRITUAL COPING (TR)

PURPOSE: To record information regarding spiritual coping and religion in the caregiver's life. This follow-up form is an abbreviated version of the baseline form. It contains questions on aspects of religiosity that may change during the course of the study.

TIME OF DATA COLLECTION: At the follow-up visit only. This form appears in the follow-up, bereavement and placement batteries.

REQUIRED RESPONSE CARD(S): RC37, RC38.

GENERAL INSTRUCTIONS:

The first section of this form asks about spiritual coping. If a caregiver states they do not believe in God, but in some other higher force or a polytheistic faiths (e.g., "gods"), please ask the questions referring to a higher force or gods.

The second section asks the caregiver about their attendance at religious activities and frequency of praying.

SPECIFIC INSTRUCTIONS:

Question 7: Examples of religious activities include services (e.g. Mass), meetings (e.g. Bible study groups) or activities (e.g. church socials). A response of "every day", or "daily" should be coded as "Nearly every day".

Question 8: A response of "every day" or "daily" should be coded as "Nearly every day".

TRANSITION REVISED MEMORY AND BEHAVIOR PROBLEM CHECKLIST (TM)

PURPOSE: This form asks about the perceived change in memory, behavioral and emotional problems that the care recipient has been having.

TIME OF DATA COLLECTION: At the six-month follow-up visit. This form appears in the placement and discontinued batteries.

REQUIRED RESPONSE CARD(S): RC1, RC18, RC19.

GENERAL INSTRUCTIONS:

This form contains only three questions that asks caregiver to rate their impression of care recipient (CR)'s overall improvement in cognition, behavior and mood over the past six months. These same questions were asked during the baseline interview following specific questions about the care recipient's memory, behavior and mood.

SPECIFIC INSTRUCTIONS:

Question 1-3: These are perception questions. The caregiver is to answer yes or no to the main question. A "yes" response is followed by asking whether the caregiver sees minimal or substantial improvement and then to check from the list provided, in which areas the caregiver sees this improvement. A "no" response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

TRANSITION SOCIAL SUPPORT (TS)

| | |
|-----------------------------------|---|
| PURPOSE: | To record information regarding the kinds and amount of support that the caregiver receives from friends, neighbors, or family members. |
| TIME OF DATA COLLECTION: | At the six-month follow-up visit. This form appears in the bereavement and discontinued batteries. |
| REQUIRED RESPONSE CARD(S): | RC1, RC18, RC19, RC33, RC34, RC35, RC36. |

GENERAL INSTRUCTIONS:

Most of the questions ask about the support received in the past month. When there is no time frame given, the question should be understood as asking about right now.

The questions throughout this form refer to persons outside the home. This means other people living in the same home are excluded from the questions. The interviewer should always ensure that the respondent's answer excludes these individuals. You may need to probe to obtain this information when necessary.

The social support items are followed by one final question that asks the caregiver to rate their impression over the past six months of the overall improvement in the social support they have received.

The response options throughout this form must be read aloud, since they vary from question to question. It may be necessary to make a statement like "I know this may seem repetitious, but I am required to read all of the possible responses."

Many of the questions use the terms someone or others. By someone or others, we mean friends, neighbors, or family members. Some of the questions, mostly in the beginning of the questionnaire, explain who someone/others are. Occasionally however, a respondent may want to know who is meant by the term "someone" or "others". If this information is requested, the interviewer should respond "By someone, we mean friends, neighbors, or family members."

"Relatives" include both blood relatives and relatives by marriage.

Throughout the form, the term "help" refers to aid, assistance or lending a hand with the actual performance of the activity/task (e.g., actually does the grocery shopping or bill paying) or some aspect of the task (e.g., drives to the grocery store or provides care to the care recipient so that you are able to go to the grocery store)

SPECIFIC INSTRUCTIONS:

Questions 1, 7, 9, 11: These questions are designed to probe satisfaction with received support. These questions ask the caregiver how satisfied they are with... If the caregiver states they do not receive the type of help or support asked about in the question, then probe to determine how satisfied the respondent is with not receiving any help. An example probe would be, "I understand that you did not receive any help with _____. Were you not at all, a little, moderately, or very satisfied with that?"

Question 2: "See or hear" includes visits in person or by telephone, as well as letters received.

Questions 6 & 7: The term "transportation" refers to driving the participant somewhere.

Question 8: For someone to “be there” in this question the person needs to be in the same place with the caregiver. If a person is with the participant but only by phone and is not there physically with the participant this would not count. Providing comfort is a subjective term and the definition should be left up to the participant. If the participant asks what “providing comfort” means, tell them that it means providing comfort to them in any way. Expressed concern is a subjective term and the definition should be left up to the participant. If the participant asks what “expressed interest or concern” means tell them that it means expressing any type of interest or concern.

Question 12: “Demands” is a subjective term and the definition should be left up to the respondent. If the participant asks what “demands” means tell them that it can mean anything that others ask them to do that they feel is a demand.

Question 13: Being critical is a subjective term and the definition should be left up to the respondent. If the participant asks what is meant by “being critical” tell them that it can mean anything that they feel is a criticism from someone else.

Question 14: The definition of “pried into your affairs” should be left up to the respondent. If the participant asks what is meant by “pried into your affairs” tell them that it can mean anything that they feel others have done to find out things that they feel are private.

Question 15: The definition of “taken advantage of” is subjective and should be left up to the respondent. If the participant asks what we mean tell them that it can mean anything that they feel others have done to take advantage of them.

Question 16: This is a perception question. The caregiver is to answer yes or no to the main question. A “yes” response is followed by asking whether the caregiver sees minimal or substantial improvement. A “no” response is followed by asking whether the caregiver sees no change, minimal decline or substantial decline.

TRANSITION BURDEN INTERVIEW (TB)

PURPOSE: To record information regarding the caregiver's burden in caring for the care recipient.

TIME OF DATA COLLECTION: At the six-month follow-up visit. This form appears in the placement and discontinued batteries.

REQUIRED RESPONSE CARD(S): RC24.

GENERAL INSTRUCTIONS:

These questions all begin with the stem, "Do you feel..." and ask the caregiver about the personal strain and role strain they experience from caregiving. The response options range from never to nearly always.

These questions are to be considered presently, so the caregiver should respond how they feel right now.

You may need to remind the respondent that "Although none of these options may match exactly how you feel, I need you to choose the closest one," or "Remember there are no right or wrong answers to these questions, we are interested in your opinion." Again, the respondent should not be pushed to the point of aggravation. If he/she cannot answer the question after prompting, mark the "unknown" response option.

BEREAVEMENT SOCIODEMOGRAPHICS (BS)

PURPOSE: This form is included in order to obtain descriptive information about the caregiver. This follow-up form is an abbreviated version of the baseline form. It focuses on sociodemographic characteristics that can change during the course of the study.

TIME OF DATA COLLECTION: At the six-month follow-up visit. This form appears only in the bereavement battery.

REQUIRED RESPONSE CARD(S): RC1, RC5, RC10, RC13, RC14, RC15.

GENERAL INSTRUCTIONS:

This questionnaire asks questions for the caregiver to answer about themselves only.

SPECIFIC INSTRUCTIONS:

Question 1: This question asks about marital status. Since this battery is for the bereaved, please consider this and be aware to ask this question with sensitivity.

Question 2: If the caregiver states that he or she is not currently employed, a probe will need to be given to determine if the caregiver has retired. If the caregiver has not retired, the response "Not currently employed, not retired" is checked regardless of whether or not the caregiver is currently looking for employment. A probe may need to be given to determine if the employment is full-time or part-time. Full-time is defined as 35 or more hours per week. If the respondent is not currently employed and not looking for a job (for example, an AFDC recipient, a seasonal worker, not currently working, or disabled not currently working), code as "Not currently employed, not retired." In other cases that may arise in which it is difficult to decide how the employment situation should be coded, it should be up to the respondent to decide which category best describes his/her situation.

Question 3: Keep in mind that many people do not like to reveal information about their income, and may have a negative reaction to this question. Although every effort has been made to ask this question in the most unintrusive manner possible, respondents may still resist answering it. The introduction to the question reminds the respondent that all the information is kept strictly confidential, it will not be associated with their name in any way, the information is very important for the study, and that they only need to indicate the number of the category on the card, not the dollar amount.

Because the assurances about confidentiality are provided at the beginning of the question and because it is a sensitive question, an initial refusal by the respondent to answer the question should be acknowledged and the interviewer should mark "Refused" and go on to the next item.

If the respondent seems unsure, but does not explicitly refuse to answer the question, you may need to remind the respondent that "because this information is kept confidential, it will in no way jeopardize your eligibility to receive services from any agency." Also, a reminder of the importance of the study might help. Of course, if the respondent refuses to answer the question, we must respect his or her privacy.

Question 6: This question refers to persons having permanent living arrangements, i.e., persons who have been residing in the dwelling for at least 6 months. If an individual lives in the house less than 6 months out of the year, they should not be included in the count. If they live in the house more than 6

months out of the year, they should be counted. A permanent resident of the home that has been living in the home less six months is not counted in the census.

BEREAVEMENT (BF)

- PURPOSE:** This form is included in order to examine possible specific effects of the care recipient's death on the caregiver's mental status.
- TIME OF DATA COLLECTION:** At the six-month follow-up visit. This form appears in the bereavement battery only.
- REQUIRED RESPONSE CARD(S):** RC1, RC45, RC46, RC47, RC48.

GENERAL INSTRUCTIONS:

This form is to be administered only to those caregivers whose care recipient has died during the course of the study.

Unless otherwise stated, definition of terms in this form is left to the respondent's interpretation.

Interviewers should be prepared to handle questions about service availability. **Site-specific guidelines on ethics and treatment fidelity should be consulted before administering this interview.**

Be aware of shifting time frames. Some questions refer to the present, while others ask about the past month, past six months or past year depending on the issue involved.

For the first section of this measure, you may need to remind the respondent that "Although none of these options may match exactly how you feel, I need you to choose the closest one," or "Remember there are no right or wrong answers to these questions, we are interested in your opinion." Again, the respondent should not be pushed to the point of aggravation. If he/she cannot answer the question after prompting, mark the "unknown" response option.

SPECIFIC INSTRUCTIONS:

Question 15 & 16: The time frame for this question is self-defined by the respondent. Sometimes the CR is in the hospital before they die, this time frame would include a hospitalization under those circumstances.

Question 20: This question asks to what extent the CG had made preparations for CR's death. Examples such as funeral arrangements and legal decisions can be mentioned to the caregiver for clarification.

Question 23: Allow the caregiver to mention all services that he/she is using. Record any services reported by the caregiver in the appropriate spaces for items 23.1.1 through 23.1.9. Read any of those that are not mentioned by the caregiver and then ask if there are any other services in question 23.1.9.

Question 24: Allow the caregiver to mention all services that he/she thinks are needed. Record any services that the caregiver thinks he/she needs in the appropriate spaces for items 24.1.1 through 24.1.9. Read any of those that are not mentioned by the caregiver and then ask if there are any other services in 24.1.9.

Question 25: Record whether (CG) would like telephone numbers and/or information on people or organizations that may be able to help with bereavement coping. Consult site-specific guidelines on ethics and treatment fidelity before providing any of this information.

BEREAVEMENT RISK APPRAISAL (BA)

- PURPOSE:** This form asks general questions in the areas of safety; social support; and caregiver emotional and physical well-being to identify risk for the caregiver.
- TIME OF DATA COLLECTION:** At the six-month follow-up visit. This form appears in the bereavement battery only.
- REQUIRED RESPONSE CARD(S):** RC1, RC41.

GENERAL INSTRUCTIONS:

Be aware of shifting time frames. Some questions refer to the present, while others ask about the past month, past six months or past year depending on the issue involved.

The questions asked require either a yes/no response or a response of never, sometimes, or often.

These questions are somewhat repetitive with questions asked previously throughout the battery. If the respondent becomes annoyed with these questions try to repeat the instructions and remind him/her that "Some of these questions are repetitive but it will not take long to answer and I am required to ask everyone all of the questions."

SPECIFIC INSTRUCTIONS:

Question 1: Both a working smoke detector and a fire extinguisher are needed by caregiver. If caregiver replies they have one of the two, mark the "no" response.

PLACEMENT SOCIODEMOGRAPHICS (PS)

| | |
|-----------------------------------|---|
| PURPOSE: | This form is included in order to obtain descriptive information about the caregiver and care recipient. This follow-up form is an abbreviated version of the baseline form. It focuses on sociodemographic characteristics that can change during the course of the study. |
| TIME OF DATA COLLECTION: | At the six-month follow-up visit. This form appears only in the placement battery. |
| REQUIRED RESPONSE CARD(S): | RC1, RC5, RC10, RC11, RC12, RC13, RC14, RC15, RC42. |

GENERAL INSTRUCTIONS:

This questionnaire asks one question (marital status) about both the caregiver and care recipient that might have changed in the past six months. There are two additional questions about the care recipient (current physical health and current living arrangement). The remaining questions are about the caregiver only.

SPECIFIC INSTRUCTIONS:

Question 2: If the caregiver states that he or she is not currently employed, a probe will need to be given to determine if the caregiver has retired. If the caregiver has not retired, the response "Not currently employed, not retired" is checked regardless of whether or not the caregiver is currently looking for employment. A probe may need to be given to determine if the employment is full-time or part-time. Full-time is defined as 35 or more hours per week. If the respondent is not currently employed and not looking for a job (for example, an AFDC recipient, a seasonal worker, not currently working, or disabled not currently working), code as "Not currently employed, not retired." In other cases that may arise in which it is difficult to decide how the employment situation should be coded, it should be up to the respondent to decide which category best describes his/her situation.

Question 2.3.1: Indicate the amount of time in hours and minutes, that the caregiver has reduced his or her work load. If the caregiver indicates a fraction of an hour, the fraction must be converted to minutes (e.g. twenty and three quarters of an hour = "20:45").

Question 4: Keep in mind that many people do not like to reveal information about their income, and may have a negative reaction to this question. Although every effort has been made to ask this question in the most non-intrusive manner possible, respondents may still resist answering it. The introduction to the question reminds the respondent that all the information is kept strictly confidential, it will not be associated with their name in any way, the information is very important for the study, and that they only need to indicate the number of the category on the card, not the dollar amount.

Because the assurances about confidentiality are provided at the beginning of the question and because it is a sensitive question, an initial refusal by the respondent to answer the question should be acknowledged and the interviewer should mark "Refused" and go on to the next item.

If the respondent seems unsure, but does not explicitly refuse to answer the question, you may need to remind the respondent that "this information is kept confidential, and it will in no way jeopardize your eligibility to receive services from any agency." Also, a reminder of the importance of the study might help. Of course, if the respondent refuses to answer the question, we must respect his or her privacy.

Question 7: This question refers to persons having permanent living arrangements, i.e., persons who have been residing in the dwelling for at least 6 months. If an individual lives in the house less than 6 months out of the year, they should not be included in the count. If they live in the house more than 6 months out of the year, they should be counted. A permanent resident of the home that has been living in the home less six months is not counted in the census.

PLACEMENT (PL)

| | |
|-----------------------------------|--|
| PURPOSE: | This form is to examine possible specific effects on the caregiver of having placed the care recipient in a long-term care facility. |
| TIME OF DATA COLLECTION: | At the six-month follow-up visit. This form appears in the placement battery only. |
| REQUIRED RESPONSE CARD(S): | RC1, RC36, RC43, RC44. |

GENERAL INSTRUCTIONS:

This form is to be administered only to those caregivers whose relative has been placed, and remains, in a long-term care facility. If the care recipient has died between placement and time of interview, the Bereavement (BF) form should be administered. If the care recipient has returned to the caregiver's care, the follow-up battery should be administered instead of this form and a Care Recipient Tracking form should be completed to document the return.

For the ADL questions (items 1-10), the time frame is **the past week**. It may be necessary to remind the respondent of this when asking these questions. The last three ADL questions may involve asking the respondent for time estimates; see the general guidelines for time estimates in the REACH II Interviewer Instruction Manual for directions in obtaining these estimates.

It is important to emphasize the statement concerning confidentiality that precedes item #11.

Throughout the form, the facility in which care recipient (CR) is staying is referred to in brackets as follows: [the care facility/name of facility]. If the name of the facility is known, the interviewer should use it. If the name of the facility is not known, it should be referred to as "the care facility".

SPECIFIC INSTRUCTIONS:

Question 8.2, 9.2, & 10.2: Record the response in minutes. If the response is in hours, convert to minutes. If a range of time is given, probe for the caregiver's best estimate.

Question 12: If the caregiver is not sure what the social environment is, "social environment" refers to the opportunities afforded to facility clients to interact informally with other clients and staff, and to the temperament and politeness of the clients and staff at the facility.

Question 13: If the caregiver is not sure what the physical environment is, "physical environment" refers to the quality of the physical structure that the client lives in, and to the quality of the furnishings and facilities within the structure.

Question 16.1: Record the amount in dollars, rounded to the nearest ten dollars.

Question 16.2: If the caregiver responds in days, convert to months (30 days = 1 month), and round to the nearest month. For example, "2 months and 14 days" = 2 months, "2 months and 15 days" = 3 months. An answer of "indefinite" should be coded as "999".

Question 17.4.1: Read this question only if the response to 17.1, 17.2, 17.3 or 17.5 is "yes". Record, in months, how long it will be before the caregiver's family financial resources are completely depleted, if expenditures remain the same as they are currently for the care recipient's care. If caregiver responds in days, convert to months (30 days = 1 month), and round to the nearest month. For example, "2

months and 14 days" = 2 months, "2 months and 15 days" = 3 months. An answer of "indefinite" should be coded as "999".

PLACEMENT RISK APPRAISAL (RP)

PURPOSE:

This form asks general questions to identify risk for the caregiver in the areas of: education; safety; social support; and caregiver emotional and physical well-being..

TIME OF DATA COLLECTION:

At the six-month follow-up visit. This form appears in the placement battery only.

REQUIRED RESPONSE CARD(S):

RC1, RC41.

GENERAL INSTRUCTIONS:

Be aware of shifting time frames. Some questions refer to the present, while others ask about the past month, past six months, or past year, depending on the issue involved.

The questions require either a yes/no response or a response of never, sometimes, or often.

These questions are somewhat repetitive with questions asked previously throughout the battery. If the respondent becomes annoyed with these questions, try to repeat the instructions and remind him/her that "Some of these questions are repetitive but it will not take long to answer and I am required to ask everyone all of the questions."

SPECIFIC INSTRUCTIONS:

Question 3: Both a working smoke detector and a fire extinguisher are needed by caregiver. If caregiver replies they have one of the two, mark the "no" response.

DISCONTINUED FORM (DF)

PURPOSE:

This form is used to get basic follow-up information on caregivers who discontinue participation in the study.

TIME OF DATA COLLECTION:

At the six-month follow-up time point if the caregiver is not willing to complete the entire follow-up battery or upon notification of dropout. This form appears in the discontinued battery only.

REQUIRED RESPONSE CARD(S):

RC1.

GENERAL INSTRUCTIONS:

In the case of a dropout, the Off-Protocol (OP) form should be filled out immediately. If the participant drops out after the baseline interview is complete and before the 30-day window for the six-month follow-up interview, the caregiver should be told "I am sorry to hear you do not wish to participate any longer. Is it alright if I contact you in (number of months until six-month follow-up time point) and check in?" Every attempt should be made to have the caregiver agree to allow you to contact them at that time. If the caregiver tells you he or she is dropping out of the study because they are moving out of the area, you should ask to complete the Discontinued Interview during the conversation or at a time most convenient for the caregiver, before they leave the area. At the six-month follow up time point, the caregiver should be contacted and asked whether they would consider completing the entire follow-up battery at this time. Every attempt should be made to complete the entire follow-up battery. If the caregiver is not willing to complete the entire follow-up battery, then every attempt should be made to have the caregiver complete the Discontinued interview (DC) at this time.

If the caregiver does not want to be contacted, he or she is considered "inactivated" and is no longer contacted for REACH II related visits.

SPECIFIC INSTRUCTIONS:

Question 1: If a respondent answers "no" to this question which asks "Caregiver agrees to answer some questions?" and also "no" to the follow-up question (1.1) "Would it be alright...call you ...in a couple of weeks?" then the form should be entered into PoP as inactive. If the caregiver answers yes to the follow-up question (1.1), then the form should not be entered into PoP until the follow-up phone call is completed.

PREVENTATIVE HEALTH (PH)

PURPOSE: To assess the preventative health behaviors of caregivers.

TIME OF DATA COLLECTION: At the six-month follow-up time point if the caregiver is not willing to complete the entire follow-up battery or upon notification of dropout. This form appears in the discontinued battery only.

REQUIRED RESPONSE CARD(S): RC1.

GENERAL INSTRUCTIONS:

Be aware of shifting time frames. Some questions refer to the past month while others ask about the past six months past year or past two years depending on the issue involved.

SPECIFIC INSTRUCTIONS:

Question 11: This question asks whether a female caregiver has had a mammogram in the past two years. This question should be asked of all female caregivers. If the caregiver is <40 years old, N/A (not applicable) will most likely be the appropriate response. Women under the age of 40 with high risk, such as family history of breast cancer may report they have had a mammogram.

Question 13: This question asks whether a male caregiver has had a prostate examination in the past year. This question should be asked of all male caregivers. If the caregiver is <50 years old, N/A (not applicable) will most likely be the appropriate response. Men under the age of 50 with high risk, such as family history of prostate cancer may report they have had a prostate examination.

PROJECT EVALUATION (PE)

PURPOSE: To assess intervention acceptability and effectiveness. This form will be administered to all caregivers involved in the study.

TIME OF DATA COLLECTION: At the six-month follow-up visit. This form appears in the follow-up, bereavement and placement batteries.

REQUIRED RESPONSE CARD(S): RC1, RC49.

GENERAL INSTRUCTIONS:

The project evaluation (PE) form is to be administered to all caregivers, including those randomized to the control group. The PE form has been placed at the end of the six-month follow-up batteries (follow-up, placement, bereavement) and will be administered after the battery as the final form. Thus, the interviewer will be administering the project evaluation.

The project evaluation contains questions for all participants and then asks the caregiver if they participated in the intervention. If they have participated in the intervention then they will ask additional questions. The interviewer will then remove the CTIS phone if the caregiver was in the intervention group.

SPECIFIC INSTRUCTIONS:

Question 10: If the caregiver responds yes to this question, you will ask him or her to explain why the project required too much work or effort for him/her. Please record text as concisely as possible.

INTERVENTIONIST CHARACTERISTICS (IC)

PURPOSE: To record information regarding the characteristics of the contact person.

TIME OF DATA COLLECTION: To be completed prior to any contact by anyone having contact with REACH participants with regard to their intervention.

GENERAL INSTRUCTIONS:

To be completed for each person having contact with a caregiver or care recipient at each site. This person may be an interventionist or another professional working with the project.

This form is to be filled out only once for a contact person. All information collected should be based on the characteristics of the individual at the time the person became involved with REACH II.