ACUTE BASELINE ALERTS/ADVERSE EVENTS

Formal responses to alert and adverse events must be followed by research staff at each participating site immediately upon learning of such an event. There are two categories of events: acute baseline alerts and adverse events. Acute baseline events are items that are identified and recorded by the interviewer during the baseline interview and are unrelated to the study or intervention. Adverse events are situations listed below which are identified by any member of the site's research staff that may occur at any time following randomization of a participant to treatment or control condition.

Below are the specific events that trigger a formal response by the participating site:

- Hospitalization of CG or CR
- Institutionalization of CG or CR
- Emergency room visit of CG or CR
- Severe medical problem of CG or CR
- Abuse of CG or CR
- Other

- Caregiver CES-D score greater than or equal to 15
- Caregiver reports that CR threatened to hurt him/herself 3 or more times in the past week
- Caregiver reports that CR Commented about the death of him/herself or others 3 or more times in the past week
- CR has access to a gun
- CR is currently Driving

The set of events in the first column are adverse events that are a standard part of clinical trial research. The second column lists five acute baseline alerts/adverse events that are identified by the interviewer from the baseline battery and/or follow-up battery. For caregivers that receive the placement, bereavement or discontinued batteries at six months, only caregiver depression as an adverse event may be triggered since the other battery related items do not appear in these batteries.

When a member of the site's research team identifies an event has occurred either at baseline, during study participation or at six month follow-up, the following steps will be followed. The event must be recorded on the appropriate form-either the CAREGIVER Acute Baseline Alerts/ Adverse Events form (AG) or the CARE RECIPIENT Acute Baseline Alerts/Adverse Events form (AR)(see attached forms), depending on who the event involves. The form(s) must be given to the site Project Coordinator and faxed to the REACH II Project Coordinator at the Data Coordinating Center within 24 hours from learning of the event. These forms ask date of event, whether the event is treatment related, whether the event was resolved or controlled and the resolution date. If an event is not resolved or controlled, the site Principal Investigator or Project Coordinator will need to follow-up on that event periodically and fill out an Acute Baseline Alerts/ Adverse Events Follow-up report (AF) (see attached form) when the event has been resolved or controlled.

In addition to reporting the event to the Coordinating Center, specfic procedures have been prepared so that personnel at all sites will be aware of the required response when an acute baseline alert/adverse event is triggered during the course of interaction with participants in the REACH II study. These specific procedures are described below. An attempt has been made to foresee as many potential adverse events as possible, but there is no way to predict all of them. In the event that an unclassified or emergency situation does arise, personnel are advised to consult with their site Principal Investigator, or if circumstances do not allow for such consultation, to use their best judgment (e.g. call 911 if necessary).

<u>Process for capturing the acute baseline alerts/adverse events items that appear in the battery</u> The process for identifying an acute baseline alert or adverse event at the six month follow-up includes recording the answer to the identified questions in the measure as it appears; as well as responding to the final questions of the measures. The measures involved in this process are the CES-D (SD), RMBPC (MB) and the Risk Appraisal (RA). Below are the final questions of the identified measures.

CES-D

15. Is the 10 item CES-D score greater than or equal to **15?**

No 0 ( ) →
Yes 1 ( )

15.1 Has the Principal Investigator or appropriate site personnel been notified?

No 0 ( )
Yes 1 ( )

Please notify the Principal Investigator or appropriate site personnel.

RMBPC

32. Is the answer to **question 15** "Within the past week, has (CR) threatened to hurt him/herself?" either 3 ( ) "3 to 6 times in the past week" or 4 ( ) "Daily or more often"?

No 0 ( ) →
Yes 1 ( )

32.1 Has the Principal Investigator or appropriate site personnel been notified?

No 0 ( )
Yes 1 ( )

Please notify the Principal Investigator or appropriate site personnel.

33. Is the answer to **question 23** "Within the past week, has (CR) been commenting about the death of him/herself or others "either 3 ( ) "3 to 6 times in the past week" or 4 ( ) "Daily or more often"?

No 0 ( ) →
Yes 1 ( )

33.1 Has the Principal Investigator or appropriate site personnel been notified?

No 0 ( )
Yes 1 ( )

Please notify the Principal Investigator or appropriate site personnel.

RISK APPRAISAL

52. Did the respondent answer "yes" to **question 7 "**Can (CR) get to dangerous objects (e.g., gun, knife or other sharp objects?"

No 0 ( ) →
Yes 1 ( )

52.1 Was the dangerous object identified as a gun?

No 0 ( )
Yes 1 ( )

52.2 Has the Principal Investigator or appropriate site personnel been notified?

No 0 ( )
Yes 1 ( )

Please notify the Principal Investigator or appropriate site personnel.

53. Did the respondent answer "yes" to **question 14** "Does (CR) drive?"

No 0 ( ) →
Yes 1 ( )

53.1 Has the Principal Investigator or appropriate site personnel been notified?

No 0 ( ) →
Yes 1 ( )

Please notify the Principal Investigator or appropriate site personnel.

These final questions are filled out by the interviewer and then they are entered on the interview cover page at the beginning of the battery. In this way, the interviewer is reminded more than once about the acute baseline alerts/adverse events and the actions which need to be taken when an item is triggered. The interviewer will then be able to immediately complete the appropriate form(s), and pass along the pertinent material to the project coordinator or principal investigator who will immediately be informed of the items by looking at the interview cover page and acute baseline alerts/adverse events form(s).

Principal Investigator/Project Coordinator procedures

The Principal Investigator or Project Coordinator will then follow the procedures described here for each of the acute baseline events/adverse events.

Hospitalization, Institutionalization, Emergency room visit, Severe medical problem

The primary action taken for these event types is to record and report the event. Once the Acute Baseline Alerts/Adverse Events form(s) have been completed, the Principal Investigator or Project Coordinator will determine from the information provided by the research staff whether the event has been resolved sufficiently. It is at the discretion of the Principal Investigator or Project Coordinator to follow-up with the caregiver if it appears necessary. If the event has been resolved, no further action is required by the Principal Investigator or Project Coordinator.

Abuse

The Principal Investigator or Project Coordinator will contact the caregiver to discuss the situation and devise an immediate plan of action. At that point, the Principal Investigator or Project Coordinator and caregiver can agree to monitor the situation and/or contact the caregiver's or care recipient's physician or primary care provider. If the caregiver refuses or is not able to control the abusive situation, Adult Protective Services will be contacted by the appropriate individual at the site.

Caregiver depression

The Principal Investigator or Project Coordinator will contact the caregiver to discuss the seriousness of the statements they made regarding their own mood. The Principal Investigator or Project Coordinator will devise a plan of action with the caregiver as to the actions they may take to help alleviate their depressive mood. At that point, the Principal Investigator or Project Coordinator and caregiver can agree to monitor the caregiver and/or contact the caregiver's physician or primary care provider.

Care recipient threat to hurt him/herself

The Principal Investigator or Project Coordinator will contact the caregiver to discuss the possible ramifications of the statements made by the care recipient. The Principal Investigator or Project Coordinator will devise a plan of action with the caregiver regarding the seriousness of suicidal statements. The Principal Investigator or Project Coordinator will suggest increased monitoring of the care recipient's statements and other ways to be aware of care recipient's intentions. If care recipient continues to make frequent statements regarding hurting him/herself or if any self- injurious behavior occurs, the caregiver will be informed that the Project Coordinator will contact the care recipient's physician or primary care provider will be contacted.

Care recipient comments about the death of him/herself or others
The Principal Investigator or Project Coordinator will contact the caregiver to discuss the possible ramifications of the statements made by the care recipient. The Principal Investigator or Project Coordinator will devise a plan of action with the caregiver regarding the seriousness of the care recipient's statements. The Principal Investigator or Project Coordinator will suggest increased monitoring of the care recipient's statements and other ways to be aware of care recipient's intentions. If care recipient continues to make frequent statements regarding his or her death or the death of others or if any self- injurious behavior occurs, the care recipient's physician or primary care provider will be contacted.

Care recipient access to a gun or other weapon
The Principal Investigator or Project Coordinator will contact the caregiver and devise an immediate plan of action for blocking the care recipient's access to these objects. If the caregiver refuses or is not able to block the care recipient's access, Adult Protective Services will be contacted by the appropriate individual at the site.

Care recipient driving.
First, the Principal Investigator or Project Coordinator will contact the caregiver and advise him or her to stop the care recipient from driving as well as educate the caregiver about the dangers of the care recipient driving. Caregiver in intervention will be encouraged to read the materials in the Caregiver Notebook that discuss driving and dementia. Caregivers in control group will be sent reading material on driving and dementia and encouraged to read it Next, the caregiver will be provided with information on formal driving evaluation services, if available. Lastly, the caregiver will be instructed to contact the care recipient's physician or primary care provider to discuss the topic. The Principal Investigator or Project Coordinator will also offer to contact the care recipient's physician or primary care provider on his or her behalf.

<u>Reporting Adverse Events to the Data & Safety Monitoring Board</u>
The coordinating center will be responsible for maintaining the acute baseline alerts/adverse events forms and submitting reports and/or summaries to the Data & Safety Monitoring Board.