INSTRUCTIONS FOR THE
ACHIEVE ALERT AND RESULTS REPORTING FORM (AAR)

I. General Instructions

The alert and results reporting form is designed to track the date when participants were notified of any alert value as well as track when study results were reported to participants. Alert values collected after the baseline exam, even for participants that are not randomized, must be reported using these instructions below.

The seated blood pressure and CES-D Depression alerts are calculated from data collected during the participant's clinic visit. The Alerts Report should be run while the participant is still at the clinic. Alerts that show up in the report should be processed and resolved in a timely manner. Seated blood pressure alerts can be addressed at the visit. CES-D Depression alerts are sent in a letter. In other instances, the proxy or even the physician, when the participant is unreachable, is the person notified.

The 'ACHIEVE Alerts Report' in CDART will list all unreported alerts by default. Data managers will also have the ability to run the Alerts Report for all alerts (resolved or not) for a given participant, in case they want to see when alert values were reported for a participant.

Field center staff are responsible for notifying the participant and, as determined from the participant's informed consent, the participant's physician. (Notification of alerts requires that the field center staff member review the instructions for reporting study results provided by the participant in his/her informed consent.) The level of the alert determines the length of time allowed to notify the participant and/or their physician – specific timelines for specific alerts are given in the Manual of Procedures. If the participant and/or physician could not be contacted within the time frame specified for an alert value, the Field Center PI must be notified on the day of expiration of that notification time window.

Some study participants do not identify a personal physician or another provider of medical care. Field centers keep a list of local physicians whom participants can call. The local medical society is typically a good source for such a list and one that is acceptable to practitioners in the community.

This form may be accessed more than once. Only one occurrence of this form is allowed, so updates are made to a single record in CDART. The study participant does not need to be present when this form is completed. The information required is gathered at the time of the study visit.

Alerts will continue to appear in the CDART Alerts Report until the participant and/or physician is notified and the notification details are entered in this form. Consequently, field center staff should make every effort to notify participants and/or physicians as soon as possible.

II. Detailed Instructions for Each Item– Clinic Exam

0a.   Enter the date on which the participant was seen in the clinic.
0b.   Enter the staff ID for the person who completed this form.

The AAR is organized into two sections:

Section A. Visit Exit Interview

This section denotes alerts that are known in real-time as data are collected during the visit. If there is an alert value for blood pressure or depression the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES). The Alert Report should be run at the end of the visit. These alerts will also be displayed in the Participant Summary of Results Report. These alerts should be reported to the participant while still present. The date the participant is notified is recorded. Most often this will be the date of the visit, but the system will allow for later dates.

1. If there were any alert notification at the time of the visit, select 'Yes.' Otherwise, select 'No.'

2. If the answer to question 1 is yes, enter the date of the seated blood pressure alert, if applicable. Note this item may be left blank if the alert only applies to CES-D.

3. If the answer to question 1 is yes, enter the date of the CES-D Depression alert, if applicable. Note this item may be left blank if the alert only applies to seated blood pressure.

4. If a copy of the Exit Interview results was provided to the participant, select 'Yes.' Otherwise, select 'No.'

5. If the answer to question 4 is yes, enter the date that the Exit Interview results were provided to the participant.

6. Leave this item blank. There is no letter for neurocognitive status for ACHIEVE participants.

Section B. External Alerts or Results

Skip the following two sections of the form. They are not relevant to ACHIEVE at this time.

7-15. Enter the alert or result code.

7a-15a. Enter the date notified for the corresponding alert or result code.