INSTRUCTIONS FOR PROTOCOL DEVIATION FORM (PDF)

I. General Instructions

Update this form with guidance from the ACHIEVE QC committee to document the reason for a protocol deviation (PD). Complete this form for each QC Committee-advised, reportable protocol deviation and file originals in the participant record. If protocol deviation does not pertain to a specific participant, complete document on paper and submit to ARICHELP@unc.edu

II. Detailed instructions for each item

Enter form information for Participant ID selected from the study ID list:

0a. Enter the date the form was completed.

0b. Enter staff ID of the person who administered the form.

0c. Enter the protocol deviation ID. This number will be auto-assigned by Coordinating Center or CDART.

0d. Select the study activity to which the PD pertains.

- Select A if the PD pertains to baseline data collection
- Select B if the PD pertains to 6-month data collection
- Select C if the PD pertains to 1-year data collection
- Select E if the PD pertains to 18-month data collection
- Select F if the PD pertains to 2-year data collection
- Select G if the PD pertains to 30-month data collection
- Select H if the PD pertains to ACHIEVE MRI deviation
- Select I if the PD does not pertain to a specific visit or class, record as NA.

1. Enter the start date of the PD using the format MM/DD/YYYY.

2. Enter the end date of the PD using the format MM/DD/YYYY. Note this may be the same date as the start date.

3. Select any deviation that applies that best matches the type of PD that occurred.

3a. Inappropriate Enrollment: A participant is enrolled in the study but fails to meet all of the inclusion criteria or meets any of the exclusion criteria, regardless of prior

protocol deviation approval, or for any other reasons that the participant should not have been enrolled

3b. Informed Assent/Consent Process Deviation: Any deviations related to the informed assent/consent process and documentation

3c. Test/Procedure Not Done: Protocol test or procedure does not occur

3d. Test/Procedure Not Done Per Protocol: Protocol test or procedure occurs, but not per protocol

3e. Test/Procedure Completed Out of Window: Protocol test or procedure occurs, but out of the specified window

3f. AE Not Reported Per Requirements: AE not reported within the specified window or reported without all requirements being met

3g. Breach of Confidentiality: Breach of confidentiality occurs for one or more study records/participants

3h. Failure to Follow Randomization or Blinding Procedure: Randomization or blinding not completed per protocol

3i. Use of Non IRB Approved Material: Material used in the conduct of the protocol needed IRB approval but not was not IRB approved before its use

3j. Study Product Management Deviation or Dispensing Error: Study product not managed or dispensed per protocol

3j1. Other: Any other deviation type not described above.

4. Provide information regarding details and reason for deviation.

5. If a correction action plan was made, describe any corrective actions taken to address this deviation. Otherwise, record as N/A.

6. If a prevention action plan was made, describe any preventative actions taken to avoid recurrence. Otherwise, record as N/A.

7. Record the recommendation by the ACHIEVE QC Committee to categorize this event as a protocol violation.

- Select Y if the ACHIEVE QC Committee recommends
- Select N if the ACHIEVE QC Committee does not recommend