PROTOCOL DEVIATION FORM

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: P D F DATE: 1/28/2019 Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: *Update this form with guidance from the ACHIEVE QC committee to document the reason for a protocol deviation. 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.*

0c. Protocol deviation ID: ☐☐☐☐☐ (auto-assigned by Coordinating Center or CDART)

0d. Study activity: ☐

- Baseline data collection ..... A
- 6-month data collection ..... B
- 1-year data collection C
- 18-month data collection ..... D
- 2-year data collection ..... E
- 30-month data collection ..... F
- 3-year data collection ..... G
- ACHIEVE MRI deviation ..... H
- NA – use if deviation is not visit specific I

Protocol Deviation Details

1. Deviation start date: ☐☐/☐☐/☐☐☐☐
2. Deviation stop date: ☐☐/☐☐/☐☐☐☐

3. Type of Deviation: *(Select all that apply)*

3a. Inappropriate enrollment ..... ☐

3b. Informed assent/consent process deviation..... ☐

3c. Test/procedure not done per protocol..... ☐

3d. Test/procedure completed out of window ..... ☐

3e. AE not reported per requirements ..... ☐

3f. Breach of confidentiality ..... ☐

3g. Failure to follow randomization or blinding procedure..... ☐

3h. Use of non-IRB approved material ..... ☐

3i. Study intervention delivery error..... ☐

3j. Other..... ☐

3j1. If other, please specify: _____

_____

4. Event Description (include reason for deviation):

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5. Describe any corrective actions taken to address this deviation (or enter N/A):

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6. Describe any preventive actions taken to prevent recurrence (or enter N/A):

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7. Does the ACHIEVE QC Committee recommend categorizing this event as a protocol violation?..... ☐

   Yes……Y

   No……..N