ARIC Protocol Deviation Reporting (PDR)

Subject ID: ☐☐☐☐☐☐☐☐ Occurrence #: ☐☐ DATE: 6/23/2026
Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: _____ / _____ / _____ 0b. Staff ID: ☐☐☐
mm dd yyyy

Instructions: Complete this form for each protocol deviation (PD) **within 30 business days** of becoming aware of the deviation.

Protocol Deviation Details

Save and Reload form to generate Protocol Deviation ID.

1. Protocol Deviation ID: ☐☐☐☐ (auto-assigned by CDART)
2. Protocol Deviation Date: ..... _____ / _____ / _____
   mm dd yyyy
3. Type of Deviation: *(Check all that apply or skip to Q4)* [3a-3c]
   - ☐ Implanted Medical Device Safety Deviation
   - ☐ Adhesive Allergy Safety Deviation
   - ☐ Test or Procedure Protocol Deviation
4. Other Type of Deviation (specify): _____
5. Deviation Specifications: [enable based on response to Q3 as specified below]

   5a. If deviation type is 'Implanted Medical Device', specify the participant's implanted device(s), e.g., pacemaker, retinal implant:

   _____

   5b. If deviation type is 'Implanted Medical Device', specify the associated study device(s) or components(s) involved, e.g., CGM, Tanita:

   _____

   5c. If deviation type is Adhesive Allergy, specify the associated study device(s) or component(s) involved, e.g., CGM:

   _____

5d. If deviation type is Test or Procedure Protocol Deviation, specify the test(s) or procedure(s) involved, e.g., dementia protocol not followed for neurocognitive testing:

_____

6. Protocol Deviation Reason: *(Check all that apply)* [6a-6d]

☐ Study personnel error

☐ Participant non-compliance with study

☐ Medical judgment

☐ Other ➔Q6d1

6d1. If Other, please specify: _____

7. Event Description:

_____

_____

_____

_____

_____

_____

8. Will any corrective actions be taken to address this deviation? ☐ Yes[1] ➔Q8a ☐ No[0]

8a. Describe the corrective actions that will be taken to address this deviation:

_____

_____

_____

_____

_____

9. Will any preventative actions be taken to prevent recurrence? ☐ Yes[1] ➔Q9a ☐ No[0]

9a. Describe any preventive actions taken to prevent recurrence:

_____

_____

_____

_____

_____

_____