

ARIC Protocol Deviation Reporting (PDR)

Subject ID:

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Occurrence #:

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DATE: 6/23/2026
Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ____ / ____ / ____
mm dd yyyy

0b. Staff ID:

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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:

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 (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? ☐ Yes¹ →Q8a ☐ No⁰

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

9. Will any preventative actions be taken to prevent recurrence? ☐ Yes¹ →Q9a ☐ No⁰

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