INSTRUCTIONS FOR THE PROTOCOL DEVIATION REPORTING FORM (PDR)

I. GENERAL INSTRUCTIONS

- The Protocol Deviation Reporting Form (PDR) should be completed by study staff in CDART **within 30 business days** of awareness of a protocol deviation.
- Complete a new form for each deviation that has been identified.
- Please see MOP 2 Section 22.13 for additional information about protocol deviations.

Administrative Information:

Question 0a. Enter the date the PDR form is completed.

Question 0b. Enter the Staff ID of the person reporting the protocol deviation.

II. DETAILED INSTRUCTIONS

Question 1. Click the "Save and Reload" button on the bottom right of the screen to generate a protocol deviation ID. This ID will be used in the protocol deviation report and serves as the event reference number for the participant.

Question 2. Enter the date the deviation occurred.

- Date format is Month/Day/Year (e.g. 7/31/2026).

Questions 3 and 4. Type of deviation: *(Check all that apply)*

- Examples include when the participant reports:
  - an implanted electrically active or battery-operated device and Tanita BIA measurements are not taken in weight only mode.
  - an implanted electrically active or battery-operated device and/or adhesive allergy and is wearing a CGM.
  - an implanted electrically active or battery-operated device and is wearing an accelerometer or Fitbit.
- If none of the three listed deviations in Question 3 cover the event, **please answer Question 4**.

Question 5. Specify the deviation.

- Provide additional details based on the selections made in Question 3.

Question 6. Reason for deviation: *(Check all that apply)*

- Other may be selected alongside the three previously listed reasons.

Question 7. Brief description of the event.

- The description should expand on selections made for Questions 3 and 6 and include enough detail to describe what led to the protocol deviation.

Question 8a. Describe any **corrective actions** if applicable to address deviation.

- May include:
    - ensuring participant safety and wellness
    - informing local IRB
    - implementation of Corrective and Preventive Action Plan (CAPA)

Question 9a. Describe any **preventative actions** if applicable to prevent recurrence.

- May include:
    - altering current processes
    - re-training of site staff
    - meeting with Principal Investigator and/or site staff to discuss current issues and potential resolution
    - implementation of Corrective and Preventive Action Plan (CAPA)