

## TC IRB Instructions for Corrective and Preventive Action (CAPA) Reporting

If the protocol deviation resulted in actual or potential harm to participants, noncompliance, or data integrity concerns, please describe the immediate **corrective actions** taken and outline any **preventive strategies** you plan to implement to reduce the likelihood of recurrence.

Your response should be:

- Specific (**What exactly was done? Who was involved?**)
- Action-oriented (**What steps have already been taken?**)
- Forward-looking (**What changes will be made going forward?**)

Avoid general statements like "staff were reminded" or "we will be more careful." Instead, provide a detailed plan of action.

Please refer to the example below for guidance.

### Sample Corrective and Preventive Action (CAPA) Plan Response (for Reference Only)

1. **Issue (deviation):** A participant was enrolled who did not meet the full eligibility criteria.
2. **Corrective actions (taken immediately):**
  - Subject was promptly withdrawn from the study.
  - All data collected from the subject was deleted from study records.
  - A full review of the screening process was conducted to identify where the error occurred.
  - Staff received retraining on eligibility determination procedures.
3. **Preventive actions (to avoid recurrence):**
  - Screening procedures were updated to include a checklist and second-level eligibility verification.
  - Regular audits of the recruitment logs were scheduled for the next 6 months.
  - Clear written guidelines were distributed to the study team, along with visual aids summarizing eligibility criteria.

**IMPORTANT:** Your CAPA should be specific, actionable, and proportionate to the event. Avoid vague statements like "we will be more careful" or "staff were reminded."