How to Create a Corrective and Preventive Action Plan (CAPA)

A **CAPA** is written to identify a discrepancy or problem in the conduct of the clinical research study, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem. In general, the tone of CAPA should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study. For example, it may be appropriate to:

- Clarify or add information regarding site specific regulatory file requirements,
- Clarify or add information regarding source document standards,
- Document and address any issue that is protocol- and/or site-specific that cannot be resolved without a change from previous procedures.

Key things need to be included in a CAPA:

1) **Root Cause Analysis:** A class of problem solving methods used to identify the root causes of problems or events.
2) **Corrective Action:** Immediate action to a problem that has already occurred or has been identified.
3) **Preventative Action:** Taken to eliminate the root cause of a potential problem including the detection/identification of problems.

A CAPA should be printed on institution letterhead and should be initiated and authored by the individual or organization responsible for its content, as follows:

If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign on the CAPA.

CAPA should be signed by the author, submitted to the IRB for review, kept on file in the site regulatory file.

GUIDELINES FOR WRITING A CAPA

CAPA Template

The following is a template for the content and format of a CAPA to the study investigators.

[Institution Letterhead]

Date: [Date that the CAPA is written]

To: [IRB]

From: [Name, title, and the site or institutional affiliation of the person authoring the CAPA]

Issue:	[Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items]
Root Cause:	[The reason(s) that the issue arose]
Corrective Action:	[Description of the corrective actions taken or planned by the site personnel. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.]
Implementation:	[Description of the procedures used to document resolution of the problem, the personnel who are responsible for the procedures etc.]
Effective date of resolution:	[Effective date for corrective action (may be the same date as in the memo header)]
Preventive Action:	[Description of the preventive actions taken or planned by the site personnel.]
Evaluation / Follow-up:	[Any plan / procedure to evaluate the implementation and completion, personnel who are responsible for the evaluations, timeframe for the evaluation, etc.]
Comments:	[Any additional comments or information not noted above]

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Principal Investigator Signature Date of Signature

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Principal Investigator Printed Name