CASE WESTERN RESERVE UNIVERSITY

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

A CAPA is written to identify a discrepancy or problem in the conduct of a 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 a CAPA should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study. Rather, the CAPA should acknowledge the error, describe the reasons or potential reasons the error occurred, and provide a blueprint for preventing the error from reoccurring.

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.

The CAPA should be signed by the author, kept on file in the Study Regulatory Binder, and made available to the QIP Reviewers, sponsor auditors, or site monitors reviewing the study's documents and procedures. Follow IRB reporting requirements listed in Chapter 28 of the CWRU Investigator Manual for IRB Submissions (Reportable New Information). Investigator Manual- AAHRPP Version 12.04.2023.pdf (case.edu)

In addition, if a Data Safety Monitoring Board is handling the data management of the research study, please forward a copy to the DSMB.

Please use the template below as an example of how to organize and complete your CAPA.

Date: [Date that the Corrective Action Plan is written]

To: [Sponsor, FDA, or CWRU IRB]

From: [Name, title, and affiliation of the person authorizing the CAPA]

Protocol/IRB Number: [The study's CWRU IRB number, i.e., STUDY22221111]

Issue: [Brief description or outline of the 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 study team. If the study team was instructed to perform these corrective actions (i.e., by the sponsor or IRB), indicate by whom and as of what date. If 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 study team members who are responsible for the procedures, etc.]

Effective Date: [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 study team. If the study was instructed to perform these preventive actions, indicate by whom and as of what date.]

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.]

_____ _____

Principal Investigator Signature Date of Signature

_____

Principal Investigator Printed Name