

STANDARD OPERATING PROCEDURES (SOP) FOR CLINICAL RESEARCH TITLE: Corrective and Preventative Action (CAPA) Plan	Last Revised: 11/2019 Prior Version: 1/2017
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1. PURPOSE:

The purpose of this SOP is to provide guidance to investigators and study personnel in writing a CAPA plan, to develop plans for addressing existing or potential problems identified during the conduct of research, and to prevent reoccurrence.

2. SCOPE:

All research protocols conducted and approved by the UH Institutional Review Board (IRB), Centralized IRBs, or studies conducted at any UH facility or affiliate facility. This SOP will serve as a guide to research personnel with the steps to writing a CAPA plan.

3. 3. RESPONSIBLE INDIVIDUALS:

All Investigators, research, regulatory, and study personnel who engage in research.

4. DEFINITIONS:

Corrective and Preventative Action (CAPA) Plan - A quality process used to address an existing noncompliance issue and the steps taken to prevent further recurrence.

Root Cause - Factor that caused an issue or problem.

Root Cause Analysis - a class of problem solving methods used to identify the initial causes of problems or events.

Corrective Action - Action taken to rectify a problem.

Preventative Action - Action taken to eliminate the root cause of a problem or potential problem including the detection/identification of issues.

5. POLICY STATEMENT:

A CAPA is written to identify a discrepancy or problem in the conduct of the 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.

6. PROCEDURES:

6.1 Form a team

6.1.1 Identify the individual(s) responsible for:

6.1.1.1 Developing the CAPA plan

6.1.1.2 Implementing the CAPA plan

6.1.1.3 Training staff on the CAPA plan

6.1.1.4 Evaluating of the results of the CAPA plan

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- 6.2 Identify the issue or potential issue
 - 6.2.1 Document a brief description of the issue
 - 6.2.2 Evaluate the magnitude of the problem and potential impact
 - 6.2.2.1 Investigate the impact of the issue on the overall research
- 6.3 Identify the root cause
 - 6.3.1 Describe the reason the issue arose
 - 6.3.1.1 Investigate how or why the incident occurred
- 6.4 Describe the corrective actions taken or planned
 - 6.4.1 Indicate who will perform the corrective actions and when
 - 6.4.2 If items are incomplete or unavailable, include a statement regarding attempts made to complete the action
 - 6.4.2.1 Consider sponsor, regulatory (Food and Drug Administration, Office Human Research Protection, Office of Civil Rights) or local institutional requirements when creating the corrective action plan.
- 6.5 Implementation
 - 6.5.1 Describe the procedures implemented to resolve the problem and indicate who's responsible for the procedure.
- 6.6 Effective Date of Resolution
 - 6.6.1 Indicate an effective date for the corrective action
- 6.7 Preventative Action
 - 6.7.1 Describe the preventative actions taken or planned and who's responsible
 - 6.7.2 Create a listing of all tasks that must be completed to correct or prevent the problem.
 - 6.7.3 Send copy of the final CAPA to the appropriate authority if required
- 6.8 Evaluation and Follow-up
 - 6.8.1 Describe the procedure to evaluate the implementation and completion
 - 6.8.2 Indicate the study staff who are responsible for the evaluations
 - 6.8.3 Include the timeframe for evaluation
 - 6.8.4 Send evaluation follow-up report to appropriate authority if requested
- 6.9 Comments-Optional
 - 6.9.1 Document observations

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6.10 If the CAPA Plan is related to an internal process, maintain documentation separate from the original study files.

6.11 If the CAPA Plan is in response to an FDA audit, maintain documentation as part of your study files.

6.12 As applicable, follow any of the reporting requirements listed in Chapter 20 of the UH Investigator Manual for IRB Manual (Reportable New Information).

7. REFERENCES:

- Feinstein Institute for Medical Research
- FDA 21 CFR 820.100
- [FDA.gov- Corrective and Preventive-Actions](http://FDA.gov-Corrective-and-Preventive-Actions)
- Preventive/Corrective Actions (CAPA) Guidelines. R.M. Baldwin, Inc.
- UH Clinical Research Center Investigator Manual for IRB Submissions

8. FORMS OR ATTACHMENTS:

Appendix A - CAPA Template

APPROVALS

Signed by Dr. Grace McComsey, Vice President of Research, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center – February 17, 2020

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, kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site's documents and procedures. Follow IRB reporting requirements listed in Chapter 20 of the UH Investigator Manual for IRB Submissions (Reportable New Information).

In addition, if a data safety monitoring board is handling the data management of the clinical research study, please forward a copy to the DSMB.

Hints for working on your CAPA: PICCC: Problem, Investigate, Comparison, Clues, Cause

GUIDELINES FOR WRITING A CAPA

Corrective and Preventative Action Plan

Date: [Date that the CAPA is written]
To: [Sponsor, FDA, or IRB]
From: [Name, title, and the site or institutional affiliation of the person authoring the CAPA, and this individual's signature]
Protocol/IRB Number : [Name, title, and the site or institutional affiliation of the person authoring the CAPA, and this individual's signature]

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 the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. 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. If the site was instructed to perform these preventive actions, indicate by whom and as of what date.]

GUIDELINES FOR WRITING A CAPA

**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]

Principal Investigator Signature

Date of Signature

Principal Investigator Printed Name