DEVELOPING AND IMPLEMENTING CORRECTIVE AND PREVENTIVE ACTION PLANS

Institutional Review Board and Human Subjects Office

Contents

Introduction

The purpose of this educational tool is to establish a standardized process for identifying, documenting, and addressing deviations, noncompliance, and unexpected events in research through Corrective and Preventive Action (CAPA) plans.

Definitions

CAPA: Corrective and Preventive Action, a process to identify and address the root causes of problems and prevent their recurrence.

Deviation: Any departure from the approved protocol or standard operating procedures.

Noncompliance: Failure to adhere to applicable laws, regulations, or institutional policies.

Responsibilities

Principal Investigator (PI): Oversees the CAPA process and ensures compliance.

Research Team: Assists in identifying issues, conducting root cause analysis, and implementing CAPA plans.

Compliance Monitoring Team: Monitors the effectiveness of CAPA plans and ensures proper documentation.

What is a CAPA plan?

A CAPA plan addresses issues that arise during research studies or clinical trials. It focuses on fixing problems, ensuring data integrity, and preventing future issues in the research process.

There are two parts to a CAPA plan:

1. Corrective Actions – identifying and addressing specific errors or noncompliance in the research process
2. Preventive Actions – implementing measures to prevent similar issues from occurring in the future

When does the IRB require a CAPA?

The University of Iowa IRB may require a CAPA plan any time there is a report of potential noncompliance. The PI may report an issue to the IRB in a reportable event form (REF), following the guidelines detailed in the UI Investigators' Guide (Section II, Part 19.B). The robustness of the CAPA plan will be directly related to the seriousness and severity of the event. CAPA plans may also be a required action following a compliance monitoring event or other audit.

When a CAPA plan is required by the IRB, a member of the Compliance Program team will conduct a follow-up monitoring visit six months after the plan is approved to ensure it has been implemented.

Why is a CAPA plan important?

CAPA plans ensure research is compliant with any applicable rules and regulations such as the Health Insurance Portability and Accountability Act (HIPAA), Department of Health and Human Services (HHS), National Institutes of Health (NIH), Food and Drug Administration (FDA), etc). These plans can also ensure data integrity by addressing and correcting errors or discrepancies. Identifying and resolving issues improves research quality and reduces the potential for risks to research

subjects. Finally, CAPA plans protect the reputation and credibility of the research team and the research institution by ensuring studies are reliable and valid.

How to create an effective CAPA plan

1. **Identify the Problem**: Define the issue clearly, such as protocol deviations, data collection errors, or ethical concerns.
2. **Determine the Root Cause**: Investigate the cause, using tools like Root Cause Analysis, to find underlying issues (e.g., poor training, equipment malfunction).
3. **Implement Corrective Actions**: Address the immediate issue by re-training researchers, correcting data, or modifying protocols.
4. **Develop Preventive Actions**: Prevent recurrence by revising protocols, improving training, or enhancing quality control procedures (e.g., double-checking data collection methods).
5. **Document and Communicate**: Keep detailed records of issues, actions, and results. Share the findings with relevant research teams, sponsors, or regulatory bodies.
6. **Verify Effectiveness**: Monitor the effectiveness of the corrective and preventive actions, ensuring the issue is fully resolved.
7. **Continuous Improvement**: Regularly review and update the CAPA plan to ensure it addresses new potential risks and enhances research quality.

These action statements represent the required sections of a CAPA plan. The Human Subjects Office has a variety of CAPA plan templates that fulfill these criteria available for use in the Appendix.

Best practices for a successful CAPA plan

- Be specific and clear in defining problems and corrective actions.
- Involve all relevant parties, such as research staff, ethics committees, and regulatory bodies.
- Use data to assess the impact of issues and guide decision-making.
- Ensure accountability with assigned roles and timelines.
- Follow up to ensure that corrective and preventive measures are working and are fully implemented.

Appendix

Example 1: Corrective and Preventive Action (CAPA) Plan Template

Corrective and Preventive Action (CAPA) Plan

Study Details	
Principal Investigator:	
IRB Number / Sponsor Number:	
Study Title:	
Responsible Party: (person responsible for overseeing the CAPA Plan)	The following individual, designated by the PI, is responsible for documenting the Problem, Root Cause, and CAPA Plan, updating/revising the Plan as applicable, tracking the CAPA Plan's completion, and verifying that appropriate documentation related to its completion is included, where applicable, in the study files: _____ **Printed Name of Responsible Party** _____ **Responsible Party Role** _____ **Responsible Party Signature** _____ **Date**

Problem and Root Cause	
Description of Problem	*Describe the problem including when and how it was identified. Note policy and/or regulations that should have been followed.*
IRB Reporting Requirements *Refer to HSO Guidance on Reportable Events*	_____ **Yes**, problem should be promptly reported to IRB **If yes**, date reported to IRB: _____ **No**, problem does not meet prompt reporting criteria **Additional notes:** *Include any additional notes pertaining to whether the problem is promptly reportable to the Reviewing IRB and/or the HSO.*
Root Cause Analysis (RCA) Process	*Document the RCA process including when and how the process took place and who was involved. Refer to the RCA Information and Tools handout for more information on this step.*

Ultimate root cause	*Describe the ultimate root cause of the problem identified during the RCA process.*

Corrective and Preventive Actions

Refer to HSO guidance on modifying approved IRB applications and/or materials

List all corrective actions	Individual Assigned to Complete the Action	Proposed Date of Completion	Actual Date of Completion

List all preventive actions	Individual Assigned to Complete the Action	Proposed Date of Completion	Actual Date of completion

CAPA Plan Resolution

Assessment	*Describe how the CAPA Plan will be and/or was assessed for effectiveness, including when the assessments took place, who was involved, what decisions were made and why.*
Closeout	*Describe the process to arrive at closure, including discussions and/or meetings that took place to come to this determination, when they took place and who was involved.*

PI Attestation* (to be completed when CAPA Plan is closed)	As Principal Investigator, I attest to the completion of the CAPA Plan and confirm that it is considered closed at this time. _____ _____ **PI Signature** **Date**

Example 2: Corrective and Preventive Action (CAPA) Plan Template

IRB#:

Protocol Title:

Reportable Event: DESCRIBE

DESCRIPTION AND CAUSES OF THE PROBLEM: Provide an explanation of exactly what happened. Consider including:

- narrative of events
- timelines
- why did the event(s) occur
- how did the event(s) occur
- be sure to consider root cause(s) or the "five whys"

DATE OF OCCURRENCE(S):

DATE IDENTIFIED:

IMPACT OF ISSUE: Provide an analysis of the problem, consider:

- how many impacted
- was there harm or potential harm
- could the problem extend to other research
  - if yes, specify
- other impacts

CORRECTIVE ACTION: Provide immediate actions to correct the problem

PREVENTATIVE ACTION: Describe new procedures or processes will be put in place to prevent the problem from occurring in the future.

REPORTING REQUIREMENTS: Describe any reporting requirements outside of IRB as applicable (e.g. sponsor, department, etc.)

CAPA EVALUATION PLAN: Describe evaluation plans of the CAPA to ensure it is preventing additional occurrences of event(s). Be sure to indicate:

- what will be evaluated
- who will evaluate
- outcome

CAPA Written By (Print Name & Title)	CAPA Written By (Signature)*	Date (dd-MMM-yyyy)
CAPA Approved By (Print Name & Title)	Written By (Signature)*	Date (dd-MMM-yyyy)

Example 3: Corrective and Preventive Action (CAPA) Plan Template

Date:		**IRB Number:**	
Protocol Title:		**Principal Investigator:**	

Deficiency Identified:			
Corrective Action Plan: (Action taken to correct specific deficiency identified)			
Preventative Action Plan: (Action taken to prevent the reoccurrence of this problem in the future)			
Responsible Personnel:		**Signature* and Date:**	

Example 4: Corrective and Preventive Action (CAPA) Plan Template

Date:		**IRB Number:**	
Protocol Title:		**Principal Investigator:**	

Deficiency Identified:			
Compliance Review Report Checklist Item Number:			
Response to Deficiency:			
Corrective Action Plan: (Action taken to correct specific deficiency identified)			
Preventative Action Plan: (Action taken to prevent the reoccurrence of this problem in the future)			
Responsible Personnel:		**Signature* and Date:**	

*For FDA regulated studies, signatures/attestations need to be documented in a Part 11 compliant platform

**Researcher may choose any of the provided templates when developing a CAPA plan

Resources

General IRB Questions:
Human Subjects Office (HSO)

IRB Compliance Questions:
HSO Compliance Team

UI Investigators' Guide:
https://hso.research.uiowa.edu/get-started/guides-and-standard-operating-procedures-sops

Acknowledgment

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