THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Corrective and Preventative Action Plans

Background

While conducting research, even the most experienced and diligent research teams deviate from the approved protocol or experience unexpected events. These deviations and unexpected events must be identified, evaluated, and responded to in order to protect the rights, safety, and welfare of participants and others, and the integrity of the research data. A Corrective and Preventative Action (CAPA) plan should be developed to correct the issue and prevent recurrence of noncompliance. A CAPA should be completed upon a substantiated subject complaint, determination of a continuing noncompliance, or unanticipated noncompliance. Please review the Reporting New Information guidance for assistance.

There are five core steps needed to complete a CAPA:

1. Review the Issue
2. Immediate Correction of the Noncompliance
3. Identify the Root Cause
4. Develop Corrective and Preventative Actions
5. Assess the Effect of the Preventative Actions

Step 1: Review the Issue

Evaluate the issue(s) identified by asking these five questions:

1. What is the noncompliance?
2. Where in the process did the noncompliance occur?
3. When did the noncompliance occur?
4. How significant is the noncompliance?
5. Who is responsible for the noncompliance?

The ability to implement an effective CAPA is directly related to a thorough understanding of the noncompliance. Once CAPA specifics have been defined, and the effect and magnitude of the noncompliance has been determined, it is time to take corrective and preventive actions.

Step 2: Immediate Correction of the Noncompliance

If an investigator becomes aware of a deviation or unexpected event, they must first take immediate corrective actions. These corrective actions may be taken without first obtaining IRB approval if they are to eliminate an apparent immediate hazard to a subject. They may be in the form of a phone call or an office visit with a qualified research team member. The investigator may need to order tests and other procedures to ensure the participant is safe. Document the deviation, the reason it occurred, and immediate corrections taken. These changes ***must*** be reported to the IRB within five business days of discovery.

Step 3: Identify the Root Cause

It is important to identify the cause or source of a deviation or problem so that it can be resolved to prevent recurrence. There may be multiple reasons or causes that contribute to a problem. Conversely, there may be multiple methods to resolve each cause. The root cause is the initiating, most basic cause of a problem that may or may not lead to a chain of causes or other problems. Eliminating the root cause should prevent recurrence.

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A root cause analysis (RCA) is the process of identifying and documenting the root cause and the downstream effect on the causal chain. RCA should focus on identifying underlying problems that contribute to error rather than focusing on mistakes made by individuals.

How to Conduct a Root Cause Analysis:

1. Identify the problem
2. Interview those impacted by the problem
3. Interview those people responsible for the problem, if applicable

Questions to Identify Root Causes:

1. What happened? What is the problem?
2. Why and how did the problem occur? What were the steps?
3. Who was affected by the problem? Was it one subject or all subjects in the study?
4. What is the magnitude of the problem? Is it in one study or does the problem exist in all studies under this PI or even in an entire clinical department?

Keep asking "why" and "how" until you reach the root cause. Once the root cause has been identified, the next step is to develop a corrective and preventive action plan to eliminate the root cause.

Step 4: Develop Corrective and Preventative Actions

Corrective actions are those taken to resolve a problem and preventive actions are those actions that keep the problem from recurring.

- Corrective Actions: Now that the rights, welfare, and safety of the participants have been assessed and the root cause has been identified, the investigator should consider additional reporting to the sponsor and IRB. Ensure that the reports to the sponsor and IRB are accurate and thorough and the CAPA is included.

- Preventive Actions: Preventive actions are necessary to ensure that the problem does not repeat itself. Preventive actions should be based on process. Create and document a process or standard operating procedure (SOP). Train on the process, implement the process, evaluate the process, and amend the process, as necessary. Consider revising the protocol or informed consent, as necessary.

Step 5: Assess the Effect of the Preventative Actions

Every good CAPA process should have a built-in effectiveness checking mechanism to verify and validate that the CAPA system is working. Data tracking is a mandatory component of a CAPA plan to ensure that all CAPA-related information can be confirmed, monitored, measured, and, if necessary, corrected.

Corrective and Preventative Action Plan Example

Root Cause: *There was not a process to ensure that new hires to the research team had completed all required trainings before engaging in Human Subject Research.*

Corrective Actions: *The Research Manager reviewed the study history and IRB approved List of Research Personnel with the study team and determined that there was only one occurrence where an unapproved*

member of the study team participated in research. This review is documented in a note-to-file and will be kept in the regulatory record.

Preventive Actions: *The Research Manager created an SOP for new hire onboarding and a supporting checklist. The new hire checklist will be utilized by the Research Manager and the Principal Investigator to ensure that new hires are appropriately onboarded before participating in the research. The final step of the onboarding process is the sign-off on the checklist by both the Research Manager and the Principal Investigator. A note-to-file was created by the Research Manager indicating the start date of the new SOP and checklist. The completed checklists will be kept in the regulatory record with the Delegation of Authority Log. The Research Manager and the Principal Investigator will review the implementation of the new SOP and checklist after each of the next three new hires and will document the review in a note-to-file to be kept in the regulatory record. If the result of the reviews demonstrate the SOP and checklist are working as expected, a note-to-file will be placed in the regulatory record indicating the plan as effective with effectiveness check moving to an annual review. If the SOP and/or checklist require revision, those revisions will be documented in a note-to-file kept in the regulatory record and the process for evaluating the next three new hires will start again.*