CORRECTIVE AND PREVENTIVE ACTION (CAPA) PLANS

See the CAPA Template on the last page.

INSTRUCTIONS

While conducting research, even the most experienced and diligent research teams may deviate from the approved protocol or experience unexpected events. Research teams must identify, evaluate, and respond to these deviations and unexpected events to protect the rights, safety, and welfare of participants and others and the integrity of the research data.

Step 1: Take Immediate Corrective Actions

If you become aware of a deviation or unexpected event that endangers the rights, welfare, or safety of participants and others, you must first take immediate corrective actions without first obtaining IRB approval.

The actions 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. You must document the deviation within the research records, including why it occurred and the immediate corrections taken to address the deviation or event.

Step 2: Conduct a Root Cause Analysis

It is important to identify the cause or source of a deviation or problem to prevent a 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 a recurrence.

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

Steps

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?*
5. *Keep asking "why" and "how" until you reach the root cause.*

Once you have identified the root cause, your next step is to develop a corrective and preventive action plan to eliminate the root cause.

Step 3: Prepare the CAPA Plan

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 you have assessed the participants' rights, welfare, and safety and have identified the root cause, you should consider additional reporting to the sponsor and IRB. The PI should review Reportable New Information criteria to determine whether to report the event to the IRB. Ensure that the reports to the sponsor and IRB are accurate and thorough and that you include the CAPA plan in the report. Additionally, there may be actions that you should take to correct the problem but have not taken before IRB review since implementation of the changes was not needed to protect participants' rights, welfare, and safety.

Preventive Actions

Preventive actions are necessary to ensure that the problem does not reoccur. An example, create and document a process or standard operating procedure (SOP). Then, train on the process, implement the process, evaluate the process, and amend the process as necessary. Consider whether you need to revise the protocol or informed consent forms as a part of your plan.

Step 4: Document the CAPA Plan

CAPA plans must be thorough and well documented. In your plan, include information that is:

- *Specific: Identify the actions you or others will take to address the root cause, the individual (role) responsible for taking the actions, and where you will document the actions.*
- *Timely: Include the date(s) when you or others will complete the actions.*
- *Measurable: Include a process of assessing the action plan effectiveness and a process by which the plan will be amended if it is ineffective.*

A thorough CAPA plan must also include the following elements:

1. *Action type (corrective or preventive)*
2. *Action description*
3. *Responsible person*
4. *Due date*
5. *Plan for effectiveness check*
6. *Effectiveness check outcomes*

You must create and maintain documentation that demonstrates that you implemented the CAPA plan. The IRB or sponsor may request to review this documentation.

Example

A. *Root Cause*

There was no process to ensure that new hires to the research team had all required actions taken before participating in Human Subject Research.

B. *Corrective Actions*

The Research Manager reviewed the study history and IRB-approved personnel log with the study team history and determined that there was only one occurrence where an unapproved member of the study team participated in the research. The Research Manager documented these actions in a note-to-file, see attached, stored in the regulatory record.

C. Preventive Actions

- *The research manager created an SOP for new hire onboarding and a supporting checklist; see attached.*
- *The research manager and principal investigator will ensure they appropriately onboard new hires before they participate in research by utilizing the new hire checklist. The final step of the onboarding process is the sign-off on the checklist by both the research manager and the principal investigator.*
- *The research manager created a note-to-file indicating the start date of the new SOP and checklist; see attached. 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. They will document their review in a note to file to be kept in the regulatory record. If the result of the reviews is that 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 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.*

[Remove all blue text before submitting the CAPA to the IRB]

Template

Date:
CU IRB Protocol #:
Study Title:
Principal Investigator:

A. <u>Root Cause</u>

B. <u>Corrective Actions</u>

C. <u>Preventive Actions</u>