Corrective And Preventive Action Plan (CAPA) Guidance

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. This Guidance is designed to help study teams develop, document, implement, and evaluate effective Corrective and Preventive Action Plans (CAPA). Typically, this plan is required by the IRB in response to a reportable events or non-compliance.

A Step-by-step Approach to Developing a Corrective and Preventive Action Plan

➢ Identification – what is the issue/problem?
➢ Evaluation – what is the impact and severity of the issue? Risk assessment!
➢ Investigation – objectives, procedures and responsibilities are defined
➢ Analysis – documented root-cause-analysis
➢ Action Plan – remediation and prevention
➢ Implementation – resource allocation, execution of the plan, documentation of all steps
➢ Follow-up – verification for adherence to CAPA plan effectiveness; if CAPA plan is not effective, return to Investigation

Step 1: Take Immediate Corrective Actions:
Once a deviation occurs, immediate actions must be taken to protect the rights, safety, and welfare of the subject(s). These immediate actions are typically called "corrections" and must be distinguished from "corrective actions." Corrections are what we do in response to an error. Corrective actions are implemented after the root cause has been identified and are intended to prevent more significant deviations and/or serious non-compliance from occurring in the future.

The PI and study team should document and discuss the deviation, the reason it occurred, and any immediate corrections. Immediate corrections should be focused on protecting the rights, safety, and welfare of subjects and reporting the event. If there is a potential serious risk to several subjects, call the IRB for guidance before contacting subjects, unless a delay may result in harm.

Step 2: Evaluate Risk:
After immediate corrections have been made, the PI evaluates the risk of the deviation regarding severity and frequency. The IRB considers events that adversely affect the rights, welfare, and/or safety of subjects to be a serious risk. Events that pose a serious risk are considered serious events and must be reported to the IRB within 10 business days. Events that do not pose a serious risk can usually be reported at the time of Continuing Review.

To evaluate frequency, consider the history of past occurrences and the potential for problems to

occur again. For the past assessment, review the protocol deviation log(s) for other occurrences of the event. For the future assessment, consider the risk of the event recurring in the same subject or other subjects in the study. If you notice a pattern on the deviation log(s) or if you identify a risk of the problem recurring in the future, there is a risk of frequency. If the deviation is considered serious and frequency is ongoing or has a pattern, you must continue to investigate the problem through root cause analysis (RCA).

Step 3: Conduct a Root Cause Analysis.
When significant deviations or noncompliance occur in research, it is important to identify the causes of the problem so that they can be resolved to prevent further noncompliance. There can be multiple reasons or causes that contribute to one single 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 of the problem.

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.

Step 4: Develop and Implement Your CAPA. There are two main reasons for a CAPA plan. One is to acknowledge and correct the existing errors that have already occurred. The other is to prevent the same or similar errors from occurring in the future. A CAPA plan can be protocol specific or more broadly applicable to a departmental or institutional process. The type of CAPA plan will largely depend on the error and result of the root cause analysis.

Below is a list of questions to ask while developing and implementing your CAPA plan:

1. Who
   a. Who is going to make the change?
   b. Who is impacted by this change?
   c. Is the Principal Investigator involved in the change?
   d. Who is going to teach/implement the change?
   e. Who is going to track the changes?
2. What
   a. What specific events, failures, deviations, exceptions, or non-complianceoccurred that resulted in the need for this CAPA plan?
   b. What is the root cause of each problem?
   c. What is going to change?
   d. What is the corrective action that will be taken?
   a. What is the preventive action that will be taken?

3. Where
   a. Where are the changes being made?
4. How
   a. How is the change proposed by the CAPA plan going to occur?
   b. How will those affected by the proposed change be educated? Is education/reeducation part of the plan? What type of education will beused?
   c. How will the implementation of the CAPA plan be tracked (objective and measurable)?
   d. How does this plan correct the event, failure, deviation, exception, and noncompliance?
   e. How does this plan prevent the event, failure, deviation, exception, or noncompliance from occurring again?
5. When
   a. When is the CAPA plan going to be taught?
   b. When is the CAPA plan going to be implemented?
   c. When is the CAPA plan going to be evaluated?
   d. When does the IRB require an update on the results of this CAPA plan (if applicable)?

Step 5: Evaluate (monitor) your CAPA plan.

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 CAPA so that the organization can ensure that all CAPA-related information can be confirmed, monitored, measured, and, if necessary, corrected.

Documenting CAPAs is another vital CAPA factor to consider. If the CAPA is not thoroughly documented, auditors and regulators will assume it was not done and that investigators did not consider the non-conformity a serious matter.

If your evaluation demonstrates that the CAPA plan is not effective, you should amend your CAPA plan and begin the cycle of training, implementing, and evaluating again. It is important to remember that the primary goal of a CAPA plan is to protect the rights, safety, and welfare of study participants.

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Corrective and Preventive Action Worksheet

Description of the problem:					
Root Cause Analysis Conclusion(s) (*)	**CAPA Plan**	**CAPA monitoring plan**	**CAPA Acceptance**	**CAPA plan monitoring results & date of actual evaluation**	**CAPA plan evaluation results acknowledgement**
Conclusion #1: .	Description of Plan:	Description of how plan will be monitored: . Date of planned completion:	Responsible Party Signature**: Date: Monitor Signature***: Date:	Monitor Signature: Date: Evaluation Date: Evaluation Results: ☐ Ongoing ☐ Revision Needed ☐ Resolved Comments:	Responsible Party Signature: . Date:
Conclusion #2: .	Description of Plan: .	Description of how plan will be monitored: Date of planned completion:	Responsible Party Signature: Date:	Monitor Signature: Date: Evaluation Date: Evaluation Results: ☐ Ongoing ☐ Revision Needed ☐ Resolved Comments:	Responsible Party Signature: Date:

**The Responsible Party is the individual who is assigned the responsibility of implementing the CAPA plan.
***The Monitor is the individual who provides independent oversight for the CAPA plan. The Monitor approves the CAPA plan and then later reviews and approves the results of the implementation of the CAPA plan