Northeastern University
Human Research

Guidance: Developing Corrective & Preventive Action (CAPA) Plans

Overview

While conducting self-assessments and reviewing study records, issues may be identified. The Department of Human Research (DHR) recognizes that 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 provides an overview on how to address an incident and how to develop a Corrective & Preventive Action (CAPA) Plan.

Step 1: Take immediate corrective actions

If you become aware of a deviation or unexpected event that endangers the rights, welfare, or safety of subjects and/or others, you must first take **immediate corrective actions** without first contacting the IRB. You must document the incident in your protocol records to include why it occurred and the immediate corrections taken to address the deviation or event. All incidents are to be reported to the NU IRB by completing the Incident, Adverse Event, or Reportable New Information Form. The guidance below should be reviewed in completing the form. Reports submitted to the IRB should be submitted promptly.

Step 2: Conduct a Root Cause Analysis (RCA)

If issues are identified, it is critical that the PI conduct a root cause analysis. 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. The RCA is the process of identifying and documenting the cause or source of a deviation or unanticipated event. An RCA should focus on identifying underlying problems that contribute to error rather than focusing on mistakes made by individuals.

There may be multiple reasons or causes that contribute to a problem. Conversely, there may be multiple methods to resolve each cause. Eliminating the root cause should prevent a recurrence.

Process:

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 the root cause is identified, the PI will need to develop a Corrective & Preventive Action (CAPA) plan to address and eliminate the root cause.

Step 3: Prepare a CAPA plan

A CAPA plan details how the PI will address audit findings and can include corrective or preventive actions. Corrective actions are those taken to resolve a problem and preventive actions are those actions that keep the problem from recurring.

Corrective Actions

After the assessment of subjects' rights, welfare, and safety and root cause identified, the PI is to determine the appropriate reporting requirements. The PI should ensure that the reports to the sponsor and IRB are accurate and thorough and the CAPA plan is included in the report. The report is to include any immediate action taken, as well as actions identified but not taken prior to DHR/IRB review.

Preventive Actions

Preventive actions are necessary to ensure that the problem does not reoccur. For example, develop a process and standard operating procedures; train the research team on the process; implement the process, evaluate the process; amend the process as necessary.

Step 4: Document the CAPA plan

CAPA plans must be thorough to include information that is:

- **Specific:** Describe the problem and the identified root cause; the action type (corrective or preventive); and action description.
- **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.
- **Identify responsible parties:** for the development of the corrective action plan; who provided education and to whom; who implemented the changes; and, who evaluated the outcomes.

The research team must maintain documentation that demonstrates the plan was implemented and subsequently evaluated.

CAPA plan example

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.

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.

Preventive Actions: The research manager created a Standard Operating Procedure (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.