Executing, Documenting, and Evaluating Corrective and Preventive Action (CAPA) Plans

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Learning Objectives

- New and updated resources on the IRB Office website
  - CAPA Plan Form (HRP-1209)
  - CAPA Plan Self-Assessment Form (HRP-1210)
- Conducting the Root Cause Analysis
- Executing a Corrective and Preventive Action (CAPA) plan
- Documenting the CAPA
- Evaluating the CAPA plan

Corrective and Preventive Action (CAPA) Plans Webpage

https://irb.northwestern.edu/compliance/corrective-and-preventive-action-capa-plans.html

Corrective and Preventive Action (CAPA)

Corrective and Preventive Actions (CAPA)

- Corrective and preventive actions (CAPA) are actions that research teams can take to identify, evaluate, and respond to deviations and unexpected events to protect the rights, welfare, and safety of participants and others, and the integrity of the research data.

CAPA Plans Webpage Updates

- Further developed steps on how to conduct a Root Cause Analysis (RCA)
  - Included a specific method/technique to conduct a RCA (5 Whys)
- Clarified corrective actions versus preventive actions and provided examples
- Provided guidance on how to document CAPA plans are SMART (specific, measurable, achievable, realistic, and time-bound)
- Added two new resources and expanded the CAPA plan example

Corrective and Preventive Action (CAPA) Plan Form (HRP-1209)

https://irb.northwestern.edu/compliance/docs/corrective-and-preventive-action-capa-plan-general-1209.docx

CAPA Plan Form (HRP-1209)

- Helps investigators outline and document the root cause analysis, the implementation and resolution of the corrective and preventive actions, and PI oversight in a clear, organized format.

CAPA Plan Self-Assessment Form (HRP-1210)

https://irb.northwestern.edu/compliance/docs/corrective-and-preventive-action-capa-plan-self-assessment-general-1210.docx

CAPA Plan Self-Assessment Form (HRP-1210)

- Supports investigators to document and report on the implementation and adherence to the CAPA plan.
- IRB Office recommends completing a CAPA plan self-assessment approximately 3-6 months after CAPA plan implementation to evaluate adherence and effectiveness.

1. Take Immediate Corrective Actions

Immediate Corrective Actions Example 1

- **Event:** A study team realized that a participant was infused with a higher dosage of the study drug than approved by the study protocol.
- **Immediate corrective actions:** The study team alerted the PI who called the participant to check on their status and scheduled an in-office visit to assess their rights, welfare, and safety. The PI considered ordering additional tests and procedures to ensure that the participant is well and safe.

Immediate Corrective Actions Example 2

- **Event:** During an internal audit of the study, the PI discovered that a recent hire had performed research activities prior to the study team receiving IRB approval to add the new hire to the list of study team members in eIRB+.
- **Immediate corrective actions:** The PI immediately informed the recent hire and their manager that the recent hire cannot continue to perform research activities until the study team submit a Modification to the IRB to add them to the list of study team members in eIRB+.

2. Conduct a Root Cause Analysis

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.
- Eliminating the root cause should prevent recurrence of a deviation or problem.
- A root cause analysis is the process of identifying and documenting the root cause and the downstream effect on the causal chain.

Steps to Conducting a Root Cause Analysis

1. Identify and describe the problem clearly
2. Interview those impacted by the problem
3. Interview those people responsible for the problem, if applicable
4. Establish a timeline from normalcy until the time the problem occurred
5. Evaluate the probability of the problem happening again and analyze how to prevent recurrence

Questions to Identify Root Causes

- What happened? What is the problem?
- Why and how did the problem occur? When did the problem occur? What were the steps?
- Who was affected by the problem? Was it one participant or all participants in the study?
- What is the magnitude of the problem? Is it in one study, or does the problem exist in all studies under this Principal Investigator's (PI's) portfolio or even in an entire clinical department?

3. Prepare the CAPA Plan

Corrective vs Preventive Actions

- **Corrective Actions** are those that resolve a problem.

- **Preventive Actions** are those that will keep the problem from happening again.

Example Scenario

- **Event:** During an internal audit of the study, the PI discovered that a recent hire had performed research activities prior to the study team receiving IRB approval to add the new hire to the list of study team members in eIRB+.

Corrective Actions Example

- **Corrective Actions:** The PI and research manager reviewed the study history and IRB-approved study team member list 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 (NTF), used the Incident Assessment Tool to determine IRB reportability, and stored the NTF in the study regulatory record.

Example Root Cause

- **Root Cause:** There was no process to ensure that new hires to the research team had taken all required actions before participating in Human Subject Research. The research manager prepared a modification (MOD) to the IRB to add a new hire to the list of study team members on eIRB+. Since the new hire has not completed their human research protections training, eIRB+ did not allow the research manager to submit the MOD. After the new hire completed their required training, the research manager directed the new hire to recruit, screen, and enroll participants into the study, forgetting that the MOD still needed to be submitted and approved by the IRB.

Preventive Actions Example

- **Preventive Actions:** The research manager created an SOP for new hire onboarding and a supporting checklist. The research manager and PI 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 PI. The completed checklists will be kept in the study regulatory record with the delegation of authority log. The research manager and the PI will review the implementation of the new SOP and checklist after each of the next three new hires. They will document their review in an NTF to be kept in the study regulatory record.

4. Document the CAPA

CAPA Plans must be SMART

- **Specific**: Be specific in what are the actions that will be taken to address the root cause of the problem and who will take these actions.
- **Measurable:** Assess how your team will track and measure the progress of your actions so that you know you're moving in the right direction of addressing the root cause of the problem.
- **Achievable:** Setting goals you can meet is incredibly important in avoiding setting yourself up for failure.
- **Realistic:** Consider whether you have the resources available to accomplish the goals.
- **Time-bound:** Include the estimated date(s) when you or others will complete the actions.

CAPA Plan Example

- The study team plans to conduct retraining for study team members.
- **Is the CAPA…**
  - **S**pecific?
  - **M**easurable?
  - **A**chievable?
  - **R**ealistic?
  - **T**ime-bound?

Documentation Elements

- Action type (corrective and preventive)
- Action Description
- Responsible person
- Due date
- Plan for effectiveness check
- Effectiveness check outcomes

A useful tool to ensure these elements are captured is the HRP-1209 Form: Corrective and Preventive Action (CAPA) Plan.

CAPA Plan Form (HRP-1209)

FORM: Corrective and Preventive Action (CAPA) Plan			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-1209	IRB Office Northwestern University	04/01/2026	Page 1 of 1

Corrective and Preventive Action (CAPA) Plan

Introduction: A Corrective and Preventive Action (CAPA) plan is implemented by research teams to immediately address an issue, identify its root cause, and establish preventive actions. The CAPA plan and the event(s) that triggered the need for a CAPA plan should be documented within the Principal Investigator's (PI's) study regulatory record. This form is a tool that PIs may use to prepare and document their CAPA plan.

Instructions: Complete the fields below. Maintain this completed document in the study regulatory record. See the Corrective and Preventive Action (CAPA) Plans webpage for additional information on developing a robust and effective CAPA plan.

Email irbcompliance@northwestern.edu if you have any questions.

Date: Date that the CAPA is written.
Principal Investigator (PI): Provide the PI's first and last name.
Associated STU Number(s): The IRB # of the study or studies associated with the CAPA plan. **Event/Issue:** Provide a brief summary of the event, including dates, that triggered the need for a CAPA plan.

CAPA Plan Form (HRP-1209) Elements

Date: Date that the CAPA is written.
Principal Investigator (PI): Provide the PI's first and last name.
Associated STU Number(s): The IRB # of the study or studies associated with the CAPA plan.
Event/Issue: Provide a brief summary of the event, including dates, that triggered the need for a CAPA plan.
Root Cause: Describe the reason(s) that the issue arose. The root cause is the initiating, most basic cause of a problem.
Corrective Actions: Describe the corrective actions taken or planned by study personnel to address this event, including dates. Describe who (roles, not names) is responsible for these changes. Consider whether you need to revise the protocol or informed consent forms as a part of your plan and whether the event requires reporting to the IRB.

CAPA Plan Form (HRP-1209) Elements

Preventive Actions: Describe the preventive actions taken or planned by the study personnel to prevent recurrence in the future, including dates. Describe who (roles, not names) is responsible for these changes.
Implementation: Describe the procedures used to document resolution of the problem, the personnel who are responsible for the procedures, dates, etc. Describe the Principal Investigator's (PI) oversight in the study and CAPA plan.
Effective date of resolution: Anticipated effective date for corrective and preventative action completion.
Evaluation /Follow-up: Provide the plan/procedure to assess the action plan's effectiveness, implementation and completion, the personnel who are responsible for the evaluations, timeframe for the evaluation, outcomes for participants, any needed adjustments made to the plan, etc. Include the PI's role in the CAPA evaluation and follow-up.

Supplemental Documentation Examples

- Meeting agenda(s)
- Training sign-in sheet
- Emails
- Checklists
- Tools
- SOPs

Record Keeping

- Save all documentation related to the CAPA Plan in the research records.
- The IRB, Sponsor, or other entities may request documentation and details of the CAPA Plan. Make sure you are prepared.
- If the CAPA Plan is related to a Reportable New Information (RNI) submission, include the CAPA Plan in the submission.

Evaluating the CAPA Plan

CAPA Plan Self-Assessment (HRP-1210)

FORM: Corrective and Preventive Action (CAPA) Plan Self-Assessment			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-1210	IRB Office, Northwestern University	04/01/2026	Page 2 of 4

1. **Summarize the CAPA plan point.**
   Provide a brief summary of a CAPA plan point.

   a. **Describe how and when you implemented and adhered to the CAPA plan point.**
      Provide a description of how and when, including dates, you implemented and adhered to the CAPA plan point summarized above.

   b. **Describe how the research team (i.e., method and frequency) evaluated the effectiveness of the CAPA plan point.**
      Provide a description of how the research team, including the roles of the staff involved and dates, evaluated the effectiveness of the CAPA plan point.

   c. **Did the CAPA adequately address the root cause of the issue identified?**
      ☐ **YES – Skip the next question and repeat the assessment for the next CAPA plan point.**
      ☐ **NO – Complete the next question and repeat the assessment for the next CAPA plan point.**

Timeline

- Evaluate a CAPA plan 3-6 months after implementation to evaluate adherence and effectiveness.

CAPA Plan Points Example

1. **Corrective Actions:** Review the study history, IRB-approved study team member list, and study team history. Identify the number of occurrences where an unapproved member of the study team participated in the research. Document the events in a note-to-file (NTF), use the Incident Assessment Tool to determine IRB reportability, and store the NTF in the study regulatory record.
2. **Preventive Actions:** Create a standardized operating procedure (SOP) for new hire onboarding and a supporting checklist. Document the implementation start date of the new process in an NTF and store the NTF in the study regulatory record. Review the implementation of the new process after each of the next three new hires and document the result of the reviews in an NTF to be placed in the study regulatory record. If the new process is effective, perform the review on an annual basis to ensure continued compliance and effectiveness. If the process requires revision, make the revision, document the changes in an NTF to be stored in the study regulatory record, and repeat the review process for the next three new hires.

Implementation and Adherence Example

- **Describe how and when you have implemented and adhered to the CAPA plan point:** The PI and research manager created the SOP for new hire onboarding on February 1, 2025, and the supporting checklist on February 8, 2025. On February 10, 2025, the research manager introduced the new hire onboarding process and corresponding checklist to the study team at the team meeting, as documented in the team meeting minutes, and stated that the process is effective from that day forward. A copy of the meeting minutes documenting the implementation of the process was attached to the NTF and stored in the study regulatory record.

Evaluation Example

- **Describe how the research team (i.e., method and frequency) evaluated the effectiveness of the CAPA plan point:** The PI and research manager are to review the implementation of the new hire onboarding process and associated checklist after each of the next three hires and document the result of the reviews in an NTF to be placed in the study regulatory record. After the implementation began on February 10, 2025, the study team had one new hire in November 2025. The PI and research manager used the checklist to train the new hire, and they formally reviewed the results of the new hire onboarding process and checklist in January 2026, after they completed all tasks listed in the checklist for this hire.
- **Did the CAPA adequately address the root cause of the issue identified?**

CAPA Plan Point Modification

d. If the CAPA did not adequately address the root cause of the issue, what is the new CAPA (i.e., how have you modified or will you modify the CAPA to more effectively address the root cause of the issue identified)?

Explain why the CAPA did not adequately address the root cause of the issue and describe how you have modified or will modify the CAPA to be more effective at addressing the root cause of the issue.

i. Is the new CAPA…

Specific?	☐ **YES**	☐ **NO**
Measurable?	☐ **YES**	☐ **NO**
Achievable?	☐ **YES**	☐ **NO**
Realistic?	☐ **YES**	☐ **NO**
Time-bound?	☐ **YES**	☐ **NO**

ii. **How will you evaluate the new CAPA for its effectiveness?**

Describe how you plan to evaluate the new CAPA for whether it is working as intended to address the root cause of the issue.

CAPA Modification Example 1

- The new hire onboarding checklist that was implemented in February 2025 neglected to account for role-specific onboarding procedures, so the PI and research manager added role-specific onboarding procedures for the various positions within the research team.
  - **Is the new CAPA…**
    - **S**pecific?
    - **M**easurable?
    - **A**chievable?
    - **R**ealistic?
    - **T**ime-bound?

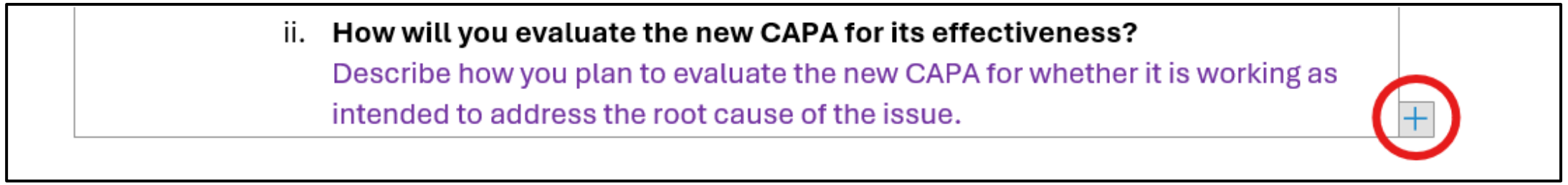
CAPA Modification Example 2

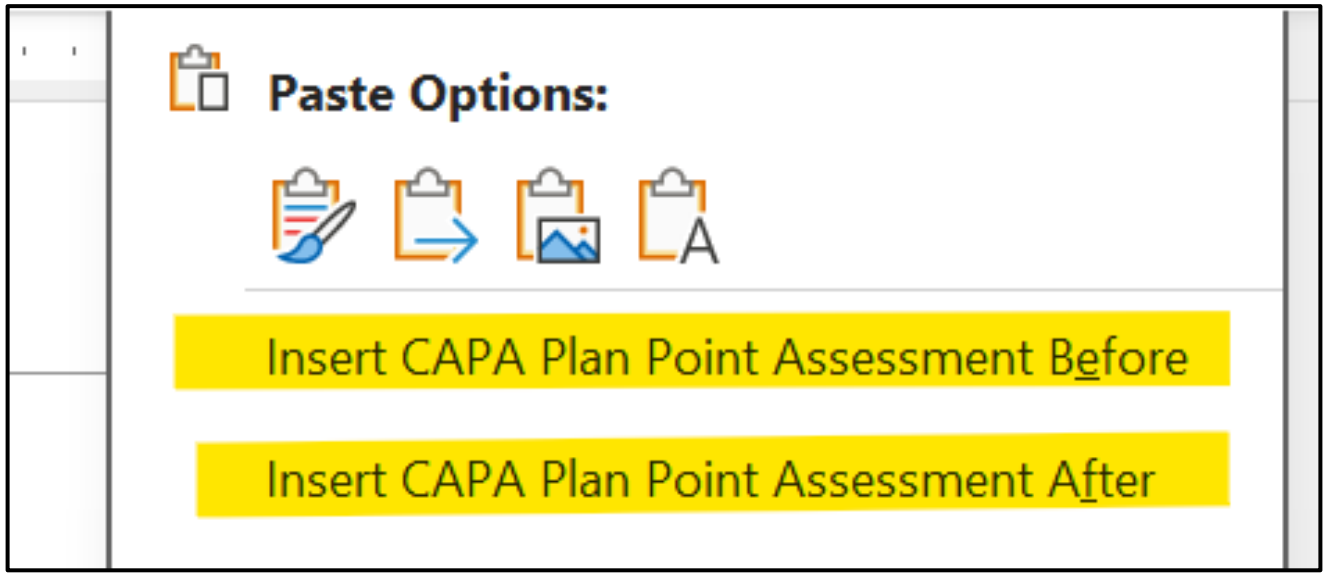
- **Original CAPA:** The study team planned to complete a CAPA plan within 60 days of the IRB review but encountered timeline constraints due participant scheduling for re-consent.
- **New CAPA:** The timeline for completing the CAPA plan needed to be adjusted to accommodate the participant's schedule and was adjusted to be completed within 90 days to allow additional time.
- **Is the new CAPA…**
  - **S**pecific?
  - **M**easurable?
  - **A**chievable?
  - **R**ealistic?
  - **T**ime-bound?

Evaluating the New CAPA Example

- The PI and research manager will repeat the review of the implementation of the revised checklist after each of the next three new hires and document the result of the reviews in an NTF to be placed in the study regulatory record.
- If the revised checklist is effective, then the review will be performed on an annual basis to ensure continued compliance and effectiveness.
- If the process or checklist requires revision, the PI and research manager will make necessary revisions, document the changes in an NTF to be stored in the study regulatory record, and repeat the review process for the next three new hires again.

Adding a CAPA Plan Point Assessment





Document, Document, Document

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Thank you