UNMC IRB Corrective Action Plan (CAP) Guide

CAPs 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 and the individual (role) responsible for taking the actions.
- **MEASURABLE**: include the process of assessing the effectiveness of the action plan and a process by which the plan will be amended as necessary.
- **ACHIEVABLE:** The plan should be feasible and address all implicated processes and causes.
- **RELEVANT:** The plan must actually address the root cause and be appropriate for the level of risk.
- **TIMELY**: the CAP must be implemented in a timely manner and have a reasonable and achievable completion date.

Best practice is to create and maintain documentation that demonstrates the CAP has been implemented. The IRB or sponsor may request to review this documentation.

Corrective Actions:

Corrective Actions are actions taken to **resolve the problem.**

These may be actions already taken to eliminate the risk of immediate harm or actions planned by the study team to reduce the likelihood of subsequent noncompliance in the future.

Examples of Unacceptable CAPs:
"The study team was retrained."
"It was an oversight, and we won't do it again."
"We will educate people."
"We will do better next time."
"We reminded the coordinator and reviewed the proper procedure."

Consider the following when describing the CAP:
• ***What*** *actions have been and will be taken?* • ***Who*** *is responsible for taking these actions?* • ***What*** *is the plan to keep this from happening again?* • ***When*** *will these actions be started and completed?* • ***How*** *will you check for effectiveness of these actions?* • *If "re-educating", specifically* ***when*** *will this be done?* ***Who*** *will be doing the training?* *The CAP should include pertinent details (e.g.* ***when, who, how****). Any CAPs lacking details will be returned for revision.*

Preventative Actions:

Preventative Actions are actions necessary to **ensure the problem doesn't occur again**.

Consider whether you need to a) revise the protocol or b) revise the informed consent form(s) as part of your plan.

Preventative actions may be taken before or after IRB review, depending on whether the implementation of the changes impacts the rights, welfare and safety of subjects.

NOTE: for more detailed information on Corrective Action Plans, please refer to the following guide: Noncompliance Root Cause Analysis and Corrective Action Plans