**University of California, San Diego**

**Office of IRB Administration (OIA)**

**Guidance on Corrective and Preventative Action (CAPA) Plans**

**General Instructions**

A successful research study relies on diligent integration of procedures and systems designed to create a high-quality product in the form of meaningful data. Research involving human subjects must further endeavor to protect the rights and wellbeing of the individuals contributing to these data by adhering to guiding ethical principles. In the course of research, events may occur which challenge the execution of these parallel goals. The purpose of a Corrective and Preventative Action (CAPA) plan is to establish a process to identify, correct, and prevent future occurrences of events that may pose a risk of harm to the rights, safety or welfare of human subjects or to the quality or integrity of research data.

A CAPA plan should be developed and submitted along with any event that meets UCSD IRB’s reporting requirements. The plan should be specific throughout the course of identifying what occurred, its root cause, proposed corrective and preventative actions, and post-CAPA plan evaluation. It may be necessary to develop additional documents outlining new workflow processes and SOPs in conjunction with the CAPA plan. As the CAPA plan is implemented and its effectiveness evaluated, additional documentation should occur, and updates may need to be applied as necessary.

An effective CAPA plan will generally require the involvement of most if not all members of a study team. It should be developed in collaboration with the PI and any staff members to whom it will pertain.

The following template may be used to create a CAPA plan for your study.

* Red text represents instructions to you – to be deleted from the final version.
* Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version.
* Black text represents section headings that should generally be incorporated as-is, if applicable.

**Template:**

**Corrective and Preventive Action Plan (CAPA) Plan**

Title of Project: Title

IRB Number: From the electronic IRB system

Principal Investigator: As listed in the protocol

Version Number: Version number for the CAPA Plan

Version Date: Date CAPA is written, updated per version

**I. Description of the Problem(s)/Event(s)**

Explain what occurred in detail sufficient for someone who is not familiar with the study to understand the issue. Do not include information that could identify subjects; while you may include subject ID#s, this is not necessary. This narrative should lay out the timeline of events, including dates, as applicable. Provide an analysis of the extent of impact such as the number of subjects that were directly impacted and/or harmed, the number that were potentially impacted and/or harmed, and/or how much study data have been impacted. Note that if contextually or chronologically related, the narrative may describe multiple problems or events and, in this case, each problem or event should be clearly delineated. Explain whether what occurred may impact or extend beyond this study, for example, if there are other protocols under the oversight of this PI or lab that follow similar procedures or share staff members associated with the issue. If so, consider this in the context of implementing your CAPA plan and assessing potential similar problems across other studies as necessary.

**II. Root Cause(s) of the Problem(s)/Event(s)**

This section should incorporate a comprehensive root cause analysis. Identifying the root cause is not always easy and may require going multiple levels beyond what appears to be a core issue on the surface. The IRB recommends utilizing the “5 Whys” method of root cause analysis. This should be a collaborative process incorporating the insight of multiple study team members. Develop a clear and specific problem statement based on the issue(s) noted above and ask why this occurred. Answers should be based in fact, that is, they should be accounts of things that actually happened rather than speculation as to what might have happened. There may be multiple answers to this initial question. For each of the answers generated from the initial “why” question, ask four further “why” questions in succession. To arrive at a root cause, you may need to ask more or less than 5 “why” questions. You should arrive at the root cause of the problem once asking “why” produces no more useful responses, and you can go no further. If multiple root causes are identified, corrective and preventative actions relevant to each should be delineated in the subsequent sections.

Example of the 5 Whys Process:

Why #1: Why wasn’t the magnesium lab ordered with all the other labs for Subject MC-004?

* Answer: Because the coordinator didn’t know it was needed at that timepoint/visit.

Why #2: Why didn’t the coordinator know it was needed at that timepoint/visit?

* Answer(s): Coordinator missed the study training at the SIV because they were sick. Magnesium lab wasn’t on the checklist for the timepoint/visit

Why #3A: Why was the coordinator working on the study without study training?

* Answer: The only trained coordinator was on vacation. The PI didn’t train this coordinator when they returned from being sick.

…etc.

Why #3B: Why wasn’t the magnesium lab on the checklist for the timepoint/visit?

* Answer: The lead coordinator thought magnesium was included in the chemistry panel they noted on the checklist. The PI didn’t review study checklists before study start.

…etc.

**III. Corrective and Preventive Actions**

[Include if any corrective actions have already been taken; otherwise explain why no corrective actions were needed.]

**Corrective Actions: What did you do or what will you do to correct the immediate problem(s)/event(s)?**

Describe the immediate actions that were taken to correct the identified problem(s). It is often the case that a problem/event was not identified or not identified as problematic at the time that it occurred, for example, if an oversight was revealed during an internal or sponsor-initiated audit. In this case, describe what you will do to remediate the problem to the extent possible. This could involve re-consenting participants, contacting participants to explain what occurred, or creating documentation, such as a Note to File. This should also specify adherence to reporting requirements outside of the UCSD IRB, if applicable (e.g., to the Privacy Office, sponsor, funding agency, lead site, FDA, etc.), and indicate when other entities were informed in relation to when the issue was identified.

**Preventive Actions: What new processes are you putting in place to prevent the problem(s)/event(s) from occurring in the future?**

Plans should be specific and measurable, and directly reflect the identified root cause(s). In order to be effective, most CAPA plans will necessitate some updated procedures/processes/ workflows. These should be identified in this section, and any new documents such as checklists or SOPs should be attached to the reportable event submission along with the CAPA plan. Revisions to study materials may also require an amendment to be submitted in conjunction with the reportable event. Re-training of study staff will also often be appropriate. This section should be specific regarding the content of the training, who will be re-trained, the date(s) that training(s) is/are expected to occur, who will lead the training(s) (if applicable), the format in which training(s) will be conducted (one-on-one, group training, electronic courses), etc. Please note that training alone is rarely an acceptable preventative action since it relies on an individual’s memory and cannot be referenced by a new study team member. In addition, if the PI of the study was not the one to discover the event through regular oversight activities (e.g. at weekly study meetings), the role of the PI in the prevention of the event recurrence should be addressed as the PI is ultimately responsible for ensuring the proper conduct of the study.

**IV. Evaluation of Implementation of the CAPA Plan**

This should include a detailed plan for how the effectiveness of the CAPA plan will be evaluated for its success or failure in correcting and preventing recurrence of the problem(s). This requires implementation of the plan for an appropriate period of time, which can vary based on the nature of the problem and when, or the frequency with which, it is most likely to potentially recur. As with the other elements of the CAPA plan, this information should be specific and measurable. Specify what will be evaluated, who will conduct the evaluation, and what the criteria will be for determining whether the CAPA plan was successful. Documentation related to these evaluations should be clear and maintained within the study regulatory files. Include a plan for notifying the IRB of the evaluation results, such as at the next continuing review or when recurrence is identified. The CAPA plan should be revised if the evaluation reveals that the current CAPA plan did not resolve the issue(s) or prevent reoccurrence. This should involve an iterative evaluation process where the steps above are repeated with the specific failure(s) of the CAPA as the problem(s) to be assessed.