**Corrective and Preventive Action Plan (CAPA) - General Instructions**TemplateVersion 1, 3/28/2025

***(Delete this page once completed)***

It is essential to have a process in place to identify, correct, and prevent future occurrences that may affect the quality of the study, process, or department. A corrective and preventive action plan (CAPA) is used for this purpose and can help protect the rights, safety, and welfare of study participants and the reliability of the data collected or can help create and update processes and workflows for teams, departments, or systems. A CAPA should be submitted along with the Reportable Events for any major deviations and/or (if applicable) Unanticipated Problems (UPs) identified in the conduct of a study.

Be as specific and detailed as possible in the proposed corrective/preventive actions. Include dates for estimated or actual completion of actions. Provide new written processes (new workflows or SOPs) that address the issues identified. Describe who will take part in the training of the new processes, who gives/conducts the training, and the contents of the training.

Note that the most effective CAPAs are the result of a team effort or collaboration and the analysis of the root cause(s) and determinations about how to best fix the issues. Focus on the systemic issues instead of individual mistakes and include all pertinent stakeholders in the creation and implementation of this CAPA. All steps of the CAPA implementation should be well documented so it is clear for the IRB, Sponsors, monitors and auditors that the CAPA was implemented, its effectiveness was assessed, and updates were made (if needed).

Use this template to create a CAPA for a study, process, or system that may need it as follows:

* ***Red italicized text*** represents instructions to be deleted from the final version.
* **Blue text** represents guidance on suggested content to be edited and changed to black for the final version.
* **Bolded text** represents section headings that are kept in, but can be removed if not applicable.

**Contact**

Please contact for questions regarding this document:

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**CORRECTIVE AND PREVENTIVE ACTION (CAPA)**

*Instructions: Replace all blue text with appropriate information*

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| --- | --- |
| **Date:** | Date that the CAPA is written |
| **To:** | Sponsor, IRB, etc. |
| **Cc:** | *[Include anyone that should be aware or a part of the CAPA plan, i.e. PI, Sub-Is, etc.; Remove section if not relevant]* |
| **From:** | Name, title, and the site or institutional affiliation of the person authoring the CAPA |

**Study** **Title and IRB Number:** *[Include if applicable to a specific project affected]*

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| **Description of Issue or Finding:** | Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items. If the same deviation occurred multiple times, these can be grouped together. The description should include a timeline with dates, whether it affected subjects (and if so, how many and how), and whether this problem is specific to a single project or multiple. Do not include any information that would identify subjects. |
| **Root Cause:** | The reason(s) that the issue arose. This should include how and why the issue occurred and the method of investigation. It is important to incorporate the “[5 Whys](https://asq.org/quality-resources/five-whys#:~:text=The%20technique%20was%20originally%20developed,a%20solution%20to%20a%20problem.)” to determine the root cause of the issue(s) discussed. |
| **Assessment of Issue/Finding:** | Assess whether the issue or finding:   * Had the potential to affect subject safety; OR * Increased risks to subjects; OR * Affected the integrity of the data; OR * Violated the rights and welfare of subjects; OR * Affected the subject’s willingness to participate in research |
| **Corrective Action:** | Description of the immediate corrective actions taken or planned by the site personnel. This should include any reportable events required, additional training, allocation of resources, or information regarding NTFs that will be accompanying the CAPA. Discuss any plans for participant communication, if applicable. If the status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed in the future. *[Or include why no corrective actions were needed (either immediately or at all).]* |
| **Implementation:** | Description of the immediate procedures used to document resolution of the problem, the personnel who are responsible for the procedures, etc. |
| **Effective date of resolution:** | Effective date for corrective action. This may be ongoing, however include the date that immediate actions were taken or include an estimated date of when you anticipate taking corrective action. |
| **Preventive Action:** | Description of the preventive actions taken or planned by the site personnel to avoid this being an issue again in the future. This should be clearly addressing the root cause(s) and how to eliminate potential issues. To be effective, this should include new procedures or workflows and how they will be documented. Additionally, training should be documented on these new procedures/workflows and should include who was trained and led the training, date of training, and how the training will be conducted (self-training, group training, etc.) |
| **Evaluation / Follow-up:** | Any plan / procedure to evaluate the implementation of the CAPA and resolution of the issue(s), personnel (or personnel position) who are responsible for the evaluations to assess compliance, and timeframe for the evaluation. Additionally in this plan, if the CAPA did not resolve the issue next steps should be included for notifying the IRB and updating the CAPA. The evaluations should be thoroughly documented and filed in the regulatory system. |
| **Comments:** | Any additional comments or information not noted above |