**IRB #: Principal Investigator:**

**Study title:**

**Person completing this form:**

Investigators are responsible for developing, implementing, and evaluating CAPA plans promptly.

**Instructions to complete this form:** Please use this form to document a Corrective and Preventive Action (CAPA) Plan in response to an event.

Root Cause Analysis (RCA): method to identify the factors that resulted in the nature, magnitude, location, and timing of noncompliance or other problems. The RCA identifies behaviors, actions, inactions, or conditions that need to be changed to prevent recurrence of similar noncompliance and to determine the lessons to be learned to promote compliance.

Corrective and Preventive Action (CAPA) plan: a plan developed by the research team, following a root cause analysis into an instance of noncompliance or other problems in human subjects research. The CAPA plan must include measures designed to correct the immediate problem and prevent its recurrence or the recurrence of a similar problem.

CAPA monitoring plan: strategy to assess the effectiveness of the corrective and preventive action plan.

Need help? Don't hesitate to get in touch with us:

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| --- | --- | --- | --- | --- | --- |
| **Description of the problem:** | | | | | |
| **Root Cause** | **CAPA Plan** | **CAPA monitoring plan** | **CAPA Acceptance** | **CAPA plan monitoring results & date of actual evaluation** | **CAPA plan evaluation results** |
|  | Corrective:  Preventive: | Date of planned evaluation: | PI Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: | Date: | Ongoing  Date of next eval (\*)  Revision Needed (\*)  Resolved  PI signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
|  | Corrective:  Preventive: | Date of planned evaluation: | PI Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: | Date: | Ongoing  Date of next eval (\*)  Revision Needed (\*)  Resolved  PI signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
|  | Corrective:  Preventive: | Date of planned evaluation: | PI Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: | Date: | Ongoing  Date of next eval (\*)  Revision Needed (\*)  Resolved  PI signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
|  | Corrective:  Preventive: | Date of planned evaluation: | PI Signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: | Date: | Ongoing  Date of next eval (\*)  Revision Needed (\*)  Resolved  PI signature:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

(\*) Complete a new entry below