Ascension Wisconsin Research Education and Quality Management

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

This guidance and template have been created to provide tips to help study sites create complete CAPA plans.

**Tips for Writing a CAPA**

A **CAPA** is written to identify a discrepancy or problem in the conduct of a clinical research study, note the cause of the problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem. For example, it may be appropriate to:

* Clarify or add information regarding site specific regulatory file requirements,
* Clarify or add information regarding source document standards,
* Document and address any issue that is protocol- and/or site-specific that cannot be resolved without a change from previous procedures.

**Key things need to be included in a CAPA:**

**1) Cause Analysis:** Collection and analyses of information to identify the cause(s) of the problems or events.

**2) Corrective Action:** Evaluation, planning and documenting action needed and implementing such action, including, as appropriate, reviewing the effectiveness of corrective action taken and updating documentation.

**3) Preventative Action:** Evaluation of the need for action to prevent occurrence, planning and documenting action needed and implementing such action, including, as appropriate, reviewing the effectiveness of the preventive action taken and updating documentation.

A **CAPA** should be signed by the author and investigator, submitted to the IRB for review (if written in response to a recommendation based on Research Education and Quality Management Review), kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site’s documents and procedures.

**Template**

The CAPA template on the next page can be used by study investigators.

**Corrective Action Preventive Action (CAPA) Template**

**Date:** (Date the CAPA is written)

**To:** (IRB or Regulatory File)

**From:** (Name and Title)

**Issue:** (Brief Description of the problem being documented; can be a paragraph, numbered list or bulleted list.)

**Cause:** (The reason that the issue occurred.)

**Corrective Action:** (Description of the actions taken or planned by site personnel.)

**Implementation:** (Description of the process used to document resolution to the problem.)

**Effective Date:** (Effective date for corrective action.)

**Preventative Action:** (Description of the preventive actions taken or planned.)

**Follow Up:** (Any plan or procedure to reevaluate the implementation and completion.)

**Comments:** (Any additional comments or information not noted.)

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Signature of Author Date

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Signature of Investigator Date