


Standard Operating Procedures for Clinical Research at USF Health CRC		
	CORRECTIVE AND PREVENTATIVE ACTION PLAN	
	Effective Date: 10/14/2016	Revision Date:
SOP#: 603	Version: 1.0	Page: Page 1 of 3

PURPOSE: The purpose of this SOP is to establish a Corrective and Preventative Action (CAPA) Plan for conducting and documenting internal activities for continual assessment of compliance with clinical trials conducted at the CRC.

SCOPE: This SOP applies to the PI and designated clinical research personnel involved in the regulatory implementation and coordination of clinical trials at the CRC.

RESPONSIBILITY: The PI is responsible for the overall conduct of a research study at the CRC, however; delegation allows clinical research team members to perform CAPA activities under the direct supervision of the PI in the implementation and conduct of clinical trials.

DEFINITIONS:

Audit: A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Corrective action: Action to eliminate the cause of an identified problem or deviation. Corrective action is taken to prevent recurrence.


Corrective and Preventive Action (CAPA): The processes taken and process improvements initiated to eliminate causes of nonconformities or other undesirable situations.

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Monitoring Report: A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs


Preventive Action: An action to eliminate the cause of a potential non-conformity or other undesirable potential situation. Preventive action is taken to prevent occurrence.

Root Cause Analysis: A class of problem solving methods used to identify the root causes of problems or events.

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PROCEDURE:

1. Research personnel will be aware that a Corrective and Preventative Action (CAPA) Plan can be triggered in a number of ways that may include:
 - During a Site Initiation Visit (SIV) or Routine Monitoring Visit (RMV) when a monitor reports that a site requires a “for cause” or “not for cause” audit.
 - During an internal audit
 - During an FDA audit
 - Preventative actions for potential problems and issues
2. To minimize the need for a CAPA, research personnel will maintain ongoing training requirements necessary to work in research and comply with the Standard Operating Procedures (SOPs) of the CRC.
3. Research personnel will recognize that a CAPA plan can include more than one activity and issue whereas, a Note to File (NTF) usually addresses one problem or issue that has occurred.
4. Research personnel will adhere to the following principles when developing and executing a CAPA plan:
 - 4.1. The plan should make sense.
 - 4.2. The plan should be easily implemented and managed.
 - 4.3. The plan must be systematic and measurable. It must be proactive and able to correct problems at all levels of the research site. It should be easy to use and track progress of the action to be able to show results that are working.
 - 4.4. The plan should account for more than a reaction to problems. It should have the potential to improve efficiency and effectiveness of the clinical trial.
5. Research personnel will complete a CAPA Plan Response Form (Appendix JJ) that includes the following when preparing a CAPA plan:
 - 5.1. Identify: Pinpoint the problem or potential problem.
 - 5.2. Evaluate: Assess the magnitude and impact of the problem.
 - 5.3. Investigate: Research the problem.
 - 5.4. Analyze: Perform a root cause analysis of the problem.
 - 5.5. Act: Create a list of required actions and due dates to eliminate the problem and prevent recurrence.
 - 5.6. Implement: Execute the action plan and track action item, responsibilities and completion status
 - 5.7. Follow-up: Verify and assess the effectiveness of the plan. Make changes to the plan if needed.

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REFERENCES:	FDA Guidance for Industry: Guideline for the Monitoring of Clinical Investigator. FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects. October 2009 21 CFR 312 21 CFR 812 21 CFR 820, Subpart J: Corrective and Preventive Action Requirements ICH Guideline E6: Good Clinical Practice
RELATED POLICIES:	
APPENDICES:	Appendix JJ: CAPA Plan Response Form
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016