Purpose

To describe and address an identified protocol deviation/noncompliance event that was discovered during the conduct of a human subject research study.

When the deviation/noncompliance event is discovered, study teams should take immediate measures to mitigate risk and protect rights, welfare, and safety of the subject(s). Corrective and Preventive Actions (CAPA) are implemented to prevent the occurrence and recurrence of an event.

Procedure

Research personnel will be aware that a CAPA is required by an FDA audit, an IRB Not for Cause or For Cause audit, or a site internal audit.

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.

When developing and executing a CAPA plan the study team should:

- Make sure the plan make sense.
- Make sure the plan is easily implemented and managed.
- It must be proactive and correct problems at all levels of the research site. You should be able to use it and track progress to show the plan is working.
- It should improve efficiency and effectiveness of the clinical trial.

Research team should use the Corrective and Preventative Action Plan template found below.

The study team should:

- Identify the deficiency- briefly state the deviation, event, or issue identified. State what occurred, when and where it occurred, what should have occurred, who discovered the deviation, if someone other than the compliance monitor.
- Identify the cause- what is the magnitude of the problem, how many times did it occur, how many subjects did it affect, what contributed to this event, etc.
- Explain how the deviation, event, issue has been corrected.
- Explain the preventative plan you have implemented to ensure this deviation/issue does not reoccur.
- Explain who the responsible person is to oversee this problem from happening again.
- Investigator should sign and date the document to confirm that they agree with these changes.

Implementing the CAPA

The CAPA may be relevant only for the study or it may need to be implemented systematically across the department. This should be stated in your CAPA. It is important to document that the study team has been trained on the CAPA.

CAPAs must be evaluated over time. If the CAPA has not addressed the issue, amend the CAPA, retrain, and re-evaluate.

To avoid the need for a CAPA, study teams should have prevention and quality assurance procedures in place to proactively avoid problems.

Resources

http://louisville.edu/research/humansubjects/researcher-toolbox/researcher-toolbox

Date:		**IRB Number:**	
Protocol Title:		**Principal Investigator:**	

Deficiency Identified:	Investigator signed more than 14 days after the subject.		
Cause Identified:	Investigator was not aware of the local policy manual		
Corrective Action Plan: (Action taken to correct specific deficiency identified)	The investigator has been educated on the local policy to sign within 14 days of the subject consenting.		
Preventative Action Plan: (Action taken to prevent the reoccurrence of this problem in the future)	The study coordinator will meet with the investigator on a weekly basis to discuss subjects and sign consent forms.		
Responsible Personnel:	Mark Smith, MD	**Signature and Date:**	