**What is a CAPA?**

Despite a study team’s best efforts, errors in the conduct of research may occur. Errors may include deviations from the IRB approved study plan or noncompliance with applicable research regulations or policies. Whether the result of human oversight, process deficiencies or technology failures, such errors should be identified and when appropriate, the steps taken to resolve them and to ensure they do not happen again, should be well documented in the research records. This important documentation is known as a Corrective and Preventive Action (CAPA) Plan.

A CAPA Plan is a collective process, or series of measures, to correct the immediate problem, to determine the cause or causes of the problem, and to develop and implement a plan to prevent the problem from recurring. CAPA Plans are required in response to most promptly reportable events and study teams are asked to describe them in the Reportable Event submission form. Developing an effective CAPA Plan requires analysis and problem-solving skills and should represent a collaborative effort by the members of the study team. CAPA Plans should be followed through completion and should be monitored by the study team for their success in preventing recurrence of the problem. The entire process should be documented, and this documentation should be maintained as part of the research record.

**Instructions to complete the attached worksheet:** Please use this form to document a Corrective and Preventive Action (CAPA) Plan in response to an event. *(example: visit out of study window, each time the site has the same type of visit out of study window use the same form to document it as a bigger issue, Use a new form for a new deviation- example wrong consent version not completed.)* Monitor how many forms you are having for sites to see if there is more of a systemic problem with following protocol.

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. It is the Who, What, When, Why and How?

*(example: protocol deviation- subject seen out of visit, RCA- Study visit window is 5 days, visit needs 5 team members to see patient during that visit and all available on Tuesdays- if someone is not available visit was scheduled the next week out of visit)*

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 subject’s research. The CAPA plan must include measures designed to correct the immediate problem and prevent its recurrence or the recurrence of a similar problem. *(Immediate problem- provide subjects and study team the visit windows in advance to ensure they can be present for visit or have trained back-up staff if it is always one person who cannot attend. Preventative Measures: train and add staff to the DOR, OR if this is a problem for many sites perhaps you can adjust visit window to be plus or minus 7 days so that there is multiple Tuesdays of the week that all team members could attend)*

Monitoring of the Deviations happens as an agenda item during the monthly team meetings: This can be implemented into redcap. This is good for all studies to ensure reportable events to the IRB but **necessary** for [FDA studies](https://www.fda.gov/corrective-and-preventive-actions-capa).

|  |
| --- |
| **Description of the problem:**  |
| **Root Cause**  | **Date of Evaluation** | **No Change Needed** | **Study Team CAPA Plan changes/updates to sites response** | **CAPA plan monitoring results if Requested Change/Updates** | **CAPA plan evaluation results** |
|  |  |  | Corrective change Needed: | Who Informed Site of Requested changes | [ ] Ongoing (\*)[ ] Revision Needed (\*)[ ] Resolved**Form Completed by:****PI Signature/Date:** |
| Preventive change Needed: | Date informed: |
|  |  |  | Corrective change Needed: | Who Informed Site of Requested changesDate informed: | [ ] Ongoing(\*)[ ] Revision Needed (\*)[ ] Resolved**Form Completed by:****PI Signature/Date:** |
| Preventive change Needed: |
|  |  |  | Corrective change Needed: | Who Informed Site of Requested changesDate informed: | [ ] OngoingDate of next eval (\*)[ ] Revision Needed (\*)[ ] Resolved**Form Completed by:****PI Signature/Date:** |
| Preventive change Needed: |

**Study Short Name: IRB#: Site ID:**

**Principal Investigator: Site PI:**

This worksheet is to be completed while developing the CAPA plan after initial review of study team’s protocol deviation and their CAPA Plans. Attach PD information or list where one can find it.