UTRGV Post Approval Monitoring
Office of Research Compliance
Standard Operating Procedure

I. Corrective and Preventive Action (CAPA) Plan

A. PURPOSE:

1. To provide guidance to investigators and key study personnel in writing a Corrective and Preventive Action (CAPA) Plan, to develop plans for addressing existing or potential problems identified during the conduct of research, and to prevent reoccurrence.

B. SCOPE:

1. All regulatory research protocols approved by the UTRGV regulatory committee or studies conducted at any UTRGV facility or affiliate facility regardless of regulatory committee of record.

C. RESPONSIBLE INDIVIDUALS:

1. All Investigators, research, regulatory, and study personnel who engage in regulated research.

D. RELATED TERMS AND DEFINITIONS:

1. **Corrective action:** Action taken to rectify a problem. See Corrective and Preventive Action Plan (CAPA).
2. **Corrective and Preventive Action plan (CAPA):** A quality process used to address any existing noncompliance issue and the steps taken to prevent further recurrence. Actions taken to collect information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.
3. **Root cause:** Factor that caused an issue or problem. See Corrective and Preventive Action Plan (CAPA)
4. **Root cause analysis:** a class of problem-solving methods used to identify the initial causes of problems or events. See Corrective and Preventive Action Plan (CAPA)

E. POLICY STATEMENT:

1. A CAPA is written to identify a discrepancy or problem in the conduct of the research study, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.

F. PROCEDURES:

1. <u>Form a team</u>
    a. Identify the individual(s) responsible for:
        i. Developing the CAPA plan.
        ii. Implementing the CAPA plan.
        iii. Training staff on the CAPA plan.
        iv. Evaluating results of the CAPA plan.
    b. <u>Identify the issue or potential issue.</u>
        i. Document a brief description of the issue.
        ii. Evaluate magnitude of the problem and potential impact.
        iii. Investigate the impact of the issue on overall research.
    c. <u>Identify the root cause.</u>

i. Describe the reason the issue arose.
ii. Investigate how or why the incident occurred.

d. Describe the corrective actions taken or planned.
i. Indicate who will perform the corrective actions and when.
ii. If items are incomplete or unavailable, include a statement regarding attempts made to complete the action.
iii. Consider sponsor, regulatory or local institutional requirements when creating the corrective action plan.

e. Implementation
i. Describe the procedures implemented to resolve the problem and indicate who is responsible for the procedure.

f. Effective date of resolution
i. Indicate an effective date for corrective action.

g. Preventive action
i. Describe the preventive actions taken or planned and who is responsible.
ii. Create a listing of all tasks that must be completed to correct or prevent the problem.
iii. Send a copy of the final CAPA to the appropriate authority as required.

h. Evaluation and follow-up
i. Described the procedure to evaluate implementation and completion.
ii. Indicate the study staff who are responsible for the evaluations.
iii. Include the timeframe for evaluation.
iv. Send evaluation follow-up report to appropriate authority, if requested

i. Comments – Optional
i. Document observations
ii. If the CAPA Plan is related to an internal process, maintain documentation separate from the original study files.
iii. If the CAPA Plan is in response to an FDA audit or any other type of study specific audit, maintain documentation as part of your study files.
iv. As applicable, follow any of the reporting requirements listed in the IRB Manual or Post Approval Monitoring SOPs.

G. REFERENCES:

1. FDA 21 CFR 820.100
2. FDA.gov-Corrective and Preventive Actions
3. Preventive/Corrective Actions (CAPA) Guidelines. R.M. Baldwin, Inc.

H. FORMS OR ATTACHMENTS:

1. UTRGV CAPA Template