UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Quality Management and Corrective Action and Preventive Action Plans
SOP #:	OTO 203
Version #:	4
Effective Date:	May 4, 2022
Supersedes:	OTO 203 Quality Management and Corrective Action and Preventive Action Plans v3

1. POLICY

Research studies will be conducted according to Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) regulations to protect the safety and welfare of study subjects and result in the highest standard of data integrity. Quality Management and Corrective Action and Preventive Action Plans (CAPA) are essential to the clinical study process as they help ensure the ongoing quality standards set forth by regulating bodies, Good Clinical Practices and Standard Operating Procedures.

2. SCOPE

These policies and procedures apply to all personnel who conduct or are involved in clinical research of human subjects involving investigational product(s) approved for dispensing by means of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) clinical trial.

3. RESPONSIBILITY

The Principal Investigator is responsible for overseeing proper quality management. The Principal Investigator may delegate, audit, and document practices associated with this SOP to other members of the research team.

4. APPLICABLE REGULATIONS AND GUIDELINES

All 21 CFR 50, 21 CFR 56, 21 CRF 312 and 21 CFR 812 regulations and ICH E6 standards apply to this SOP

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

Attachment A: Meeting and File Review Plan

Attachment B: CAPA Worksheet

8. PROCESS OVERVIEW

A. Quality Assurance and Internal Monitoring

B. Corrective Action and Preventive Action (CAPA) Procedures

1. When to initiate a CAPA

2. Investigation
3. Correction methods
4. Preventive methods
5. Implementation plan
6. Verification of effectiveness
7. CAPA closure

9. SPECIFIC PROCEDURES

A. Quality Assurance and Internal Monitoring

#	*Who*	*Task*	
1.	Investigator Research Nurse/Coordinator	*A schedule of periodic meetings and/or communication is to be established at the start of each trial. Meetings and/or communication should include the Principal Investigator and active study personnel.* *A schedule of periodic file reviews is to be established at the start of each trial. File reviews include clinical data and regulatory documentation to review completeness and compliance with applicable requirements.* *Use Attachment A, Meeting and File Review Plan to document the timelines and responsibilities of these plans*	
2.	PI Designee	*Meeting minutes and/or a communication log are to be recorded and maintained for the life of the trial.* *A summary of pertinent file review findings, if any, should be recorded at a study meeting and/or communication*	
3.	Investigator Research Nurse/Coordinator	Any and all forms of non-compliance should be evaluated to determine if a Corrective Action and Preventive Action Plan is necessary.	
	Note:		

B. Corrective Action and Preventive Action (CAPA) Procedures

1. When to Initiate CAPA

#	*Who*	*Task*	
1.	Investigator	Identification of a problem can originate from a number of sources including patients, study personnel, study sponsor or an inspector. A CAPA should be initiated when: 1) A problem is found to affect data integrity, patient safety, or compliance with applicable regulations/SOPs. AND 2) A risk assessment warrants the use of a CAPA	

#	Who	Task	
2.		Use Attachment B, CAPA Worksheet to assess when a CAPA process should be used. If it is determined that a CAPA should be used, Attachment B, CAPA Worksheet must be completed in its entirety and maintained for the life of the study. The PI must sign the CAPA plan prior to initiation of the CAPA.	
	Note:		

2. Investigation

#	Who	Task	
1.	Investigator	An investigation should be launched to determine the details of the problem which has already occurred. Include two areas: 1) How widespread is the problem across this study and other studies? 2) What is the root cause?	
	Note:		

3. Correction Methods

#	Who	Task	
1.	Investigator	Determine how to appropriately handle the problem which has already occurred.	
2.	Investigator	Ensure the correction methods include an action plan for the entire scope of the problem.	
	Note:		

4. Preventive Methods

#	Who	Task	
1.	Investigator	Determine how to appropriately fix the problem to prevent it from happening in the future.	
	Note:		

5. Implementation Plan

#	Who	Task	
1.	Investigator	Create a plan to initiate change required for preventive action. Include the following elements: 1) Timelines 2) Personnel responsible 3) Personnel affected	
	Note:		

6. Verification of Effectiveness

#	*Who*	*Task*	
1.	Investigator	Determine a plan on how the change(s) will be considered successful. Include documentation procedures to indicate the plans were followed appropriately. Determine timelines to include periodic reviews and a total amount of time necessary to effectively demonstrate the success of the plan.	
2.	Investigator	Consolidate documentation per plan	
	Note:		

7. CAPA Close

#	*Who*	*Task*	
1.	Investigator	Once it is determined and documented that a CAPA plan was successful, it can be closed.	
	Investigator	Sign Attachment B, CAPA worksheet as approval of CAPA closure	
	Note:		