UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Subject Management While on Study
SOP #:	OTO 202
Version #:	4
Effective Date:	July 17, 2019
Supersedes:	OTO 202 Subject Management While on Study

1. POLICY

The safety and well-being of subjects is of paramount concern to the research team. Study team members must constantly evaluate each subject's response to the investigational article. Through close monitoring and careful assessment of subjects, adverse events can be detected early and treated appropriately. By following these procedures, close attention is paid to subject well-being and to integrity of the data.

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. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.20	General requirements for informed consent
21 CFR 56.109	IRB review of research
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 812.1	Scope (of the Regulation)
ICH GCP	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

4. REFERENCES TO OTHER APPLICABLE SOPs

OTO 101	Informed Consent
OTO 102	Recognizing, documenting and reporting adverse events
OTO 103	Research Team Training
OTO 201	Subject Screening and Recruiting

5. ATTACHMENTS

A. Medical History
B. Physical Examination
C. Concomitant Medication Log
D. Adverse Event/Intercurrent Illness Log

6. RESPONSIBILITY

The Principal Investigator is responsible for ensuring study subjects are followed throughout the study in a thorough and consistent manner. The Principal Investigator is responsible for ensuring the study team adheres to the requirements of this standard operating procedure.

7. PROCESS OVERVIEW

A. Enrollment assessments and management
B. Follow-up, completion and early termination from the study
C. Managing unscheduled visits
D. Communication with primary or referring medical providers
E. Management of ineligible subjects

8. PROCEDURES

A. Enrollment assessments and management

Identify which clinical research team members are responsible: • PI • Research nurse/coordinator	Prior to conducting any research, the subject will complete the informed consent process (OTO 101) and be accepted as an "enrolled" subject (OTO 201). Elicit and document the subject's medical history. Use form provided by sponsor or Attachment A. Perform a complete or directed physical examination. Use form provided by sponsor or Attachment B. Establish the subject's baseline signs and symptoms. Review with the subject the use of any current medication (Use form provided by sponsor or Attachment C, Concomitant Medication Log). Inform the subject about the required study procedures and visits. Collect specimens as directed by the protocol. Administer questionnaires as directed by the protocol. Order tests/procedures as directed by the protocol. Provide contact information to the subject. Schedule the follow-up visit.
• PI • Study pharmacist • Research nurse/coordinator	Randomize and dispense the test article, as specified in the protocol. Review with the subject the use of any study aids, such as a diary.

B. Follow-up, completion and early termination from the study

• PI • Research nurse/coordinator	Perform a complete or directed physical examination. Assess the subject for signs and symptoms of any intercurrent illness and document adverse events appropriately (Attachment D, Adverse Event/Intercurrent Illness Log). Collect specimens as directed by the protocol. Order diagnostic tests and procedures as necessary. Institute appropriate therapy if required by the subject's condition. Review any use of concomitant medication. Schedule follow-up visits per protocol.

• PI • Study pharmacist • Research nurse/coordinator	Assess the subject's compliance with the test article**.** Collect unused test article, if appropriate. Dispense additional test article, as required**.**
• PI	Diagnose and document any intercurrent illness and endpoints. Review the subject's laboratory and other test results.

C. Managing unscheduled visits

• PI • Research nurse/coordinator	If it is necessary for a subject to be seen outside of scheduled study visits as outlined in the protocol (i.e., an adverse event, reprogramming of device), a Protocol Waiver Form or Protocol Deviation Form must be submitted to the sponsor and IRB, as applicable. Forms and guidelines for completion are supplied by sponsor and/or IRB.

D. Communication with primary or referring medical providers

• Research nurse/coordinator	Inform the subject's primary care provider about the subject's progress while on study, if the subject agrees. Ensure that the primary care provider receives copies of the subject's laboratory test results and reports of procedures, etc. if the subject agrees. Confer with the primary care provider, as appropriate**.**

E. Management of ineligible or withdrawn subjects

• PI • Research nurse/coordinator	Document the reason for ineligibility or withdrawal. Retain any supporting data available. Complete any clinical and laboratory assessments required by the protocol. Collect any remaining test article and any used test article containers. Record data in the investigational drug or device log, as appropriate. Discuss treatment alternatives with the subject. Follow the subject as required by the protocol. Notify the sponsor as required.