UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Subject Recruitment and Screening
SOP #:	OTO 201
Version #:	4
Effective Date:	July 17, 2019
Supersedes:	OTO 201 Subject Recruitment and Screening

1. POLICY

Investigators will develop and monitor a subject recruitment plan for trials regulated by the Food and Drug Administration (FDA). Recruitment methods and documents (i.e., fliers, letters, etc.) will be approved by an Institutional Review Board (IRB) prior to implementation. Subject screening activities will be recorded and maintained in accordance with OTO 104 – Records Management and Retention Policy and Standard Operating Procedure.

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 or designee is responsible for obtaining IRB approval for all documents used to recruit subjects. The Principal Investigator or designee is responsible for recording and maintaining accurate screening logs for all subjects who sign an informed consent. The Principal Investigator is responsible for documenting the eligibility of each subject to the inclusionary and exclusionary criteria defined by the protocol.

4. 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 812.140	Records
FDA Information Sheets, October 1998	Screening Tests Prior to Study Enrollment and Recruiting Study Subjects
May 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

5. REFERENCES TO OTHER APPLICABLE SOPS

OTO 100	Institutional Review Board (IRB) Oversight
OTO 101	Informed Consent
OTO 104	Records Management and Retention

6. ATTACHMENTS

A. Screening and Enrollment Log

B. Inclusion and Exclusion Checklist

8. PROCESS OVERVIEW

A. Develop and implement an overall recruitment plan
B. Assess the effectiveness of the recruitment plan
C. Screening documentation procedures

9. PROCEDURES

A. Develop and implement an overall recruitment plan

Principal Investigator or designee	Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study subjects. Establish a recruitment timeline. Identify sources of potential participants.
	Determine recruitment methods (e.g., radio ads, letters, community talks, newspaper articles, patient support groups, Internet). Develop recruitment materials and submit to obtain IRB approval as appropriate.
	Project costs associated with each recruitment strategy. Hire additional staff if necessary and provide training.

B. Assess the effectiveness of the recruitment plan

Principal Investigator or designee	Monitor progress and assess results of the recruitment strategy. Develop appropriate alternative strategies, if necessary. Institute alternative strategies if enrollment projections lag. Evaluate final results.

C. Screening documentation procedures

• Research nurse/coordinator	Record all subjects screened for study participation in the Screening and Enrollment Log (Attachment A). Develop an Inclusion and Exclusion Checklist based upon the study inclusion/exclusion criteria to collect screening information on each potential subject (Attachment B).
• PI • Research nurse/coordinator	If subject does not fully meet inclusion/exclusion criteria but may still be an acceptable candidate, a Protocol Waiver must be submitted to and approved by the sponsor prior to enrolling the subject (only applicable to non-sponsor-investigator research). The Protocol Waiver form is supplied by the sponsor.
• PI • Research nurse/coordinator	Obtain informed consent. Maintain a log of when informed consent was obtained from each subject.

	Retain all signed informed consent forms from subjects, even those who terminate their participation in the study during the screening process. Note if individuals went on to enroll in the study. If they were not enrolled, document the reason.