UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Institutional Review Board (IRB) Oversight
SOP #:	OTO 100
Version #:	4
Effective Date:	April 18, 2022
Supersedes:	OTO 100 Institutional Review Board (IRB) Oversight v3

1. POLICY

Investigator shall not commence a trial until there is written documentation of approval from an Institutional Review Board (IRB) with jurisdiction over the site.

2. SCOPE

These policies and procedures apply to all personnel who conduct or are involved in research involving human subjects.

3. RESPONSIBILITY

The Principal Investigator is responsible for obtaining written and dated approval from an accredited IRB to conduct a study involving human subjects prior to recruiting and enrolling subjects. Additionally, the Principal Investigator is responsible for obtaining written and dated approval from the IRB prior to implementing study amendments to protocol, informed consent form (ICF), and application. The Principal Investigator must ensure approval is kept current during all study activity and must submit a closure report to the IRB at the conclusion of the study.

The Principal Investigator is responsible for receiving and maintaining copies of IRB approvals and must be able to present such documentation upon request.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312.30	Protocol Amendments
21 CFR 312.66	Assurance of IRB Review
21 CFR 312.47	Emergency Research Under 50.24 of This Chapter
21 CRF 312	
Subpart D	IRB Review and Approval
21 CFR 812.42	FDA and IRB Approval
21 CFR 812.47	Emergency Research Under 50.24 of This Chapter
21 CFR 812 Subpart D	IRB Review and Approval
ICH E6, 2.1, 2.2, 2.3, 2.6 & 2.9	The Principles of ICH GCP
ICH E6, 3.0	Institutional Review Board/Independent Ethics Committee

ICH E6, 4.4	Communication with IRB/IEC
ICH E6, 4.8	Informed Consent of Trial Subjects
ICH E6, 5.8	Compensation to Subjects and Investigators
ICH E6, 5.11	Confirmation of Review by IRB/IEC

5. REFERENCES TO OTHER APPLICABLE SOPS

OTO 101 – Informed Consent

OTO 104 – Records Management and Retention

OTO 201 - Subject Screening and Recruiting

6. ATTACHMENTS

NONE

7. PROCESS OVERVIEW

A. IRB Initial Submissions and Continuing Review

B. Study Modifications

C. Emergency Use of device or drug

8. SPECIFIC PROCEDURES

A. IRB Initial Submissions and Review

#	*Who*	*Task*	*Attachment*	
1.	Principal Investigator or delegate	Ensure all study personnel have appropriate and up to date human subject protection and privacy training		
2.		Use current templates provided by IRB when appropriate. Download a new template for each study to ensure the latest template is being used.		
3.		Submit application and supporting documents (ex: subject documents: questionnaires, information letters; Investigators Brochure (IB); calendars) to the IRB(s) for initial review.		
4.		Make any requested changes that are stipulated by the IRB as conditions of approval[1]		
5.		Once IRB approval is received, maintain a copy of the IRB approval letter, stipulation(s) of the protocol, and any other special requirements (e.g., periodic reporting)		
6.		Maintain copies of all other relevant IRB-investigator correspondence		

7.		File the IRB member roster, approval letter, stamped documents and copies of all IRB-investigator correspondence in the appropriate section of the Regulatory Binder and/or electronic file[2]		
8.		Track IRB approval dates to ensure timely submission of the continuing review application		
9.		Submit continuing review application as instructed by specific IRB		
	Note: [1]Provided changes are appropriate and in accordance with applicable regulations. [2]Refer to OTO 104 – Records Management and Retention.			

B. Study Modifications

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	Principal Investigator and/or designee	Identify the need for a study amendment (ex: modification to protocol, ICF, application, or study materials).		
2.		Determine the impact on study documentation and processes including, but not limited to, the application, protocol, informed consent, and subject material.		
3.		Complete modification application as instructed by IRB		
4.		Make any requested changes that are stipulated by the IRB as conditions of approval[1]		
5.		Once approval is received, note any IRB requirements on the approval letter (i.e., need to re-consent patients)		
6.		Maintain all approval and correspondence documents within the regulatory binder and/or electronic file[2]		
	Note: [1]Provided changes are appropriate and in accordance with applicable regulations. [2]Refer to OTO 104 – Records Management and Retention.			

C. Emergency Use of device or drug

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	Principal Investigator	Emergency use of an investigational device or drug for a patient not enrolled in the study must be pre-approved by the IRB or reported to the IRB within 5		

		working days[1]		

Note:

[1]The investigator and a physician who is not otherwise participating in the clinical study certify in writing all of the following: (1) the subject was confronted by a life-threatening situation necessitating the use of the investigational product, (2) informed consent could not be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject, (3) time was not sufficient to obtain consent from the subject's legal representative and (4) there was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the subject.