UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Informed Consent
SOP #:	OTO 101
Version #:	5
Effective Date:	April 18, 2022
Supersedes:	OTO 101 Informed Consent v 4

1. POLICY

Research personnel must obtain informed consent from study participants in accordance with Code of Federal Regulations (CFR) 21 Parts 50, 56, 312, and 812, CFR 45 Part 46, ICH GCP (E6) guidelines, and Institutional Review Board (IRB) policy.

2. SCOPE

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

3. RESPONSIBILITY

The Principal Investigator and/or delegate is responsible for obtaining informed consent from study participants prior to the commencement of any research activity, unless otherwise pre-approved by the IRB of record.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards (Subpart C)
21 CFR 312.62	Investigators Recordkeeping and Record Retention
21 CFR 812.140	Records and Reports
21 CFR 812.50	Reports
45 CFR 46.116	General Requirements of Informed Consent
45 CFR 46.117	Documentation of Informed Consent
ICH E6 4.8	Informed Consent of Trial Subjects

5. REFERENCES TO OTHER APPLICABLE SOPs

OTO 104 – Records Management and Retention

OTO 201 – Subject Screening and Recruitment

6. ATTACHMENTS

Attachment A: Assessing Comprehension of Informed Consent

7. PROCESS OVERVIEW

A. Informed Consent Content

B. Institutional Review Board Approval of Informed Consent

C. Consent Procedures

D. Re-Consent Procedures

8. SPECIFIC PROCEDURES

A. Informed Consent Content

The Informed Consent Form and consent process discussion must include the following elements. The Informed Consent Form should be written at an 8th grade reading level.

- That the study involves research.
- The purpose of the research study.
- The study treatment(s) and the probability for random assignment to each treatment, as applicable.
- The expected duration of the participant's participation in the research study.
- The approximate number of participants to be involved in the research study.
- The alternative treatment(s) that may be available to the participant, and their important potential benefits and risks, as applicable.
- The participant's responsibilities.
- Those aspects of the study that are investigational.
- The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, fetus, or nursing infant.
- The reasonably expected benefits. When there is no proven clinical benefit to the participant, the participant should be made aware of this.
- The compensation and/or treatment available to the participant in the event of study-related injury, as applicable.
- The anticipated expenses to the participant for participation in the research study.
- That the participant's participation in the research study is voluntary and that the participant may refuse to participate or withdraw from the research study at any time.
- That study sponsor monitor(s) (if applicable), auditor(s) IRB and regulatory authority(ies) will be granted direct access to the participants original medical records for verification of clinical research procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing the written informed consent the participant or participant's legally responsible representative is authorizing such access.
- Those records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.
- That the participant or the participant's legally responsible representative will be informed in a timely manner if information becomes available that may be relevant to the participant's participation in the trial.
- The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of an emergency.
- The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.

B. Institutional Review Board Approval of Informed Consent

#	*Who*	*Task*	*Attachment*	
1.	Principal Investigator or delegate	A study-specific informed consent must be approved by an Institutional Review Board (IRB) prior to its use. In certain situations, an IRB may waive the requirement to consent participants. Refer to 21 CFR 50 and 56 and the IRB policies for more		

		information on obtaining a waiver to obtain consent		
2.		Ensure the participant is signing the current and stamped copy of the informed consent		
3.		If revisions are required, IRB approval will be obtained prior to implementing the changes[1]		
4.		Ensure no participants will be consented in the event of an IRB approval lapse. Consenting procedures may resume if approved by the IRB		

Note: [1]If new information becomes available that may be relevant to the participant's decision to participate in the trial, the investigator must re-inform participants of this new information. This information may be best disseminated by certified letter or amended informed consent. In either case, the IRB must approve the communication prior to its use unless the risk to the participant necessitates relaying that information prior to obtaining IRB approval. In that case, the IRB must be notified as soon as possible.

C. Consent Procedures

#	*Who*	*Task*	*Attachment*
1.	Principal Investigator or delegate	Whenever possible, the consent process should occur in a private setting	
2.		Neither the investigator, nor the research staff, should coerce or unduly influence a participant to participate or to continue to participate in a research study	
3.		The investigator, or a person designated by the investigator, should fully inform the participant or, if the participant is unable to provide informed consent, the participant's legally acceptable representative, of all pertinent aspects of the research study including the written information and the approval by the IRB	
4.		Before informed consent may be obtained, the investigator or designee should provide the participant or the participant's legally responsible representative ample time and opportunity to inquire about details of the research study and to decide whether or not to participate in the research study. All questions about the study should be answered to the satisfaction of the participant or the participant's legally responsible representative. When possible, patient will be given the opportunity to take the unsigned consent home to review with family or friends prior to the consenting process	
5.		The informed consent form must be signed and dated by the participant or by the participant's legally responsible representative and initial each page, if applicable, prior to the participant's participation in the research study. The person who conducted the informed consent discussion (PI or PI designated individual) must sign the final page, if applicable. If an impartial witness needs to be available, they must also sign and date the last page of the consent form. The impartial witness CANNOT be any personnel	

		that are directly involved in the research project (this includes the PI, Sub-Investigators, Clinical Research Coordinator or Research Nurse)	
6.		The witness line will only be used when it is necessary (ex: the participant is illiterate, or blind, or incompetent, etc.), but otherwise will be left blank	
7.		If the participant or legally responsible representative is unable to understand or read English, the informed consent document must be translated, or a short form can be used fewer than three (3) times if approved by COMIRB, in a language that the participant understands. An impartial witness must be present during the entire informed consent discussion and document the translation by using a short form – OR - the consent form must be translated into the participant's language and presented in written format. The process of providing informed consent in another language may be subject to policies set forth by individual IRBs. It is the Principal Investigator's responsibility to understand and abide by the IRB's policies regarding informed consent translation	
8.		Prior to participation in the research study the participant or the participant's legal representative should receive a copy of the informed consent form	
9.		The individual obtaining consent will assess the participant's ability to comprehend participation in the study. A sample list of questions which could be used for this assessment is available in Attachment A. If there is any question in the participant's comprehension of the study, a third party will be involved to evaluate the participants ability to sign the informed consent	Attachment A
10.		When a research study (therapeutic or non-therapeutic) includes participants who can only be enrolled in the research study with the consent of the participant's legal representative (e.g., minors, or patients with severe dementia), the participant's assent (ages 7-13) should be obtained if, in the judgment of the physician, they possess the emotional and intellectual ability to comprehend the concepts. The participant should be informed about the research study to the extent compatible with the participant's understanding and, if capable, the participant should sign and personally date the written assent form in addition to having the legal representative sign and date the informed consent form. If a child is age 13-17 they should personally sign and date the main consent form along with the participant's legal representative	
11.		The original, signed informed consent is to be maintained in the participant's study file or combined file	
12.		In the event an investigator fails to obtain informed consent prior to the commencement of study activities, or informed consent was obtained improperly, the Unanticipated Problem (UAP) will be	

		reported to the IRB within 5 days and/or a protocol deviation will be written.	

D. Re-Consent Process

If a patient is currently enrolled on a trial and the consent is amended, the IRB approval letter will guide the study team on if a patient will need to be re-consented or not. A general rule is that if the consent amendment is for administrative changes only, there is no need to re-consent. If the consent change involves new safety data or a change in procedure, (either frequency or a new procedure) the patient should be re-consented at their next visit with the updated consent.