

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

Title	Informed Consent
SOP #:	OTO 101
Version #:	3
Effective Date:	July 17, 2019
Supersedes:	OTO 101 Informed Consent

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 subjects.

3. RESPONSIBILITY

The Principal Investigator and/or delegate is responsible for obtaining informed consent from study subjects 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

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

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 subject's participation in the research study.
- The approximate number of subjects to be involved in the research study.
- The alternative treatment(s) that may be available to the subject, and their important potential benefits and risks.
- The subject's responsibilities.
- Those aspects of the study that are investigational.
- The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- The reasonably expected benefits. When there is no proven clinical benefit to the subject, the subject should be made aware of this.
- The compensation and/or treatment available to the subject in the event of study-related injury, as applicable.
- The anticipated expenses to the subject for participation in the research study.
- That the subject's participation in the research study is voluntary and that the subject 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 subjects original medical records for verification of clinical research procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing the written informed consent the subject or subject's legally responsible representative is authorizing such access.
- Those records identifying the subject 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 subject's identity will remain confidential.
- That the subject or the subject's legally responsible representative will be informed in a timely manner if information becomes available that may be relevant to the subject's participation in the trial.
- The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of an emergency.
- The foreseeable circumstances and/or reasons under which the subject'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 subjects. Refer to 21 CFR 50 and 56 and the IRB policies for more information on obtaining a waiver to obtain consent	

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

2.		Ensure the subject 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 subjects will be consented in the event of an IRB approval lapse. Consenting procedures may resume if approved by the IRB		
<p>Note: ¹If new information becomes available that may be relevant to the subject's decision to participate in the trial, the investigator must re-inform subjects 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 subject necessitates relaying that information prior to obtaining IRB approval. In that case, the IRB must be notified as soon as possible.</p>				

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 subject 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 subject or, if the subject is unable to provide informed consent, the subject'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 subject or the subject'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 subject or the subject'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 subject or by the subject's legally responsible representative and initial each page, if applicable, prior to the subject'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 an impartial witness needs to be available, they must also sign and date the last page of the consent form. The impartial witness <u>CANNOT</u> be any personnel that are directly involved in the research project (this includes the PI, Co-PIs, Clinical Research Coordinator or Research	

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

		Nurse)	
6.		If the subject 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 subject understands. An impartial witness must be present during the entire informed consent discussion and document the translation on using a short form – OR - the consent form must be translated into the subject’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	
7.		Prior to participation in the research study the subject or the subject’s legal representative should receive a copy of the informed consent form	
8.		The individual obtaining consent will assess the subject’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 subject’s comprehension of the study, a third party will be involved to evaluate the subjects ability to sign the informed consent	Attachment A
9.		When a research study (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the research study with the consent of the subject's legal representative (e.g., minors, or patients with severe dementia), the subject'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 subject should be informed about the research study to the extent compatible with the subject's understanding and, if capable, the subject 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 subject’s legal representative	
10.		The original, signed informed consent is to be maintained in the subject’s study file or combined file	
11.		In the event an investigator fails to obtain informed consent prior to the commencement of study activities, or informed consent was obtained improperly, the deviation will be reported to the IRB within 5 days	

D. Re-Consent Process

If a patient is currently enrolled on a trial and the consent is amended, the IRB approval letter

**UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE**

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.