

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

Title	Research Team Training
SOP #:	OTO 103
Version #:	4
Effective Date:	April 18, 2022
Supersedes:	OTO 103 Research Team Training v3

1. POLICY

Research studies will be conducted according to Food and Drug Administration (FDA) and/or Department of Health and Human Services (HHS) regulations to protect the safety and welfare of study subjects that must be ensured by a research team knowledgeable about ongoing study protocols and investigational articles. Investigators and all key members of the research team are individuals who are interacting and/or intervening with human subjects or handle personally identifiable data of a human subject. They may be personal who are working on or overseeing programs that conduct research on human subjects. They will receive initial and ongoing training regarding the responsible conduct of research to ensure ethical and scientifically sound conduct of human subject research.

Training of study personnel will be scheduled and supervised by the Principal Investigator and/or Sponsor when appropriate. In addition to completion of human subjects training, research personnel will be trained to the protocol. Additional training may be required depending on the requirements of the protocol and experience of the researcher(s).

2. SCOPE

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

3. RESPONSIBILITY

The investigator is responsible for ensuring that all employees are qualified by training and experience to conduct their designated research-related duties.

The trainers are responsible for providing initial and continuing training to all personnel, to document such training and to assess training effectiveness through appropriate testing strategies.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.100	General Responsibilities of Sponsors
ICH E6, 2.8	The Principles of ICH GCP
ICH E6, 5.5	Trial Management, Data Handling and Record Keeping

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

Attachment A: Training/Education Program Compliance Form

7. PROCESS OVERVIEW

A. Training Plan

1. Initial Training

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2. Continuing Education

3. Periodic Field Review

B. Documentation of Training

8. SPECIFIC PROCEDURES

A. Training Plan

1. Initial Training

#	Who	Task
1.	Investigator	<p><u>Minimum Training Requirements:</u></p> <p>Human Research Subjects Protection: Each individual of the study team must provide documentation of Human Research Subjects Protection (Group 1: Biomedical Investigators OR Group 2: Social and Behavioral Research) training through the CITI program prior to being added to the study protocol. Documentation must be current which is defined as completed within the previous 3 years unless the research is conducted at the Veterans Affairs Medical Center (VAMC), then documentation must be current within the previous 2 years.</p> <p>Health Information Privacy and Security (HIPS): Each individual of the study team must provide documentation of Health Information Privacy and Security training through the CITI program prior to being added to the study protocol. An equivalent course taken through the university prior to the implementation HIPS will also suffice. HIPS must be renewed every 3 years.</p> <p>Good Clinical Practice (GCP): If individual will be involved in the conduct of research that involves research drugs or devices then Good Clinical Practices training must be completed every 3 years.</p> <p>Standard Operating Procedures (SOPs): All research staff will be required to be trained on the department's SOPs based on the type of study conducted. (Refer to the Department of Otolaryngology List of Standard Operating Procedures for a categorization of SOPs required per research type). This training will require each individual of the study team to read the SOPs and sign off that s/he has read and understands the SOPs (the individual involved in research that is not FDA-regulated, they need to read OTO 100 – OTO 104 and any SOPs in the OTO 300 series that specifically pertain to their study. For those individuals who are performing FDA-regulated research, they must read the first two sections – OTO 100 through OTO 203). If questions remain after they have read the documents, all questions will be clarified with the investigator or designee.</p> <p>(continued to following page)</p>

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#	Who	Task
		<p>(continued from previous page)</p> <p>Protocol Training: The PI and/or designee(s) will ensure that the study team has adequate training on the protocol. The PI or designee will be responsible for ensuring that all research team members receive in-depth protocol training whenever a new study is initiated or when a new team member joins the team. The team will not rely solely on the Sponsor to conduct this training (where applicable). Training will require at minimum that the research staff read the protocol. Protocol training should be documented on the Protocol Training Log – OTO 104 Attachment A or other form collecting equivalent information.</p> <p>NIH – Responsible Conduct of Research (RCR): National Institute of Health (NIH) and National Science Foundation (NSF) require that all trainees, fellows, and scholars receiving support through any training grant, career development award, research education grant, or dissertation research grant must receive instruction in responsible conduct of research. Training through the CITI program prior to being added to the study protocol. Documentation must be current which is defined as completed within the previous 3 years. An equivalent course taken through the university will also suffice.</p> <p>Other Training: The above-listed training is the <u>minimum</u> requirement for each study team member. Other training may be necessary as required by the study protocol. Other training may include, but is not limited to: data recording methods, training on specific procedures required by the protocol, biological specimen processing, etc. This training should be documented on the Training/Education Program Compliance Form or electronically.</p>
	Note:	

2. Continuing Education

#	Who	Task
1.	All research personnel	<p>Human Research Subjects Protection, HIPS, GCP, and RCR: All researchers listed on an active protocol must hold current certification depending on what type of study is being conducted. Refresher courses are offered through the CITI training program.</p> <p>Standard Operating Procedures: All researchers listed on an active protocol must retrain to the department's SOPs when they are revised or when new SOPs are added to the Department of Otolaryngology List of Standard Operating Procedures.</p> <p>Protocol Training: The PI or designee will be responsible for ensuring that all research team members receive in-depth protocol training whenever it is updated and IRB approved.</p>
	Note:	

B. Documentation of Training

#	Who	Task
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1.	Principal Investigator or designee	Maintain updated training records for all employees in personnel training files (electronic and/or paper). Appropriate forms of training documentation include: <ul style="list-style-type: none">• Paper or electronic certificate provided by training entity• Attachment A for training that does not otherwise have training certificates• An email indicating the specific training and that the individual has read and understands the training document. This is only appropriate for types of training where reading and comprehending is an adequate means of learning the specified material (i.e., SOP and minimal protocol training)
2.		Permit regulatory authority review of appropriate training records as evidence that personnel are qualified by training and experience to conduct their duties.