UNIVERSITY OF COLORADO
DEPARTMENT OF OTOLARYNGOLOGY
STANDARD OPERATING POLICY AND PROCEDURE

Title	Records Management and Retention
SOP #:	OTO 104
Version #:	3
Effective Date:	July 22, 2020
Supersedes:	OTO 104 Records Management and Retention

1. POLICY

Investigators are responsible for maintaining study documents in accordance with applicable federal regulations, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements and departmental procedures. Study documents must be readily accessible for audit by the Food and Drug Administration (FDA), approving Institutional Review Board (IRB), and/or departmental personnel as appointed by the Department Chair.

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 ensuring all study documentation is maintained in a complete, presentable and organized fashion. The Principal Investigator or designee must maintain and retain documents in adherence with this standard operating procedure.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR Part 11	Electronic Records
21 CFR Part 312.57	Recordkeeping and record retention
21 CFR Part 312.68	Inspection of Investigator's Records and Reports
21 CFR Part 812.140	Records
21 CFR Part 812.145	Inspections
ICH E6, 5.5	Trial Management, Data Handling and Record Keeping

Health Insurance Portability and Accountability Act (HIPAA)

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

Attachment A: Protocol Training Log

Attachment B: Delegation of Authority Log

7. PROCESS OVERVIEW

A. Location of research records – Paper records

B. Location of research records – Electronic records

C. Required regulatory documents

D. Required subject documents

E. Records retention

8. SPECIFIC PROCEDURES

A. Location of research records – Paper records

#	*Who*	*Task*
1.	Principal Investigator or designee	Ensure there is adequate space available for paper records required for the study.
	Principal Investigator or designee	Paper records must be stored in a locked cabinet with access limited to study personnel.
		Original records should be retained by the study team. The original informed consent must always be retained by the Principal Investigator or designee.
	Note:	

B. Location of research records – Electronic records

#	*Who*	*Task*
1.	All research personnel	Electronic records must be stored in a manner to lessen the incidental or purposeful sharing of research information as much as possible. The following security features must be in place when storing electronic data: I. **Secure Storage.** Research data and records must <u>not</u> be stored on an individual's hard drive unless it is encrypted and first approved by the IRB[1]. II. **Password protected.** Data must only be accessible by using a password unique to the individual (for databases) or the study (for Excel). Study approval documents do not need to be password protected. III. **Limited access.** Access to electronic data and records must be limited to study personnel or a subset of study personnel.
2.		Electronic research data associated with an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) study must be compliant with 21 CFR Part 11.
	Note: [1] Excel spreadsheets without password protection is not sufficient for data with PHI.	

C. Required regulatory documents

#	*Who*	Task
1.	Principal Investigator or designee	Investigators must maintain up-to-date regulatory study documents based on the following matrix. Applicable documents must be readily available for inspection at all times.
	Note:	

Document	Format	Requirement
All Studies		
Protocol	Paper or electronic	All studies. All IRB-approved versions must be readily available.
Protocol Training	Paper or electronic. May use Attachment A or email confirmation of training.	All studies. Investigator must be able to provide documentation indicating protocol training for study personnel. Study personnel need to be retrained to the protocol when it is revised.
Informed Consent	Paper or electronic	All studies involving informed consent. All IRB-approved versions must be readily available.
Delegation of Authority	Paper or electronic. Use Attachment B	All studies requiring expedited or full board review.
Curriculum Vitae (CV)	Paper or electronic	A copy of each study personnel's CV to indicate qualification by training and experience.
Hospital / RI Approvals	Paper or electronic	All studies requiring IRB approval.
IRB Approvals	Paper or electronic	All studies requiring IRB approval. Must maintain record of all submissions, approvals, stipulations, and responses.
IRB Correspondence	Paper or electronic	All studies requiring IRB approval.
Adverse Events	Paper or electronic	All reports of adverse events. Copies of reports to IRB and sponsor where applicable.
Recruitment materials	Paper or electronic	All approved by IRB.
Investigational Device Exemption (IDE) or Investigational New Drug (IND) Studies. All of the above requirements plus the following:		
FDA Form 1572 (IND) or Investigator's Agreement (IDE)	Paper	All versions signed and dated
Financial Disclosures	Paper or electronic	All versions signed and dated
Investigator's Brochure	Paper or electronic	All versions approved by IRB
Professional licenses, certificates	Paper	Applicable documentation covering entire time span individual is active on study
Sponsor Correspondence	Paper or electronic	Must keep all correspondence associated with study. This includes emails, phone logs, site letters, mail, etc.
Equipment certifications	Paper or electronic	Must maintain copies of equipment certificates if used in study (i.e., calibration certificates).

Document	Format	Requirement
Subject Enrollment Log	Paper or electronic	Log indicating all subjects who signed consent, including screen failures and withdrawals.
Site Visit Log	Paper or electronic	Log indicating when the trial was monitored and by whom.
Protocol Waiver/Deviation Log	Paper or electronic	Log listing any and all protocol waivers and deviations. Include supporting documentation where applicable.
Training records	Paper or electronic	Documentation of training completed by study staff. This includes general research training and study specific training.
Drug and/or device accountability logs	Paper	Record of receiving, dispersing and returning investigational product for each subject. Includes log and shipping receipts as applicable. May reside with pharmacy.
Case Report Forms – blank set	Paper or electronic	Copy of readily available case report forms.
Data Safety Monitoring Board (DSMB) reports, when applicable	Paper or electronic	Maintain copies of reports for studies that have a DSMB.
Audit documentation, when applicable	Paper or electronic	Keep copies of documents related to internal and external study audits. This includes corrective action plans and any correspondence surrounding the audit.

D. Required subject documents

#	***Who***	Task
2.	Principal Investigator or designee	Investigators must maintain up-to-date subject documentation based on the following matrix. Applicable documents must be readily available for inspection at all times.
	Note:	

Document	Format	Requirement
	All Studies	
Signed Informed Consent, when applicable	Paper – original OR Electronic – original (if approved by IRB)	All signed informed consent documents must be retained. This includes screen failures and withdrawals.

Document	Format	Requirement
Signed HIPAA forms, when applicable	Paper – original or Electronic - original	All signed HIPAA authorizations must be retained. This includes screen failures and withdrawals.
Candidacy Checklist	Paper or electronic (if never recorded on paper)	Documentation that the subject meets candidacy criteria.
Case Report Forms - completed	Paper or electronic (if never recorded on paper)	All completed forms for each subject.
Source documentation	Paper or electronic	Original documentation of participant test results, medical history, and/or questionnaires as required by protocol.

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E. Records Retention

Study records must be retained for a specific amount of time depending on the regulations and policies that apply to the specific research study. For studies where multiple regulations and/or policies apply, the records must be maintained for the period which is longest.

Regulated by:	**Retention Period**
HIPAA	7 years after closure with IRB
NIH	> 3 years from the date the Final Financial Status Report is submitted
FDA – IND	2 years following the date a marketing application is approved or abandoned (or as required by sponsor)
FDA – IDE	2 years following the date a product receives pre-market approval or is abandoned (or as required by sponsor)
VA	Indefinitely (until otherwise approved by VA)
CHCO	Youngest child in the study turns 28 years old