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

| Title | Document Development and Change Control |
|---|---|
| SOP #: | OTO 300 |
| Version #: | 4 |
| Effective Date: | April 18, 2022 |
| Supersedes: | OTO 300 Document Development and Change Control v 3 |

## 1. POLICY

The Department Chair shall ensure that critical documents are developed, approved and modified in a manner that adheres to the concepts of document and change control. These concepts include:

- New documents are written using established templates as models,
- New documents undergo documented review and approval,
- Only the current version of a document is being used at any time,
- Changes to documents are properly incorporated and tracked,
- The Department Chair has control of the document development, review, approval and change process.

Following the completion of the approval (signature) process, the document becomes effective. The date the document becomes effective is the date of the last of the required signatures. The effective date is also the first day the new or revised document can be used.

Changes to current documents constitute a revision and require a formal approval process.

Documents, forms and templates are either controlled or non-controlled

In general, “controlled” documents will:

- Follow a single format and be DEPARTMENT OF OTOLARYNGOLOGY-wide in scope
- Be developed and approved according to the procedures below
- Have revisions tracked on a Table of Modifications Form – Attachment A
- Become effective when the original copy has an “Effective Date” and all required approval signatures have been secured

Non-controlled documents, such as checklists, are management tools that do not carry regulatory weight and require less control.

## 2. SCOPE

These policies and procedures apply to departmental research personnel who are involved in the creation, revision, and distribution of controlled documents.

## 3. RESPONSIBILITY

The Department Chair is responsible for granting final approval for all controlled or required documents and for ensuring adequate training on new and revised documents.

The Department Chair or Designee is responsible for writing/revising SOPs, securing the necessary review and approval, distributing them to all affected parties and collecting/archiving prior versions.

The research team members are responsible for contributing to the development and approval process and for being trained in the proper use of all documents.

## 4. APPLICABLE REGULATIONS AND GUIDELINES

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|---|---|
| 21 CFR 812.100 | General Responsibilities of Investigators |
| ICH E6, 2.13 | The Principles of ICH GCP |
| ICH E6, 5.1 | Quality Assurance and Quality Control |
| 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

A. Table of Modifications and Document Approval Form

## 7. PROCESS OVERVIEW

A. Document Initiation, Change and Approval Procedures

B. Document Implementation

## 8. SPECIFIC PROCEDURES

### A. Document Initiation, Change and Approval Procedures

| # | *Who* | *Task* |
|---|---|---|
| 1. | Department Chair or Designee | Determine the need for a new controlled document (new SOP, form, etc.). Documents and forms should be reviewed periodically and when affected by outside influences (i.e., regulation change) |
| 2. | | Determine who will draft the first version of the new document. |
| 3. | | Determine who must review and approve the draft of the new document |
| 4. | | Use templates where available |
| 5. | | Initiate the drafting process. Use track changes where appropriate |
| 6. | | Circulate draft, securing comments/suggestions from appropriate research team members |
| 7. | | Revise document per initial review process, negotiate and resolve conflicting comments |
| 8. | | Document periodic review and changes to a document and describe changes that are made, on a Table of Modifications Form (Attachment A) for each document |
| 9. | | Approve final draft by signature (Attachment A) |
| 10. | | Give all newly approved documents a version number (whole integer) and effective date |

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|---|---|---|
| 11. | | Retain original document on the appropriate section of the department shared drive clearly marked as archive. This original document will be removed from the department website and the shared drive marked as current. The new, approved SOP will be stored on the department website and on the department shared drive in a folder clearly marked as current. Access to the shared drive folder will be limited to avoid unauthorized individuals from accessing out of date SOPs. All SOPs once approved will be named by the appropriate SOP title, version, and date. |
| 12. | | Update related indices (e.g., SOP List, Forms List) to reflect new document |
| | Note: All SOPs must be signed off on by the department chair. | |

## C. Document Implementation

| # | *Who* | *Task* |
|---|---|---|
| 1. | Department Chair or Designee | As appropriate, notify all affected parties and regulatory authorities about changes to documents and provide new versions |
| 2. | | Train all affected personnel on the use of the new or revised document |
| 3. | | Record that document training was received by all affected personnel |
| 4. | | The approved document and revision history will be shared on the department website. The most recent version will always be available electronically to avoid the need to collect outdated versions. |
| | Note: | |