

**STANDARD OPERATING PROCEDURES**  
**DIVISION OF COMPARATIVE MEDICINE**  
**UNIVERSITY OF SOUTH FLORIDA**

SOP#: 001.5

Date Issued: 3/99

Date Revised: 9/14

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<b>TITLE:</b>	<b>Document Controls</b>
<b>SCOPE:</b>	All Divisional Personnel
<b>RESPONSIBILITY:</b>	Program Administrative Personnel
<b>PURPOSE:</b>	To Outline the Proper Procedures to Control All Policy, Standard Operating Procedures, and Recording Documents.

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**I. PURPOSE**

1. This Division establishes and maintains the following procedures to control all documents required by:
  - a. Title 9 CFR 1 Animal Welfare
  - b. Public Health Service Policy
  - c. The Guide for the Care and Use of Laboratory Animals
  - d. Animal Care provisions of Title 21 CFR 58 Good Laboratory Practice for Non Clinical Laboratory Studies (e.g., subpart C, 58.41-45, and subpart E, 58.81b, items 1, 2, 6, and 12)
  - e. Division of Comparative Medicine

**II. RESPONSIBILITY**

1. The Administrative and Professional Staff shall draft, review for adequacy, and propose revisions to documents relating to Divisional policies, Standard Operating Procedures (SOPs), and record-keeping, and, once approved, shall ensure distribution to relevant personnel.
2. The Director shall review and approve all new or revised Divisional policies, documents, and SOPs prior to issuance.

**III. PROCEDURES**

1. Creating a Document
  - a. SOPs are created in a standard format, which includes Title, Scope, Responsibility, Purpose, and Procedures. Each SOP is numbered, the date it was originally issued or revised indicated, and revisions are numbered.
2. Document Approval and Distribution
  - a. The Director shall review for adequacy and approve prior to issuance all Divisional policies, documents, and SOPs.
  - b. The approval date and signature of the Director shall be documented on all SOPs.
  - c. Newly approved documents shall be communicated to the appropriate personnel (e.g., all Comparative Medicine staff, IACUC) within 30 days of approval and shall be available at all locations for which they are designated,

used, or otherwise necessary. The signed printed paper format of an SOP is the official version and will be maintained as such.

- d. Newly approved documents relevant to the conduct of studies conducted in accordance with 21 CFR 58, Good Laboratory Practices, shall be communicated to the GLP testing facility management at the time they are communicated to Comparative Medicine staff and, for active studies, also copied to the study director(s) and Quality Assurance Unit (QAU) personnel.
- e. All obsolete documents shall be promptly removed from all points of use by the Facility Manager, or their designee and prevented from unintended use.

### 3. Changes to Documents

- a. Changes to documents shall be reviewed and approved by the Director of Comparative Medicine.
- b. Approved changes shall be communicated to the appropriate personnel (e.g., all Comparative Medicine staff, IACUC) within thirty days of revision and shall be available at all locations for which they are designated, used, or otherwise necessary.
- c. Approved document changes relevant to the conduct of studies conducted in accordance with 21 CFR 58, Good Laboratory Practices, shall be communicated to the GLP testing facility management at the time they are communicated to Comparative Medicine staff and, for active studies, also copied to the study director(s) and QAU personnel.
- d. Records of changes to SOPs shall be maintained. Document version number and effective date shall be recorded on all tracked documents.
- e. Change records of SOPs shall include a description of the change, identification of the affected documents, signature of the Director, and approval date.
- f. Obsolete division SOPs will be marked "VOID" and a copy kept in the division's SOP Historical file.

### 4. SOP Historical File Maintenance

- a. When an SOP is revised, a Change to Document memo is generated stating that the SOP is being replaced with a revised version, and the memo is signed by the Director of Comparative Medicine.
- b. The revised SOP is stamped "VOID."
- c. The Change to Document memo, the voided original SOP, and the revised SOP in "track changes" format indicating the changes made, are all attached and placed in the SOP Historical file sequentially by SOP (revision) number.
- d. The SOP Historical file is maintained by the Assistant Director in Comparative Medicine's administrative office.

**Approved:**

**Date:**