

Name:	SOP Development	Created:	7/17/17
Number:	FSU-SOP-100.01	Revised:	--
Category:	General Procedures	Author(s):	T. Schoenfeld, A. Steacy

1.0 Purpose

This SOP is designed to establish a set of standards for the development, editing, review, and approval of SOPs pertaining to vertebrate animal care at Fitchburg State University (FSU).

2.0 Policy

- 2.1 A Standard Operating Procedure (SOP) is a clearly written set of instructions that documents a procedure for the different activities involved in research at FSU.
- 2.2 SOPs are considered “living documents” as they may be revised to reflect the most current information and practices for the care of laboratory animals as recommended by the American Veterinary Medical Association, National Institutes of Health, and other organizations concerned with laboratory animal welfare.
- 2.3 This SOP serves as a guiding document for the development and revision of SOPs at FSU.
- 2.4 Each SOP is meant to create a systematic approach to using vertebrate animals in teaching and research at FSU.
 - 2.4.1 These documents outline the procedures and best practices of the field, but with specific application to the infrastructure and resources for teaching and research at FSU.
 - 2.4.2 While not all practices will have a specific SOP developed, if it is determined that one is essential for continued research and funding, this document outlines the steps necessary for the development and approval of new SOPs.
- 2.5 SOPs will be constructed in a clear and concise manner to assure that all parties can follow the instructions without ambiguity. Additional information can be included as necessary to establish context for the procedure.

3.0 Materials *(Not applicable)*

4.0 Procedure

- 4.1 A recommendation is made by a PI, the Institutional Animal Care and Use Committee (IACUC), the Attending Veterinarian, the Vivarium Facility Manager, or Institutional Official for the need of a new SOP or current SOP revision.
- 4.2 New SOP submissions or current SOP revisions will be proposed to the IACUC only by a PI or the Facility Manager.

- 4.3 A SOP name and number will be proposed, subject to IACUC approval. The number proposed should conform to the categories and associated number ranges listed in section 8.0.
- 4.4 The development will include sections outlined below and any other supplemental sections required to clarify and contextualize the procedure.
- 4.5 The document will be submitted for review and approval by the IACUC, by a standard process that may include requests for modification.
- 4.6 Once finally approved, the SOP will be posted in a central repository in a clearly organized format and easily accessible by all faculty and students who might be conducting teaching or research at FSU to which the SOP applies. Reference to a currently approved SOP in an animal protocol submitted to the IACUC for review can substitute for detailed description of the procedure in the protocol.

5.0 Required Sections

- 5.1 All SOPs must include the following sections with detailed information without exception.
 - 5.1.1 An SOP template file will be available on the IACUC website, to be used in guiding SOP preparation with inclusion of required sections.
 - 5.1.2 If an SOP does not require one of these sections, it must still be listed with the detail "Not Applicable".

5.2 **Header:**

The header consists of the following:

- Name:* This is the functional title of the SOP. It should clearly, but succinctly reflect the purpose of the SOP.
- Number:* FSU-SOP-procedure#.revision#; ex: FSU-SOP-101.01
(See section 8.0 for guidance in selecting procedure numbers.)
- Category:* This is the category (see section 8.0) that the SOP is created under.
- Created:* This is the initial date of final approval.
- Revised:* If any revisions are made, the date will be posted here.
- Author(s):* Name(s) of author(s) of the *current* version.

5.3 **Purpose:**

This section is a brief, clearly constructed declaration of what the SOP is about and to whom the SOP applies.

5.4 **Policy:**

This section provides a rationale for the SOP, briefly identifies the key elements of the SOP, and provides a context for the procedure(s) that will be articulated in detail in the subsequent sections.

5.5 **Materials:**

This section details the equipment necessary to conduct the procedure. All materials must be clearly identified including, but not limited to any chemicals, reagents, equipment, and instruments required.

5.6 **Procedure:**

This is main procedural section. This provides the step-by-step instructions to be followed by all personnel engaging in the specific activity. The instructions should be clearly outlined and worded.

5.7 References:

A reference list must be included on every SOP to assure academic integrity and credit given to accessed resources.

5.8 SOP Revision History:

A running tally of revisions is maintained here in each subsequent revision, starting with a listing of the original version (-.01) and the original authors, for the record.

6.0 Optional Sections

The following sections are not required, but may be included to provide greater context for the outlined procedure.

6.1 Additional Resources:

This section provides links to further reading and imagery that may be helpful in understand the procedure outlined in the SOP.

6.2 Attachments:

Where necessary, supplemental documents will be included with the SOP. These may include forms, diagrams, scientific publications, etc. Each will be numbered specific to the SOP such that it will be listed as FSU-SOP-xxx.xx-attachment-xx.

6.3 Keywords/Definitions:

This section will be included when specific vocabulary is necessary to understand the procedure outline in the document.

6.4 Other:

While this document seeks to be comprehensive, there are inevitably unforeseen required sections for specific practices and procedure. As deemed necessary by the PI, IACUC or other faculty, these sections will be added into the specific SOP to which they are required.

7.0 Review and Revisions

- 7.1 All approved, actively used SOPs must be reviewed by the IACUC at FSU on a recurring schedule of every three (3) years to assure that they maintain a high degree of fidelity to the best practices and current information regarding the specific procedures.
- 7.2 Additional reviews will be conducted when it is determined that the procedure requires further modification to meet the specific needs of the FSU teaching and research facilities and resources.
- 7.3 If a revision is required, the document must be updated to reflect the revision and the corresponding revision number must be updated.
- 7.4 Once finally approved, the new revision will replace the outdated SOP.
- 7.5 If available, minor revisions may be pursued via an IACUC form for minor amendments.
- 7.6 Approved SOPs that govern activities that are not in current use by FSU staff may be retired and deemed inactive. Inactive SOPs may be reactivated by a PI or the Facility Manager who brings it to the IACUC for review and approval.

8.0 SOP Categories and Procedure Number Ranges

- General Procedures (100-199)
- Animal Husbandry (200-299)
- Veterinary Care (300-399)
- Occupational Health and Safety (400-499)
- Managing Pain and Discomfort (500-599)
- Euthanasia (600-699)
- Experimental Procedures (700-799)

A current list of pending and approved SOPs will be maintained and categorized under General Procedures for reference purposes, as FSU-SOP-1.

9.0 References

1. US EPA Guidance for Preparing Standard Operating Procedures (SOPs).
<http://www.epa.gov/QUALITY/qs-docs/g6-final.pdf>
2. Writing and Revising SOPs.
<https://animalcare.ubc.ca/sites/default/files/documents/sop%20for%20writing%20sops.pdf>
3. Standard Operating Procedures.
<https://www.mcgill.ca/research/researchers/compliance/animal/sop - animalcare>

SOP REVISION HISTORY

VERSION #	APPROVED	DETAILS
100.01	12/20/17	Authored by T. Schoenfeld and A. Steacy