

UBC Animal Care Guidelines.

SOP: Writing and Revising SOPs

SOP # ACC-2014-ADM-001

Date approved: January 15, 2014

Writing and Revising SOPs

PURPOSE:

To establish the format in which Standard Operating Procedures (SOPs) should be written and revised.

RESPONSIBILITY:

It is the responsibility of the PI to ensure that all SOPs comply with Animal Care Committee (ACC) Policies and Guidelines, as well as employee health and safety practices as required by UBC, provincial or federal policies and guidelines.

POLICY:

SOPs are not mandatory but do expedite Animal Care Protocol writing and review.

SOPs exist in one of two forms.

1) SOPs pre-approved by the Animal Care Committee.

These SOPs can be referred to on Animal Care Protocols. New SOPs can be submitted to the Animal Care Committee for review independent of protocol submission and if approved, will be given an identification number.

ACC approved SOPs should be reviewed by the responsible parties every two years as a status review or as changes are made to a procedure and must be resubmitted to the Animal Care as necessary or when requested.

All SOP reviews and revisions should occur on a timely basis to ensure that all documentation is as current as possible.

Abbreviations and acronyms may be used within the SOP provided they are initially described in full when they first appear, followed by the abbreviation or acronym in brackets e.g. Quality Control (QC).

PROCEDURE:

All customary operating procedures and activities relating to the conduct of a study should be described in detail. Manuals, articles and books may be used as supplements to the SOPs but may not replace them. Once established, SOPs must be strictly followed.

SOP identification numbers are issued by the ACC.

Any deviation from an approved SOP must be documented on Animal Care Protocols.

REQUIRED AND OPTIONAL SOP SECTIONS

All SOPs must include certain sections. Additional sections are optional. Below is a description of common required and optional sections.

Required Sections

- Header/Title: Contains the title, procedure number, author, superseded SOP number, page number referenced to total pages of the SOP (not including attachments) and the effective date.
- Purpose: A statement indicating the general purpose of the SOP and the personnel to whom the SOP applies.
- Policy: A statement listing the key points of the SOP that are to be adhered to.. The items mentioned in the policy section must be described in detail in the PROCEDURE section.
- Responsibility: This section will describe the specific responsibilities by staff (including management) to the SOPs.
- Materials and Supplies: e.g chemicals, reagents, equipment and instruments. Details must include the supplier and specification information, if important i.e., model number, size, or grade, etc. This statement may also be included in this section: "Other materials and equipment can be used provided that they meet the same specifications."
- Procedure: Detailed account of the steps involved in the SOP.

Optional Sections:

- Attachments: A section to list all items that are associated with the SOP such as a reference document, scientific publication, product insert, list of relevant forms, flow chart, diagram, or picture. Each attachment is numbered sequentially with a single digit, i.e. 1,2,3,4. This attachment number must appear in the top right hand corner of the page along with a reference to the SOP number.
- Keywords/Definitions: A short list of distinguishing words that allow the reader to quickly identify the main concepts of the procedure. A glossary of terms that require a definition or further background information.
- References: A numbered list of all applicable reference materials used in the SOP, including other SOPs, manuals, instructions, monographs, articles or regulatory guidelines.
- Revision History: An account of any change that is incorporated into a new revision.
 - o Major additions or deletions should be described in sufficient detail, with justifications provided. References to other documents that led to the SOP revision should be made. Minor grammatical or formatting changes can be grouped together as a summary statement (i.e., do not require thorough description).
 - o Revision history for previous versions of the SOP is not carried over to the new revision.

REVIEW AND REVISIONS OF SOPS AND FORMS

ALL SOPs and Forms should be reviewed by the responsible parties every two years as a status review or as changes are made to a procedure and must be resubmitted to the Animal Care as necessary or when requested. . All reviews and revisions should occur on a timely basis.

If revisions are being submitted to the ACC, the author should make all necessary changes within the context of the SOP using the "Track Changes" editing option. In addition, all changes should be listed and described in the Revision History section.

2) SOPs not approved by the ACC.

These may be attached to a protocol and will be reviewed as part of the protocol