IACUC Policy # 420: Review of Animal Facility Standard Operating Procedures (SOPs)

This policy describes the procedure for reviewing the Standard Operating Procedures (SOPs) for animal care facilities that are subject to the review of the Cornell Institutional Animal Care and Use Committee (IACUC).

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1) Policy
   A. The SOPs for every facility must be reviewed, at a minimum, every 3 years.
   B. New SOPs or proposed revisions to existing SOPs must be approved by the Animal Care and Use Procedure (ACUP) subcommittee prior to implementation. The ACUP subcommittee is appointed by the IACUC and is comprised of IACUC members, CARE Veterinary staff and Facility Managers.
   C. Facility managers must ensure that SOPs are reviewed and that current, approved SOPs are available for any individual that is working with animals in that facility.
   D. The Chair of the subcommittee, who is a Regular or Alternate IACUC member, must sign off on all final, approved SOPs.
   E. Facility managers shall ensure that all Principal Investigators who may be affected by any proposed change in a facility SOP are informed of any change before it is implemented.
   F. In cases of disagreement regarding the proposed changes, between the affected PI, the facility manager and/or the subcommittee, the IACUC will make the final decision on the facility SOP.
2) Procedure

A. Facility Manager

1. Review, every three years, existing SOPs and propose any procedural changes that may be necessary.
   - Complete the review submission cover sheet (see Appendix 1) and submit the SOP(s) to the ACUP subcommittee.
     - Date the SOP with the exact review date (header or footer).
     - Revise the SOP to incorporate any proposed changes.
     - If procedural changes are proposed, review the changes in the SOP with all Principal Investigator(s) that may be affected, provide the PIs 10 days to respond in writing with any objections, and follow the process laid out below for resolution of any differences related to the proposed changes.
   - Once the SOP is finalized:
     - Notify the affected PIs when the SOP is finalized and before the changes are implemented.
     - Post the final approved SOP in a location that is easily accessible by personnel working in the animal facility.

B. Principal Investigator (PI)

1. Review the changes to the SOP proposed by the facility manager and respond in writing within 10 days regarding any concerns or objections to the proposed changes.
2. Upon receipt of the notification for the final revised SOP, ensure that all members of the research staff are made aware of the change.

C. CARE Staff

1. The facility CARE veterinarian and CARE veterinary technologist review the facility SOPs for accuracy and clarity and communicate with the facility manager any recommendations for change.

D. IACUC ACUP Subcommittee

1. SOP submissions with no changes or minor revisions that do not change or affect the processes or intent of the original SOP (e.g., change in room # or minor wording) are administratively reviewed by the subcommittee chair, approved and communicated to the facility manager.
2. SOPs with proposed revisions that change facility processes, or intent of the original SOP (e.g., introduction of a novel species or change in disinfectant method), are reviewed by the ACUP subcommittee.
   - Any suggestions for revision are attached to the SOP and returned to the facility manager for correction and subsequent resubmission. The SOP is approved once the subcommittee agrees that appropriate changes have been made.
   - If the subcommittee and facility manager are unable to agree to the changes, the SOP is referred to the IACUC for review and final decision.
   - If there are concerns raised by the PI that cannot be resolved between the facility manager and the PI, the subcommittee will consider possible modifications proposed by the PI. If the subcommittee is unable to resolve the differences between the PI and the facility manager, the SOP will be forwarded to the IACUC for further deliberations and a final decision.
   - The subcommittee Chair will sign off on the final SOP on behalf of the IACUC.
E. IACUC
   1. Review any proposed changes to the SOPs referred to by the ACUP subcommittee and make a decision by majority vote.
   2. Where differences between the PI, facility manager and the ACUP subcommittee are not resolved by the ACUP subcommittee, incorporate input from affected parties, as appropriate and make a decision by majority vote.

F. Communication and Record Keeping:
   1. Before any procedural changes are implemented, the facility manager will send a copy of the approved SOP to all the Principal Investigators affected by the changes.
   2. The facility manager will keep a copy of the approved SOP in the facility records.
   3. The IACUC office will record discussions and decisions regarding SOPs referred to the IACUC in the minutes of the meeting.

3) Regulatory Guidance
   A. US Government Principle VII states, “The living conditions of animals should be appropriate for their species and contribute to their health and comfort.”
   B. There is no regulatory requirement for Standard Operating Procedures to be developed. However, both the USDA and OLAW expect that institutionally-developed and IACUC-approved SOP’s be reviewed at least once every 3 years. (Transcript August 21, 2014 Guidance on Significant Changes to Animal Activities)
   C. Additionally, the Guide for the Care and Use of Laboratory Animals (ILAR, 2011) states that “Appropriate housing strategies for a particular species should be developed and implemented by the animal care management, in consultation with the animal user and veterinarian, and reviewed by the IACUC. (Chapter 2, page 52)
4) Appendix 1- Facility SOP Review Submission Cover Sheet

Animal Housing Facility Standard Operating Procedure Review

The attached animal housing facility Standard Operating Procedures (SOPs) are being submitted to the Institutional Animal Care and Use Committee (IACUC) for review (animal facility manager must select and initial the applicable sections below). List of SOP(s) submitted for review (attach if needed):

________ I have reviewed the SOPs for my facilities and have made no changes in the procedures or in the wording of the document. I have affixed a current date to the SOPs to reflect this review and have attached a copy for the IACUC.

________ I have reviewed the SOPs for my facilities and have made minor changes in the procedures and/or document wording. I have highlighted the changes, affixed a current date to the SOPs to reflect this review, and have attached a copy for the IACUC.

________ I have reviewed the SOPs for my facilities and have made significant changes in the procedures and/or document wording. I have highlighted the changes, affixed a current date to the SOPs to reflect this review, and have attached a copy for the IACUC. I have notified all affected PIs and facility CARE staff of the proposed changes.

Names of PI(s) consenting to the attached SOP(s): ______________________________________

________________________________________________________________________

Submitted by ___________________________ (Animal Facility Manager)

Animal Facility Name: ______________________________

Date received: _______________ received by: ______________________________

-------------------------------------- Administrative section below, do not fill out --------------------------------------

________ Approved by ACUP subcommittee   Date:__________ Initial________

________ Changes need to be made (see attached sheet for changes); please edit the SOPs and return to the subcommittee Chair with the attached sheet.

Date:__________ Initial________

_______ Revision approved by ACUP subcommittee   Date:__________ Initial:_______
5) Appendix 2: Guidelines for Writing Standard Operating Procedures

A. SOP Content Guidelines
   1. State the facility and part of the facility (where applicable) for which the SOP is intended.
   2. State the procedure, how it is accomplished.
      • The wording of the SOP should provide sufficient detail that someone previously un-familiar with the process will understand.

B. If the procedure is limited to staff with special training, state which members of the staff will perform the procedure.

C. Planning:
   1. Determine the need for an SOP.
   2. Examples of processes that benefit from having an SOP are:
      • Change in procedure
      • Acquiring new equipment
      • Planning for disasters
   3. Determine who should write the SOP, typically this should be done by someone familiar with the procedure.
   4. Determine the audience for the SOP.

D. Use tools to organize information.
   1. Diagram all associated tasks, ideas, necessary to complete the procedure.
   2. Use flowcharts and/or tables to coordinate the tasks in a sequential order.
   3. Recognize the need to separate information into more than one SOP.

E. Use Methods to Improve Readability of the SOP.
   1. Clearly state the details so that someone new to the process can perform the procedure based on information on the SOP.
   2. Concisely state the details required for the procedure.

F. Use Simple Command Statements:
   1. Start with an action verb, follow with an object, and add the supportive information (e.g. clarifications on time or location).
      • “Wash hands before handling animals.”
      • “Keep animal records in the animal room.”
   2. Simplify Action Steps:
      • Use short precise statements: “Turn on work station”
      • Limit action verbs per sentence:
         (a) Poor example: “Remove, shake, stack and record cages changed.”
         (b) Good example: “Remove, shake and stack the cages.”
   3. Avoid complex terms (e.g. hematochezia vs. bloody stool); whenever possible, limit to 3 syllable words.
      Avoid hidden instructions:
      • “Gauges should measure flow…” Is the user supposed to do something here?
   4. Avoid vague pronouns:
      • “it” … What is “it”?
   5. Use standard and consistent acronyms, abbreviations, terms and definitions.

G. Avoid the passive voice, do not use words such as:
H. Identify the Responsible Person:
1. Address the procedure to the primary user.
2. Identify who is responsible for what.
3. Use job titles consistently.
   • Vet tech, tech, technician, vet technician, veterinary technician – choose one title and stick to it.

I. Use Quantitative Information:
1. Specify numbers when dealing with quantities.
2. Avoid the use of vague words, e.g. lots, many, a few; or terms like “at least”.
3. Make sure you write what you mean “between” 1 and 10 = 2 to 9

J. State the Conditions First (e.g. “If pH is below 6 or above 10, notify a supervisor.”).
1. Use conditional words:
   • If
   • Then
   • When

K. Use Lists for Multiple Objects:
1. Use a single action verb followed by several objects (e.g. Verify the temperature, pressure and pH level…).
2. List longer statements in vertical format.
3. Use bullets when there are a number of “if” statements.

L. Use Consistent Structure:
1. Use the outline and bullets in a consistent manner.
2. Use the same tense throughout the SOP.
3. Fit steps into a pattern.

M. Emphasize Important Information:
1. Use words to make information stand out (e.g. “Warning”, “Caution”, “Alert”, “Note”).
2. Do not put instructions in the emphasized sections.
3. Capitalize, box or center important information to make it stand out.

N. Use Referencing and Branching Appropriately:
1. Direct user to sources of information.
2. Refer to another section within the same SOP (e.g. “Refer to Table 1…”).
3. Refer to related SOPs or ACUPS (e.g. “Refer to ACUP #.. Transportation of animals…”).
4. Refer to manufacturer manuals (e.g. “In accordance with manufacturer’s instructions”).

O. Refer to related forms (e.g. “Record information on animal record”).

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