Title: IACUC Policy on Standard Operating Procedures for Animal Care and Use, Administrative Policy P-0021-01
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Authorized by: Vice President for Research and the Institutional Animal Care and Use Committee (IACUC)
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I. Purpose

This policy describes the expectations of the Vice President for Research and Innovation and the Institutional Animal Care and Use Committee (IACUC) regarding the procedures required for acceptable evaluation and implementation of Standard Operating Procedures (SOPs) or any other reference documents that impact the Animal Care and Use Program at Central Michigan University. The intent of this policy is to ensure that SOPs are used in a manner that is consistent with the requirements of the Guide for the Care and Use of Laboratory Animals and the expectations of the Public Health Service Office of Laboratory Animal Welfare (OLAW). OLAW offers significant guidance on the appropriate use of SOPs including the following from The IACUC Handbook, Third Edition page 238, OLAW guidance: http://grants.nih.gov/grants/olaw/faqs.htm:

"The *Guide* clearly defines the animal care and use program as including SOPs and assigns responsibility for regular review of the program to the IACUC. The PHS *Policy* and AWARs allow the IACUC to determine the best means of evaluating the research facility's programs and facilities. The IACUC should approach this responsibility by developing a policy that gives reasonable latitude for changes deemed necessary by the animal facility management and also limits the burden to the committee. Some research facilities refer to SOPs in their training programs for scientists, research technicians, animal technicians and other personnel involved in animal care and treatment. Such SOPs should be evaluated by the IACUC to ensure that personnel are qualified to carry out their duties. Some IACUCs allow investigators to reference SOPs in their protocols rather than provide a written narrative of common animal use procedures. Such SOPs should be reviewed by the IACUC at appropriate intervals for proposed activity review (at least once every three years according to PHS *Policy* or semi-annually, if they involve USDA-regulated species) to ensure that they are up-to-date and accurate."

The processes described below are designed to:
- Allow animals users to maintain control of their SOPs to enable the greatest degree of flexibility for implementation of required changes.
- Ensures access of SOPs to animal users to minimize the chance of protocol drift (non-compliance).
- Ensure access to the IACUC to meet their obligations for review as described above and in the AWARs.
- Ensure that SOPs and other reference documents are reviewed and updated at the appropriate intervals as described above and in the AWARs.

II. Definitions

    A. SOP: Standard Operating Procedure
    B. OLAW: Office of Laboratory Animal Welfare of the Public Health Service
    C. USDA: United States Department of Agriculture
    D. AWARs: Animal Welfare Act Regulations
    E. Guide: The Guide for the Care and Use of Laboratory Animals
    F. AV: Attending Veterinarian
    G. Responsible Party: The individual, laboratory or department responsible for drafting an SOP

III. Procedures

A. <u>Drafting Standard Operating Procedures</u>:

1. Anyone in the Animal Care and Use Community may draft an SOP. The individual drafting the SOP or the faculty member whose laboratory they work in will be considered the party responsible, or Responsible Party, for the purposes of the SOP.

2. When drafting an SOP, animal users are encouraged to obtain a blank template from the <u>IACUC Office</u>. This will allow for uniformity of SOPs across the program.

3. IACUC standard operating procedures will describe programmatic policies and are not guidelines.

4. SOPs must be written in plain language and with enough detail that a new employee can easily understand the procedures described.

5. Unless critical for the context of the SOP, IACUC SOPs will not include specific building references and are applicable campus wide.

6. Electronic versions of the IACUC SOPs located on the ORC website represent the most current and accurate version.

B. <u>Access to and Evaluation of Standard Operating Procedures</u>:

1. Whether developed for limited use, for multiple users, or for use by the entire animal care and use program, SOPs must be periodically reviewed. Often, SOPs will need to be revised for clarity and to comply with changes in, or in the interpretation of, animal use regulations, including PHS Policy and the AWARs. The SOPs pertaining to animals covered by PHS policy must be reviewed every three years and SOPs for animals covered by the AWARs must be reviewed every six months.

2. SOPs developed for limited use (single laboratory/single location)
    a. An SOP developed for single laboratory use should be made accessible to all members of the research team in the laboratory where the procedure is carried out. This can be accomplished by:
        i. Maintaining a binder of SOPs within the laboratory
        ii. By maintaining electronic copies of the SOPs on a shared drive or computer accessible to all members of the research team
        iii. The final draft can be maintained on the IACUC web page under "Policies, Guidelines and SOPs"
    b. If SOPs are to be referenced in an IACUC protocol, additional procedures will apply, see section C below.

3. SOPs developed for multiple users (multi laboratory, department or facility use).
    a. Multiple user SOPS must be made available to all researchers who will employ the procedures.
    b. The mechanisms employed to provide access can be the same as described above or can be accomplished by following the additional procedures outlined in section C below.

4. SOPs developed for use by the entire animal care and use program
    a. Due to their wide use, these SOPs must be made available to the entire animal care and use community.
    b. Program wide SOPs must follow the additional review and access procedures outlined in section C below.

C. <u>Additional procedures for SOPs or other documents that will be referenced in an animal care and use protocol or</u>

used by multiple users in different physical locations:

1. To facilitate meeting their review responsibility, any SOP or other document referenced in an IACUC protocol must be accessible to the IACUC for review.

2. Additionally, the IACUC must be able to confirm that the SOP or document has been reviewed and updated as needed in compliance with PHS or USDA policy.

3. To facilitate access and confirmation of review, any new document or SOP referenced in an IACUC protocol or employed in multiple physical locations must follow additional steps related to evaluation and access.
   a. The party responsible for an SOP must submit the document to the Office of Research Compliance (ORC) or IACUC Office to initiate review.
   b. The SOP will be reviewed by the ORC and IACUC Office staff to ensure that it is in compliance with AWARs and in consultation with the AV to ensure it is consistent with acceptable animal care and use practices.
   c. If changes are needed, the ORC and IACUC Office will work with the Responsible Party to arrive at a final draft.
      i. The IACUC Office and ORC will provide the Responsible Party with specific regulatory references any time a change is requested.
      ii. If the regulatory reference is a requirement (a "must") the owner will be required to edit in a specific manner to meet that requirement.
      iii. If the regulatory requirement provides non-specific direction (a "should") the Responsible Party should decide the best approach to meet the requirement in consultation with the AV, IACUC Chair or ORC as appropriate.
   d. The final draft will be maintained on the IACUC web page under "Policies, Guidelines and SOPs".
   e. A database will be maintained by the ORC to ensure that parties responsible for an SOP are notified when the document is due for review or update.
   f. Disputes regarding the acceptability of an SOP that cannot be resolved between the ORC/IACUC Office and the SOP Responsible Party will be referred to the IACUC.

D. IACUC Subcommittee Review Process:

1. Existing SOP's and policies will be reviewed and updated as per PHS and USDA policy. New IACUC policies and procedures will also be generated and reviewed similar to the process indicated below.

2. The ORC will maintain a database with the SOP document listings and the dates of review or final approval.

3. The IACUC Chair will create subcommittees to lead specific SOP reviews.

4. The review process will consist of multiple stages:
   a. The initial review will be an email request to review sent to appropriate animal users and committee members eliciting recommendations for changes or additions to the existing SOP. The responses will be provided to the SOP subcommittee for further review and consideration for implementation.
   b. The subcommittee will prepare a revised draft to be presented to the IACUC Committee for review and approval. This draft will be provided to the IACUC Chair or Coordinator prior to a convened meeting to be included on the meeting agenda and allow members appropriate time for review.
   c. If applicable, the Vice President for Research and/or the General Counsel may be consulted for additional review and approval. Note: Additional review is required for University Policies.

5. The final draft will be maintained on the IACUC web page under "Policies, Guidelines and SOPs" or on the General Counsel website for University Policies.

6. The IACUC Coordinator or designee will alert appropriate staff when the final version is posted.