Animal Care & Use Program
Policies & Procedures

Policy Development

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I. BACKGROUND

The Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA), Animal Welfare Act (AWA), Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi), and OHSU's Institutional Animal Care and Use Committee (IACUC) Assurance require that policies be developed and implemented for the use of vertebrate animals in research and education. Having a transparent policy development process that involves all stakeholders allows the Animal Care & Use Program (ACUP) to function more efficiently while meeting regulatory and accreditation requirements and standards.

II. SCOPE

This policy applies to the development of policies for the OHSU ACUP.

III. POLICY

a. Policies for the ACUP will be developed through a process that is responsive and transparent, gathers and incorporates input from appropriate experts, and includes stakeholder consultation.
b. Policies will be drafted by the OHSU West Campus (WC) and Central/Waterfront Campus (CWC) Research Integrity Officers with input from the OHSU IACUC Advisory Council (OIAC).
c. Final approval of policies will be done by the CWC/WC IACUCs.
d. Once approved, policies will be posted to the OHSU Research Integrity Office (ORIO) IACUC Policies web page.
e. Approved policies guide the processes of the IACUC but may not be interpreted as mandating any particular IACUC vote or action.

IV. PROCEDURES

a. **Initiating a Policy Request**
   i. A request for development of a new policy or modification of an existing policy may be initiated by any stakeholder in the OHSU ACUP. This includes but is not limited to researchers, IACUC members, Veterinary staff, OIAC members, ORIO administrators, or other research and institutional administrators.
   ii. In the absence of any request for reconsideration of an existing policy, each policy will be considered for re-review on a periodic basis. The timeline for reconsideration of policies will vary depending upon institutional interest, regulatory or accreditation guidance, or federal or state agency action.
   iii. Requests for new policy development or policy re-review may be submitted to any member of the IACUC or OIAC.

b. **Consideration of a Policy Request.**

i. The IACUC will consider each request and determine if a new policy or policy modification is needed.
ii. Issues that warrant consideration of a new policy or policy modification may include:
    a) Recent changes in law, regulation, or guidance;
    b) Time elapsed since last consideration;
    c) Disagreement or confusion regarding existing policy; or
    d) Adverse action at OHSU or other research institution as the result of or findings from an audit performed by a regulatory or accreditation agency.

c. **Development and Approval**
    i. Once it is determined that a new policy or policy change is needed, the Research Integrity Officers will collaboratively create a draft following the standard policy or procedure format. The Research Integrity Officers will consult with appropriate stakeholders in the process of creating the draft policy.
    ii. The drafting process shall include as many of the following items as appropriate:
        a) Assessing the relevant current practices and/or polices at OHSU;
        b) Conducting an analysis of applicable state and federal laws and regulations, and consulting with legal counsel as needed;
        c) Reviewing guidance documents issued or posted electronically by regulatory or accreditation agencies, and reviewing relevant determination letters from regulatory or accreditation actions at other institutions;
        d) Reviewing the policies and practices of peer institutions; and
        e) Analyzing current research and best practices on the topic.
    iii. The OIAC will review the draft, either in a regular meeting or electronically.
    iv. A policy draft that is approved by the OIAC will be posted to the ORIO web page on the electronic kiosk for an open comment session of ten business days.
        a) Notification of the open comment session will be provided to all stakeholders and will occur via the CWC IACUC listserv. The WC Research Integrity Officer will assure distribution to all WC stakeholders.
        b) The OIAC and CWC/WC IACUCs also will be invited to provide input during the open comment session.
        c) Major/substantive edits that result from the open comment period will be taken back to the OIAC for another round of review, followed by re-posting to the electronic kiosk for review by all stakeholders.
        d) IV.C.iv.a-c will be repeated until no or only minor edits are received.
        e) The policy will be presented for discussion and considered for final approval at a combined meeting of the CWC and WC IACUCs. The policy will be formally approved after receiving an approval vote from a majority of the IACUC members participating in the combined meeting.

d. **Implementation and Activation**
    i. All approved policies shall be posted on the IACUC Policies web page.
    ii. The date on which the new or revised policy is posted will be its effective date.
    iii. New or revised policies will always be announced via email and depending upon the impact of the policy, additional research communication avenues (e.g., the Research News) will also be used. New policy announcements will include the activation date and any planned educational activities.
    iv. All new policies will have communication and educational plans that are appropriate for implementation.
        a) The ORIO Education Manager and Education Coordinator, in consultation with ORIO leadership, will be responsible for designing/implementing communication and educational plans.
        b) The OIAC will be consulted in regard to design of the implementation plan when there is a substantive change in practice.

V. AUTHORITY

PHS Policy

The PHS requires institutions to use the *Guide for the Care and Use of Laboratory Animals* (*Guide*) as a basis for developing and implementing an institutional program for activities involving animals.

Guide for the Care and Use of Laboratory Animals: Eighth Edition (2011)

Programs should be operated in accord with the *Guide* and relevant regulations, policies, and principles. Also, institutions are encouraged to establish and periodically review written procedures to ensure consistent application of *Guide* standards.

… the primary oversight responsibilities in the Program rest with the IO, the AV, and the IACUC. Together they establish policies and procedures, ensure regulatory compliance, monitor Program performance, and support high-quality science and humane animal use.

OHSU PHS Policy Animal Welfare Assurance

This Institution has established and will maintain a program… for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

VI. DEFINITIONS

a. IACUC – Institutional Animal Care and Use Committee
b. OHSU IACUC Advisory Council (OIAC) – an advisory group of OHSU researchers and administrators assembled to provide advice to the IACUC Chairs and ORIO in the development of policies and procedures for the IACUC.
c. OHSU Animal Care & Use Program (ACUP) - includes but is not limited to research staff, IACUC members, Veterinary staff, OIAC members, ORIO administrators, and other research and institutional administrators.
d. ORIO – OHSU Research Integrity Office