CONTENTS
I. Definitions........................................................................................................................................... 2
II. Institutional Animal Care and Use Committee (IACUC) ........................................................................ 3
   A. Institutional Authority .................................................................................................................. 3
   B. Purpose ........................................................................................................................................ 3
   C. Scope of Oversight ....................................................................................................................... 4
   D. Functions ....................................................................................................................................... 4
   E. Structure ........................................................................................................................................ 8
   F. Member Training Requirements .................................................................................................. 11
   G. Operations of the IACUC ............................................................................................................ 11
   H. Conflicts of Interest ..................................................................................................................... 16
   I. Confidentiality ............................................................................................................................. 17
III. Principal Investigator, Staff, and Student Responsibilities .................................................................... 17
   A. Regulations and Guidelines ......................................................................................................... 17
   B. PI Eligibility Requirements ........................................................................................................ 19
   C. Reporting Protocol Deviations and Adverse Events .................................................................... 19
IV. Noncompliance ................................................................................................................................... 20
   A. Internal Reporting Structure ....................................................................................................... 20
   B. External Reporting Requirements .............................................................................................. 20
   C. Consequences ............................................................................................................................. 21
V. Whistleblower Policy .......................................................................................................................... 21
VI. References ......................................................................................................................................... 22

I. Definitions

   A. Adverse Event
   Any occurrence of an unforeseen event that negatively impacts the welfare of animals, usually
   involving pain, distress, or death of an animal.

   B. Animal
   Any vertebrate creature.

   C. Animal Activity
   Teaching, research, demonstration, or testing, using live animals, performed on University owned
   property, or engaged in by University personnel.

   D. Animal Facility
   Any facility owned by the University that is used to house animals for 12 or more hours.

   E. IACUC Protocol
   The form used to propose an animal activity to the IACUC. The most recent version of the protocol
   form can be downloaded from the IACUC website.

   F. Minor Deficiency
   A problem for which an immediate solution is not necessary to protect life or prevent distress.
G. Noncompliance
Intentional or unintentional deviation from applicable regulations or University policies.

H. Personnel
All University employees, students, and volunteers working on University sanctioned activities.

I. Protocol Deviation
Any departure from methods approved in an IACUC protocol or the conduct of animal-related activities without appropriate IACUC review and approval.

J. Significant Deficiency
A problem that is or may be a threat to the health or safety of animals.

K. USDA-Regulated Animal
“Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research; horses not used for research purposes; and other farm animals, such as, but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber” (AWA R 1.1).

II. Institutional Animal Care and Use Committee (IACUC)
A. Institutional Authority
The Institutional Official (IO) is authorized to ensure all programmatic and regulatory requirements of animal activities are met. The IO is the Vice President for Research and Economic Development and is appointed in writing by the President of the University. The IO signs the Public Health Service (PHS) Assurance and thus commits the institution to abide by PHS Policy and Animal Welfare Act Regulations (AWAR).

B. Purpose
The purpose of the IACUC is to ensure all University animal activities are conducted ethically, humanely, and in compliance with applicable federal regulations [Animal Welfare Act (AWA), Animal Welfare Act Regulations ("AWAR"), the PHS Policy on Humane Care and Use of Laboratory Animals ("PHS Policy")], federal guidance [Guide for the Care and Use of Laboratory Animals ("Guide"), Guide for the Care and Use of Agricultural Animals in Research and Teaching ("Ag Guide")], and University policies [APM 45.01, FSH 1640.12].

C. Scope of Oversight
The IACUC oversees the care and use of all live vertebrate animals utilized in University teaching, research, demonstration, or production. There are exceptions to this oversight, as defined below.

1. Exempt Activities
Some animal activities are exempt from IACUC oversight. It is best practice for a Principal Investigator (PI) to notify the Office of Research Assurances (ORA) of any proposed animal activity
for a determination of whether IACUC oversight is required. Examples of activities that do not require IACUC approval include, but are not limited to the following:

- Invertebrate animal activities
- Retrospective literature studies of projects where animals were used
- Obtaining tissues from deceased animals where animals were not euthanized specifically for the purpose of obtaining the tissues
- Surveys of animal health or production data from third parties where the data was obtained for some other purpose
- Processing samples as a service where animal products (hair samples, blood samples, other sources of DNA, etc.) are submitted for analysis and a report of results returned to the party requesting the analysis. If the test itself involves the use of live animals, a protocol must be approved for the testing procedure.
- Only data analysis is being provided where the University employee or student has had no involvement in study design or collection of samples
- The project is being funded, designed, and implemented by Idaho Fish & Game where only population management procedures are being conducted. Population management procedures may include capturing and transportation of animals or any health monitoring procedures deemed necessary by IF&G where publication of data obtained for research purposes is not part of a research trial. University-provided personnel may not receive academic credit for the activity.

Other exemptions may be granted but are considered on a case by case basis.

D. Functions

The IACUC must inspect animal facilities and review the animal care and use program semiannually, review and approve requests to utilize animals, provide recommendations to the IO, and investigate animal welfare complaints.

1. Facility Inspections

The IACUC is responsible for inspecting animal facilities at least once every six months. Outside of semiannual inspections, the IACUC may inspect any space used for animal activities prior to use or in response to an issue, complaint, or statement of concern. Animals may not be housed for more than 12 hours in any facility that is not approved by the IACUC.

In the event University personnel are housing animals at a non-University owned facility, there must be a written collaboration agreement between the University and the collaborating institution.

Inspections may or may not be announced, and no IACUC member may be denied participation in an inspection. At least two IACUC members must be present at an inspection. For any facility where USDA-regulated animals are housed, two or more voting members must participate. Members with a conflict of interest may not be the sole inspector or contribute to the minimum of two voting members for facilities housing USDA-regulated animals. As approved by USDA-APHIS Animal Care, inspection of the Caine Veterinary Teaching Center may be conducted and videotaped by one voting member of the IACUC who then reviews video of the inspection with a second voting member.

The procedures for conducting semiannual facility inspections are as follows:
- ORA assists IACUC members in scheduling inspections. Each inspection occurs approximately six months from the date of the previous inspection, never to exceed seven months.
- The inspection team performs the inspection using OLAW's "Sample Semiannual Facility Inspection Checklist" as a guide. A modified checklist is used for agricultural production farms or other facilities, where appropriate.
- The inspectors view all required records and areas used for housing, restraint, procedures, transportation, and storage of feed, bedding, and medical materials.
- The inspection team identifies deficiencies and classifies each as minor or significant.
- Inspectors verify IACUC-approved departures from the Guide for relevancy and inclusion in the semiannual report to the IO.
- Upon completion of the inspection, the team debriefs the facility manager on-site of any significant or minor deficiencies. Immediate action must be taken by appropriate parties (e.g. facility managers) to resolve significant deficiencies.
- The IACUC coordinator (or other appointee) compiles findings into facility-specific inspection reports. Each report includes the date of inspection, names of inspectors, facility manager present, a description and justification of each minor and significant deficiency, and a date by which the deficiency must be corrected. Reports may also include recommendations, observations, and kudos.
- ORA distributes draft reports to the IACUC for review and approval. Once approved, the IACUC coordinator sends the inspection reports to facility managers.
- Facility managers must respond to each deficient item with a plan for correction or confirmation that the deficiency has been resolved.
- The IACUC reviews and approves each response. This is documented on the inspection report.
- Follow-up inspections may be conducted to ensure correction of all significant and minor deficiencies noted in the inspection reports.
- Inspection reports are included in the semiannual report to the IO. See section II.D.3, "Recommendations and Reports to the IO" for more information.

2. Program Review
The IACUC is responsible for reviewing the animal care and use program not less than once every six months. The program review covers all aspects of the animal research and teaching program including, but not limited to, facilities, veterinary care, occupational health and safety standards, protocol review, and IACUC operations.

The procedures for conducting semiannual program reviews are as follows:
- The IACUC chair appoints a subcommittee of two or more voting IACUC members to participate in the semiannual program review exercise. All other IACUC members are invited, but attendance is optional.
- The OLAW template entitled "Semiannual Program Review and Facility Inspection Checklist" is used as the basis for the program review evaluation.
- During the program review exercise, IACUC members use the above-named checklist to identify minor deficiencies, significant deficiencies, areas for improvement, and IACUC-approved departures from the Guide.
- The IACUC coordinator (or other appointee) compiles the findings of the exercise into a report. It is best practice for the report to include descriptions of how identified deficiencies...
will be resolved, who is responsible for resolving each deficiency, and a deadline for resolving each deficiency.

- The IACUC reviews the findings of the program review at a convened meeting. The IACUC can request amendments or accept the report. This is documented in the meeting minutes.
- Once approved, the program review report is included in the semiannual report to the IO. See section II.D.3, “Recommendations and Reports to the IO” for more information.
- As applicable, the IACUC notifies OLAW of any significant or ongoing noncompliance. The IACUC must also report to USDA-APHIS any failure to correct a significant deficiency at a USDA-regulated facility by its established deadline. See section IV, “Noncompliance” for more information.

3. Recommendations and Reports to the IO

The IACUC is authorized and expected to make recommendations to the IO regarding any part of the animal care and use program.

These recommendations may occur at any time, but the IACUC is responsible for submitting a formal "Report to the IO" not less than once every six months. At a minimum, the report must include a summary of any changes to the animal care and use program, a description of the IACUC-approved departures from the Guide, a description of the deficiencies identified during the program review and facility inspection reports, any minority views expressed by the IACUC, and the status of the institution’s AAALAC accreditation. A quorum of IACUC voting members must sign the report.

The procedures for submitting the Report to the IO are as follows:

- The IACUC Coordinator (or other appointee) completes OLAW’s template entitled, “Semiannual Report to the Institutional Official” and appends the finalized program review and facility inspection reports.
- The IACUC reviews and approves the entire report. A quorum of the IACUC signs the report.
- ORA submits the signed report to the Institutional Official. Typically, the chair, ORA director, campus veterinarian and IACUC coordinator present the findings in a meeting with the IO.
- The IO either directly allocates resources or works with other administrative units to ensure that any programmatic or facility deficiencies are corrected in a timely fashion.

4. Review, Approve, and Suspend Animal Activities

The IACUC has the primary authority to approve, require modifications to, disapprove, conduct post-approval monitoring of, or suspend any animal activity or IACUC protocol.

The IACUC functions independently of other University committees in that it makes an independent determination to approve or deny a protocol based upon animal welfare and scientific merit. Research reviewed and approved by the IACUC may be subject to further review and disapproval by the IO, University President, or Regents. However, the IO may not approve research if it has been previously disapproved by the IACUC. The IO, President and Regents also have the authority to suspend or disapprove research, even if the IACUC has approved it.

5. Investigate Animal Welfare Concerns

The IACUC has the authority and responsibility to review and investigate all reported concerns, and take any action necessary to protect the welfare of animals.
The procedures for reviewing animal welfare concerns are as follows:

- On behalf of the IACUC, the chair, campus veterinarian, ORA director, or other pertinent party will gather factual information on the incident. The individual(s) involved will be given ample opportunity to explain the circumstances from their point of view.
- The IACUC will be notified of the events in a timely manner, either by email or at the next convened meeting. Notification will include the type of incident (e.g. unapproved procedures, housing violations, lack of skill/training, neglect, unnecessary or excessive use of animals) and details of the specific events (e.g. species, procedures performed, adverse effects, individuals involved).
- Committee members consider and discuss the following questions:
  - What were the adverse effects on the animals involved?
  - Did the animals experience unanticipated pain or distress and if so, under what pain category?
  - Might the adverse effects have been prevented if the procedures had been reviewed by the IACUC and the veterinary staff?
  - Was medical intervention by the veterinary staff required?
  - Were the individuals involved aware that IACUC approval was required before performing the procedures?
  - Has the investigator repeatedly violated IACUC policies? Were the previous violations the same or different than the current action?
  - Was it necessary for the IACUC to intervene to temporarily or permanently interrupt the activities?
  - Was there intent to circumvent committee authority?
  - Have the actions jeopardized the health or well-being of the animals being used or resulted in animals being harmed or dying?
  - Is there evidence that the investigator or the investigator’s staff disregarded the institutional animal care and use policy in order to perform procedures without obtaining approval from IACUC?
- Based on the findings and committee discussion, the committee will determine what actions to take. Examples include:
  - Issuing a notification of a finding of no wrong doing, with or without accompanying suggestions for changes in procedures.
  - Issuing a written warning to the individual(s) with a copy to the appropriate departmental chair.
  - Requiring investigators or staff to complete additional training.
  - Making other appropriate stipulations to ensure that standards are met (e.g. increasing the number of inspections, requiring changes in protocol procedures, etc.).
  - Suspending the project in question until deviations can be remedied.
  - Permanently revoking approval for the project in question.
  - Suspending or revoking all animal care and use privileges for the investigator or staff.
- The IACUC will provide written notice of the findings to the IO and the individuals involved.
E. Structure

1. Composition and Appointments.
The IACUC is constituted according to PHS Policy IV.A.3 and AWAR 2.31. IACUC members are qualified through their experience and expertise to oversee the institution’s animal care and use program and facilities. Members are appointed to three year terms by the IO. Members may serve successive terms in order to provide the necessary expertise. The IO may remove and replace a committee member in the event the member is unwilling or unable to perform committee member functions.

The IACUC must consist of at least 5 voting members. Membership must meet the minimal requirements listed below:

- One practicing scientist with experience in research involving animals;
- One Doctor of Veterinary Medicine with training or experience in laboratory animal medicine and with University-wide authority to direct activities involving animals;
- One member who is not affiliated with the University in any way other than as a member of the IACUC, who represents the interest of the surrounding community with respect to care and use of animals in instruction and research; and
- One member whose primary concerns are in a nonscientific area (e.g. ethicist, statistician, lawyer, clergy, administrative staff, etc.).

One individual who meets the requirements of more than one of the categories above may fulfill more than one requirement, at the discretion of the IO. However, no more than three voting members from the same department can be on the IACUC at a given time.

Additionally, it is best practice to include the following individuals on the IACUC:

- The director of ORA as a standing, non-voting member;
- The manager of the Laboratory Animal Research Facility; and
- One member of the faculty or staff with responsibilities involving the utilization of animals in teaching or research from each of the following:
  - The College of Agriculture and Life Sciences,
  - The College of Natural Resources,
  - The College of Science, and
  - One faculty member at-large.

a. Alternates
Alternates are available for all required areas of expertise (i.e. scientist, DVM, nonscientist, nonaffiliated) and fulfill the same membership role on the committee as the person for whom they are substituting. Alternates are expected to “vote their conscience” as opposed to representing the position of the regular member for whom they serve. Alternates may only vote or be counted toward quorum when the member for whom he or she is substituting is not present. Protocols and other meeting materials are provided to alternates only when the regular committee member is unavailable.

b. Consultants
The IACUC is encouraged to rely upon consultants for advice and information in specialized areas, when needed. These consultants may be University faculty or staff, or may be unaffiliated with the
University. The consultants may present their assessments in writing or in person. Non-member consultants cannot vote on committee actions.

2. Roles and Duties
IACUC members are expected to regularly prepare for and attend monthly IACUC meetings, participate in semiannual inspections and program review activities, and complete required member trainings. Members are also expected to freely and openly discuss animal care and use matters during convened meetings. All expressed opinions, whether majority or minority, are considered and documented in the minutes.

a. Chair
The chair is responsible for directing IACUC meetings and overseeing IACUC activities. The chair is also expected to improve the animal care and use program by staying current on regulatory trends and interpretations, and championing changes to institutional policies. The chair may be required to interact with other departments, e.g., Environmental Health and Safety or Human Resources, to resolve compliance issues. The chair serves six important constituent groups: the IO, the scientific community, other IACUC members, University administration, the federal government, and the public.

The chair is responsible for overseeing the coordination and implementation of efficient, compliant protocol review. During convened meetings, the chair should ensure that a quorum of the IACUC is present to conduct official business and, as appropriate, declare a loss of a quorum, resulting in the end of official business. The chair should also:

- Oversee the preparation of meeting minutes and official reports;
- Report to the IO any activities that have been suspended by the IACUC for noncompliance with PHS Policy or the AWAR;
- Establish a sound system of written communication for the IACUC with investigators concerning the approval status of protocols and the steps necessary to secure approval; and
- Designate, as specified in PHS Policy (IV.C.2), at least one qualified member of the IACUC to conduct designated member review if full committee review is not requested.

b. Attending Veterinarian (AV)
The AV is responsible for the health and well-being of all animals used at the University. As a member of the IACUC, the AV is expected to:

- Provide veterinary consultation on the recognition and palliation of pain;
- Provide direction of animal care and use;
- Oversee procedures used for aseptic surgery and postoperative care;
- Provide oversight of multiple major survival surgery resulting from a veterinary condition in an animal that also had experimental surgery;
- Advise the IACUC on new procedures or procedures with the potential to cause pain and distress that cannot be reliably controlled; and
- Ensure that veterinary care is available to mitigate illnesses, lesions, or behavioral abnormalities associated with animal restraint.
c. Nonaffiliated Member
The nonaffiliated member represents the general community interests in the humane care and treatment of animals (AWAR 2.31.b.3.ii). The involvement of this member enhances the public’s confidence in the IACUC review processes and the University’s commitment to transparency. The unaffiliated member is regarded as a full member of the IACUC and invited to participate in all official business. However, this member may not be the sole designated member reviewer of a protocol if he or she does not have the needed expertise.

d. Scientist
The scientist ensures the interests of scientific colleagues are being fairly represented in the protocol review process and aids in the IACUC’s assessment of the relevance, validity, and technical aspects of the proposed animal activities.

e. Nonscientist
The role of the nonscientist is to ensure proposed animal activities are easily understood by all members of the committee. This position provides balance to the scientific members who may be regarded as having a vested interest in the promotion of animal studies.

3. Support Staff/Organizational Chart
ORA supports the activities of the IACUC. This office houses the IACUC coordinator who directly supports all IACUC operations. More specifically, the IACUC coordinator is responsible for the following:

- Processing IACUC protocols through the appropriate review processes;
- Maintaining the current IACUC roster and membership appointment letters;
- Advising faculty, staff, and students in the preparation IACUC protocols;
- Training IACUC members, faculty, staff, and students;
- Tracking upcoming protocols expirations and notifying PIs of upcoming expiration dates;
- Communicating with and documenting correspondence between the IACUC and investigators; (Note: all members of the committee can communicate directly with investigators, however the IACUC coordinator must save these correspondences in appropriate IACUC files);
- Preparing various correspondence, internal and external reports, and meeting agendas and minutes;
- Maintaining all electronic and paper filing systems;
- Providing certification to funding agencies of IACUC approval;
- Facilitating the approval of administrative changes;
- Coordinating semiannual facility inspections, program review, and the report to the IO;
- Developing and managing IACUC policies and procedures; and
- Supporting or leading program development efforts.

F. Member Training Requirements
The IACUC coordinator provides training to new IACUC members. Members are also expected to complete two online training modules, “Introduction to Animal Care and Use” and “Essentials for IACUC Members” within 2 months of his or her appointment date. These trainings must be repeated at least once every three years. Additional training opportunities are regularly provided by ORA.
G. Operations of the IACUC

1. Meetings
   a. Frequency
   The IACUC meets monthly to conduct reviews of new protocols, significant changes to previously approved protocols, and any other business. The chair may choose to cancel a monthly meeting in the event there is no official business requiring action.

   b. Management
   Meetings generally follow Robert’s Rules of Order. New protocols, requests for significant changes to existing protocols, and any other materials for IACUC review are electronically distributed to all voting committee members approximately one week prior to the meeting.

   c. Quorum Requirements and Voting
   Committee actions require a quorum. A quorum is a simple majority (greater than half) of all voting members. All committee actions are the result of a majority of votes cast. Voting must occur real-time at a convened meeting with quorum and not through the use of email. Members may connect to a convened meeting via telephone or video conferencing. Non-official business may be conducted via email.

   d. Minutes
   All deliberations, committee actions, and minority opinions are documented in the minutes. Specifically, the minutes must document the IACUC’s review of new, renewing, and amended protocols, including the protocol number, title, species, important discussion items, and committee actions. Investigator names, DMR assignments, and facility locations are typically excluded from the minutes for the protection of all involved individuals. Minutes of the previous meeting are reviewed and approved by quorum at the subsequent meeting. Copies of minutes are made available to the Institutional Official.

   e. Public and Non-Member Attendance
   Investigators and other non-members are welcome to attend IACUC meetings to discuss their protocols or other animal care and use concerns. IACUC meetings are open to members of the public. Meeting dates, times, and locations are available on the ORA website.

2. Protocol Review Processes
   All requests to utilize live, vertebrate animals must be submitted by the Principal Investigator to the IACUC via a protocol form and approved by the IACUC before animal activities may begin. The IACUC may approve new, renewing, or modified protocols through Full Committee Review (FCR) or Designated Member Review (DMR).

   a. Full Committee Review (FCR)
   Protocol review by full committee is conducted by a quorum of the IACUC at a convened meeting. The purpose of FCR is for all IACUC members to be involved in protocol review and decision-making through interactive discussion. Absent members may provide review comments prior to a convened meeting, however these may not be counted toward a vote or considered as part of the quorum.
b. Designated Member Review (DMR)

The DMR process may be used to perform protocol reviews outside of a convened meeting. The DMR process may be initiated only after all IACUC members have been provided the opportunity to call for FCR. DMR can be used in place of FCR if the proposed procedures do not produce more than slight or momentary pain (i.e. pain categories D and E). DMR can also be used to finalize the review and approval of a protocol that was initially reviewed by FCR but required modifications to secure approval.

The following procedures describe the DMR process used to replace FCR:

- The IACUC coordinator provides a copy of the new protocol or amendment to the full committee and requests their vote on the review process, either FCR or DMR.
- Members have five business days from the time of distribution of materials to respond. Email replies, phone replies, fax or written replies are all acceptable. Nonresponse at the end of the five day period is considered a vote in favor of the DMR process.
- Members are asked to include any requests for additional clarification or additional information with their vote. This information is given to the assigned DMR.
- If any voting member requests FCR, the protocol is placed on the agenda of the next convened meeting of a quorum of the IACUC. If no voting committee member requests FCR, the DMR review process is used.
- The chair appoints one or more qualified IACUC members to act as designated member reviewer(s).
- The designated member reviewer(s) may:
  - Approve the protocol or significant change as submitted,
  - Require modifications to the protocol or significant change in order to secure approval, or
  - Refer the protocol to the full committee with or without modifications for FCR.
- If more than one designated member reviewer is used they must be unanimous in any decision. Reviewers receive identical versions of the protocol and any modifications requested by any reviewer.
- IACUC members are informed of the reviewer’s comments and decisions at the next meeting.

The following procedures describe the DMR process used after FCR:

- When the committee votes to require modifications to a protocol, the members present at a convened meeting must decide whether to finalize the review by DMR or at the next convened meeting.
- If the members are in unanimous agreement for DMR, the chair appoints one or more designated member reviewers. This is documented in the meeting minutes.
- If more than one designated member reviewer is used they must be unanimous in any decision.
- The IACUC coordinator informs the Principal Investigator (PI) of the required modifications and asks for a response.
- Once a response is received, the IACUC coordinator forwards the revised protocol materials to the reviewer(s).
- The reviewer(s) may approve the changes, require additional modifications to secure approval, or request the revised protocol be review at the next convened meeting.
- All designated member reviewers must be aware of and agree to any modifications made before approval is granted.
Investigators may not proceed with the project until all committee requests have been clarified and approved. Any member of the IACUC may, at any time, request to see the revised protocol or request FCR. All IACUC members receive training on the above DMR policy and procedure during new member orientation. Additionally, all members are required to sign the "Member Acceptance of Responsibilities" stating they agree with the DMR process described above and understand that DMR may be assigned at a convened meeting of a quorum of members.

3. Committee Actions
The committee may take any of the following actions during protocol review:

a. Approve
The committee determines the protocol is acceptable as submitted or amended at the meeting. The IACUC may move to approve a protocol that requires minor, non-consequential changes as long as the requested changes are administrative in nature (e.g. spelling or grammatical errors, formatting errors, changes to non-PI personnel information, etc.) and clearly described in the minutes. The PI may begin animal activities once notified of the approval.

b. Modifications Required to Secure Approval (MRSA)
The committee determines the protocol has sufficient ethical and scientific merit to warrant approval, but requires minor clarification(s) before full approval will be granted. The committee decides whether the review will be finalized by DMR or at the next convened meeting. The PI is notified of the committee's requests.

c. Table
The committee determines the protocol has insufficient or unclear information for adequate review. The PI is notified of the committee’s deliberations and must resubmit a revised protocol addressing the committee’s concerns. The PI may not proceed with the project until IACUC approval is obtained.

d. Withhold Approval
The committee determines the premise of the proposed activities to be inadequate and does not warrant the use of animals. This may be due to flawed science, poor experimental design, or lack of ethical justification for approval. The PI may not proceed with the project.

4. Notification to Principal Investigators (PIs)
The IACUC coordinator notifies the PI in writing via email of committee decisions. Verbal notification is permissible but is always followed up with email notification.

If modifications were requested, the PI may address these in writing or in person at a convened meeting. Revisions are documented either in meeting minutes or saved with protocol files. Revisions may only be approved under full committee review or designated member review.

5. Annual Renewal
Approved protocols expire three years from the original date of approval, but must be annually renewed for the project to remain active for the three year duration. The IACUC may require more
frequent renewal periods for high-risk projects. The PI is responsible for timely renewal of protocols, however ORA will email renewal notifications approximately 90, 60, and 30 days prior to the annual expiration date. The annual renewal notification requests the following information:

- Has the animal portion of the project been completed?
- Have any unanticipated events occurred during the year?
- Are there any proposed changes in personnel?
- Are there any proposed changes in procedures? (These must be submitted as amendments and approved separately from the annual renewal.)

If the annual expiration date is reached prior to the annual renewal being approved, no new experimental procedures may be initiated until the renewal is approved.

6. **Triennial Renewal**

For projects requiring longer than three years to complete, the PI must submit a new protocol form and obtain approval prior to the active protocol’s triennial expiration date. The PI is responsible for timely renewal of protocols, however ORA will email expiration notifications approximately 90, 60, and 30 days prior to the triennial expiration date. If the triennial expiration date is reached prior to approval of a new protocol, all experimental procedures must cease and animals must be transferred to the facility's holding protocol.

7. **Amendments**

Without exception all significant changes to approved protocols must be submitted to the IACUC in writing and approved prior to carrying out the work. Amendment requests may be submitted at any time during the year for review but must be made in writing via email. Once the amendment is approved, the protocol receives a new expiration date of either one year from the date of the amendment approval or the protocol’s triennial expiration date, whichever is sooner.

Significant changes to a protocol may be reviewed and approved by FCR, DMR, or Veterinarian Verification and Consultation (VVC), depending on the nature of the request. The chair and campus veterinarian make a joint determination in cases where it is unclear as to which review process must be applied.

a. **Changes requiring FCR or DMR**

Most significant changes in ongoing research project must be reviewed and approved by the IACUC via full committee review or DMR prior to their implementation. These include changes:

- from non-survival to survival surgery,
- resulting in greater pain, distress, or degree of increase the degree of invasiveness,
- in housing or use of animals in a location that has not been approved by the IACUC,
- in species,
- in the objectives of a study,
- in the principal investigator, or
- that impact personnel safety.

b. **Changes requiring Veterinarian Verification and Consultation**

The specific significant changes described below may be approved after verification by and in consultation with the Attending Veterinarian. These include changes to:

- Anesthesia, analgesia, sedation, or experimental substances,
Euthanasia to any AVMA-approved method including those approved with conditions (as long as the conditions are met),
Disposition of live animals, or
Duration, frequency, type, or number of procedures performed on an animal.

In this instance, the veterinarian is not conducting a DMR, but is serving as a subject matter expert to verify that compliance with the policy reviewed and approved by the IACUC is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of this policy.

c. Administrative Changes

Minor changes to an approved protocol may be administratively processed by the IACUC coordinator. These requests must be made by in writing by the PI but need not be approved by the IACUC. Examples of administrative changes include:

- Correction of typographical or formatting errors;
- Correction of grammar;
- Contact information updates; and
- Changes in personnel other than the PI;
- Changes in housing to another IACUC-approved, species-appropriate facility.

d. Changes that do not require IACUC notification

Investigators may use fewer animals than approved or may choose not to perform approved procedures. These do not require IACUC approval, notification, consultation, or administrative handling.

8. Suspension of animal activities

The IACUC has the authority to suspend any animal activity or terminate protocol approval in the event the IACUC determines work is not being conducted in accordance with the IACUC’s requirements or is in violation of applicable regulations. This includes protocols that have been associated with unexpected serious harm to the animals or personnel.

Suspension of an animal activity or termination of protocol approval must occur as the result of a committee action taken by a quorum of the IACUC at a convened meeting. However, the attending veterinarian may immediately halt any activity if animals are in immediate harm. In this case, activities may not resume until the IACUC has voted to:

- Restart the activity,
- Require modifications of procedures, additional training, or increased IACUC and/or investigator monitoring of the protocol activities as conditions of reinstatement of the activity, or
- Permanently or temporarily suspend the activity.

At a convened meeting, a quorum of the IACUC will review the situation using the same procedures specified in section II.D.5, “Investigation of Animal Welfare Concerns.” Once the investigation has been completed, a quorum of the IACUC may vote to:
Any suspension of an activity or termination of protocol approval shall be supported by a written statement explaining the reasons for the IACUC’s action. This statement will be reported promptly to the investigator and the IO.

Oversight agencies, including OLAW, USDA, and funding sponsors, will be notified within 10 working days of the IACUC suspension. The notification will include the reasons for the suspension and conditions for the suspension being removed.

**H. Conflicts of Interest**

A conflict of interest refers to an individual’s involvement in activities in which financial or other personal considerations may directly and significantly affect one’s professional judgement in exercising any IACUC duty or responsibility. Each IACUC member receives training from the IACUC coordinator about recognizing financial and non-financial conflicts of interest using FSH 6240. IACUC members must make any conflict of interest known to the IACUC chair or coordinator.

A member must abstain from participating in official business if there is an actual or perceived conflict of interest. Specifically, a member may not contribute to the quorum for an action to be taken on a project or activity in which they have an active role or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IACUC.

1. **Inspections**

A member may not inspect an animal facility if he or she has a conflict of interest, i.e. he or she manages the facility being inspected or materially participates in a project conducted at the facility. The attending veterinarian is deemed to have a conflict of interest on an inspection if he or she is acting as the principal investigator or co-investigator on a project conducted at the facility under review. The attending veterinarian is not at conflict if he or she provides veterinary expertise or procedural training for activities performed at the facility. Conflicted members may only participate on inspections as an observer.

2. **Protocol Review**

Protocol review is conducted objectively and in a manner that ensures the exercise of independent judgment of each member. A member must recuse himself or herself from a review if he or she has any real or apparent conflict of interest, i.e. the member is an investigator on the protocol under review or has any other conflict of interest related to any person or entity connected to the protocol under review. Additionally, PIs cannot select which IACUC member will or will not review their protocols.

3. **Financial**

Investigators (or other project personnel) involved in a research project or other activity involving live vertebrate animals must disclose a potential financial conflicts of interest in accordance with FSH 5600 and 5650.

1. **Confidentiality**

The IACUC views all information submitted to the committee by an investigator as confidential for the safety of all individuals involved in the project and for preservation of proprietary information. Committee members are to treat protocols as confidential and destroy the material when the review process is completed. ORA keeps an electronic copy of all protocols, PI correspondence, and
IACUC documents and maintains an online database application to perform basic protocol tracking and processing functions.

Committee members are trained to practice confidentiality in IACUC matters and agree to the following statement on the “Member Acceptance of Responsibilities”:

“I acknowledge that I will have access to and knowledge of confidential, privileged, and proprietary information ("Information"). This includes, but is not limited to, research protocols, reports, meeting materials, investigations, audits, and discussions. I agree that I will not disclose or divulge any Information to any third party. In the event that a third party individual is inquiring about or divulging Information, I agree to refer that individual to the Research Compliance Officer for assistance. I will not use any Information for my own purposes or for personal gain. Any copies made of Information will be solely for use as an IACUC member and will either be destroyed or returned to the IACUC when no longer needed.”

III. Principal Investigator, Staff, and Student Responsibilities

A. Regulations and Guidelines
The PI on an IACUC protocol is responsible for understanding and following applicable regulations and university policies, and is ultimately responsible for the compliant conduct of animal activities. The IACUC uses the Guide, Ag Guide, AWAR, and PHS Policy to review the appropriateness of proposed animal activities. In the event these documents lack the needed species-specific information, the IACUC will refer to approved taxon-specific guidelines.

1. Animal Welfare Act and Regulations
The PI and animal facility manager are jointly responsible for ensuring that activities involving USDA-regulated animals comply with Animal Welfare Act (AWA) and Animal Welfare Act Regulations (AWAR). This includes activities performed for the purpose of teaching veterinary students. All activities utilizing USDA-regulated animals must be approved by the IACUC, as specified in section II.C.

Facilities housing USDA-regulated animals will be inspected by a USDA Veterinarian Medical Officers not less than annually. These inspections are typically unannounced.

The PI must annually provide ORA with the number of animals used, by species and USDA pain category. If any animals were used under USDA pain category E, the PI must also provide ORA with an explanation of the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. This information will be compiled by ORA and reported to the USDA on the Annual Report of Research Facility (APHIS Form 7023 and 7023A).

2. Funded Projects
Vertebrate animal activities that directly or indirectly utilize any PHS or NSF funding must be approved by the IACUC, follow PHS Policy, and adhere to the Guide for the Care and Use of Laboratory Animals. It is the PI’s responsibility to know, understand, and follow PHS Policy and the Guide.

In the event that it is scientifically or otherwise justified, the PI may request that the IACUC approve a departure from the Guide. The departure and justification for the departure must be described
within the IACUC protocol. A non-IACUC-approved departure from the Guide is considered to be noncompliance.

3. **Wildlife Activities**
All wildlife animal activities must be approved by the IACUC, as specified in section II.C. Most wildlife activities are exempt from USDA oversight under the field study exemption (AWAR 2.31(d)(1)) however, projects funded by NIH or NSF must adhere to the Guide. It is the PI’s responsibility for knowing which regulations apply to his or her field studies and ensuring compliance with appropriate regulatory oversight agencies.

The IACUC will use taxon-specific guidelines to determine best practices for procedures used on wild animals when standards are not found in the Guide. The PI is expected to be the subject matter expert on best practices used for field studies and must provide references in support of proposed procedures.

4. **Agricultural Research**
It is the PI’s responsibility to know and follow applicable rules and regulation for the use of farm animals in agriculture research. Farm animals used for agriculture research are exempt from USDA-oversight as long as the goals and objectives of the research extend to agricultural purposes only. The Ag Guide is the standard for conducting animal activities for agricultural research. Any use of a farm animal for biomedical purposes is subject to USDA-oversight and compliance with AWAR and the Guide.

5. **Production Animals**
It is the responsibility of the facility manager and course instructor to know and follow applicable rules and regulations for the use of animals in production activities (i.e. fish, cattle, sheep, poultry, etc. raised only for food or fiber). University use of these animals must still be reviewed and approved by the IACUC to ensure appropriate SOPs are in place for husbandry, emergency euthanasia, occupational health and safety, and routine medical care.

The standards of the Ag Guide must be applied to production animal activities.

6. **Teaching Animals**
Use of animals in course-related or extension activities must be reviewed and approved by the IACUC.

The use of animals to teach or train students in laboratory or veterinary practices requires strict adherence to the Guide or Ag Guide. Agricultural animals used to teach husbandry or agricultural management practices are exempt from USDA-oversight but activities must adhere to the Ag Guide.

B. **PI Eligibility Requirements**
The IACUC uses the PI eligibility policy specified in APM 45.22. Specifically, “In order to ensure that....projects which include a regulated activity are conducted by those who have the requisite training and competencies and who have the appropriate relationship to the University of Idaho, PIs and Co-PIs must generally be employed by the University in a faculty or staff status” (E-1).
C. Permits

D. Externally Funded Projects

E. Veterinary Pre-Review and Consultation

F. Personnel Training

G. Reporting Protocol Deviations and Adverse Events

The PI must notify the IACUC of an adverse event affecting animals involved in research, teaching, testing or outreach or a deviation from an approved IACUC protocol. The PI or facility manager is expected to file an official report no later than seven calendar days after the identification of an adverse event or protocol deviation using the attached “Adverse Event and Protocol Deviation” report form available on the IACUC website. However, it is strongly recommended that a PI or animal facility manager promptly call or email the IACUC when there is an event that may impact or has impacted animal welfare, prior to filing an official report. Preliminary reports may also be made anonymously via the confidential hotline (see here).

Timely notification allows the IACUC and attending veterinarian to help assess the situation, find resolutions, and implement corrective actions. Consultation with the attending veterinarian must occur when adverse events or protocol deviations result in pain or distress that is beyond the anticipated level described in the protocol or when interventional control, such as analgesics, is not possible. The PI is expected to consult with ORA if he or she is unsure whether an event needs to be reported to the IACUC.

The following are a few examples of reportable events:

- Unexpected animal death or injuries related to approved animal activities (e.g., allergic reactions, broken limbs, complications during or recovering from surgery, sudden death).
- Animal morbidity or mortality in excess of that described in the approved IACUC protocol.
- Facility or equipment failure that has a negative impact on animal welfare.
- Entrapment; overexposure to heat source(s); inadequate analgesia or antibiotic use.
- Implementing protocol amendments prior to obtaining IACUC approval.
- Any intentional or unintentional use of animals that was not described in the approved IACUC protocol.
- Failure to adhere to procedures within an IACUC-approved protocol.

The following are a few examples of situations that do not need to be reported to the IACUC:

- Injury/illness unrelated to approved procedures and being treated by clinical veterinarians
- Death or morbidity of animals as expected and described in the approved IACUC protocol

IV. Noncompliance

A. Internal Reporting Structure

A PI is required to report noncompliance to the IACUC as soon as it is identified. Initial notification may be via phone, email, or in-person meeting. The PI must follow-up initial notifications with appropriate written documentation. The “Adverse Event and Protocol Deviation” report form is available on website for this reason.
The procedures for reporting noncompliance are as follows:

- Any person may bring an allegation of noncompliance to the attention of a member of ORA, the IO, AV, or the IACUC.
- Whomever receives the initial report must immediately notify the AV, IACUC coordinator, and IACUC chair. This group decides who will lead the investigation.
- Investigations follow the procedures described in section II.D.5, “Investigation of Animal Welfare Concerns.”
  - The IACUC is notified of the event by email or at the next convened meeting, participates in the investigation, and takes action.
  - The IACUC notifies the IO and involved parties, in writing, of the findings and actions taken by the IACUC.
  - The IACUC, via ORA, notifies the appropriate external agencies. See section IV.B below for more information.

B. External Reporting Requirements
The IACUC, via ORA, will report the following information to external agencies:

- Any confirmed serious or continuing noncompliance with the PHS Policy that occurs on projects directly or indirectly supported by NIH or NSF is immediately reported to OLAW by telephone. If requested, a full written report of the investigation, resolution, and preventive actions is submitted to OLAW.
- Any serious deviation from the provisions of the Guide that occurs on projects directly or indirectly supported by NIH or NSF are immediately reported to OLAW by telephone. If requested, a full written report to OLAW is submitted.
- Any suspension or revocation of an activity by the IACUC is reported to the appropriate oversight agency (i.e. USDA or OLAW).
- A failure to correct any significant deficiency within the established deadlines must be reported to USDA-APHIS and any federal funding agency, within fifteen days in accordance with AWAR 2.31(c).
- Noncompliance directly supported by non-federal funding agencies will be reported to the sponsor in accordance with the terms of the sponsor’s agreement.

C. Consequences
Consequences of noncompliance vary on a case-by-case basis, as determined by the IACUC and IO, and may include suspension of animal activities or revoking an employee’s privilege to participate in animal activities.

Additionally, OLAW, USDA, funding agencies, or publishers may impose additional punitive actions. This may include withholding or rescinding funding, requesting data be excluded from published findings, or imposing fines.

V. Whistleblower Policy
The following whistleblower policy is posted in every animal housing facility and on the IACUC website:

The University is committed to the ethical and compliant care and use of animals in research, teaching, and testing. If anyone is aware of potential violations to existing animal
care and use regulations or observes misuse or mistreatment of animals, they are strongly encouraged to report their concerns.

Allegations of noncompliance will remain confidential, to the extent permitted by law and as consistent with the need to conduct an adequate investigation of the allegations. The University will take measures to protect from adverse actions or retaliation against any person who, in good faith, makes allegations of noncompliance. For more information, see sections 3170, 3290, and 3810 of the Faculty Staff Handbook.

To report an animal welfare concern anonymously, call the University of Idaho confidential hotline at 1-800-775-1056.

To report an animal welfare concern directly, contact any of the following:
- Institutional Official, Vice President for Research
  Phone: (208) 885-4989
  Email: vpresearch@uidaho.edu
- Campus Veterinarian
  Phone: (208) 885-8958
  Email: campusvet@uidaho.edu
- Institutional Animal Care and Use Committee
  Phone: (208) 885-6162
  Email: iacuc@uidaho.edu
- Director, Research Assurances
  Phone: (208) 885-2142
  Email: iacuc@uidaho.edu

VI. References


