1. **Purpose:** To provide written guidelines for the ISU animal care and use program, the Institutional Animal Care and Use Committee (IACUC) and its interactions with other partners in the program (e.g., Occupational Medicine, LAR, Attending Veterinarian, Environmental Health and Safety). This is also a guide to assist the IACUC in its statutory responsibility or oversight of the ISU animal care and use program.

2. **Definitions:**

   **Administrative Unit:** The major administrative unit for the IACUC purposes will be defined as the Colleges, i.e. College of Agriculture, College of Veterinary Medicine, etc.

   **AV:** Attending Veterinarian.

   **Chair:** Chairperson of the ISU Institutional Animal Care and Use Committee (IACUC).

   **Clarifications or Substantive Modifications:** Are those that prohibit the IACUC from assessing that the PI has adequately addressed all review criteria based on the Public Health Service (PHS) Policy or Animal Welfare Regulations (AWRs) (e.g., justification for withholding analgesics in a painful procedure, justification for use of animals, many questions in the form are inadequately addressed) and require a response from the PI.

   **Contingencies:** Are very specific administrative modifications or clarifications (e.g., a contact telephone number, changes in the size of a needle, changes in the type of anesthesia) needed to grant Institutional Animal Care and Use Committee (IACUC) approval. In general, modifications of this type simply require concurrence by the principal investigator (PI).

   **Clarification:** Are the types of missing or confusing information that prohibit the IACUC from assessing that the PI has adequately addressed all review criteria based on the Public Health Service (PHS) Policy or Animal Welfare Regulations (AWRs) (e.g., justification for withholding analgesics in a painful procedure, justification for use of animals, many questions in the form are inadequately addressed) and require a response from the PI.

   **Committee:** The ISU Institutional Animal Care and Use Committee (IACUC).

   **Designated Reviewer:** An individual appointed by the Chair to review proposed animal use for the IACUC.

   **Designated Member Review (DMR):** At ISU, this term is synonymous with Subcommittee Review. It is a mechanism for reviewing proposals if there is not a request for full committee review from a member. The Chair or his/her designee appoints a member(s) (designated reviewer[s]) to review the proposal for the committee. The DMR schedule is distributed to members at the monthly meeting. If the designated reviewer(s) recommends approval of the proposal, the Chair may approve the proposal.
DORR: Director of the Office for Responsible Research

Full Committee Review: Proposals reviewed by the convened IACUC committee. Any committee member may request full committee review for any proposal to use animals; the protocol will automatically receive full committee review.

Home Page/Website: The ORR has developed and maintains a comprehensive website www.compliance.iastate.edu/iacuc, which contains significant information and resources for IACUC members, researchers, educators, or any other person involved or interested in animal care and use activities. The website contains the IACUC application, online training, occupational health information, and pertinent links to many other technical and regulatory sites, etc.

IACUC/IBC Administrator: The individual employed by the ORR who receives all protocol submissions for research involving animals and research involving biohazards, conducts initial review of proposed research, and coordinates communication among the IACUC, IBC, ORR, and investigators.

IACUC Consultant: A consultant is defined as an expert available to assist the IACUC in matters that may require technical or specialized expertise not resident on the committee. Consultants may be asked to review proposals or protocols or assist in other activities of the IACUC as needed, at the request of the Chair, AV and/or the DORR. Some consultants may be engaged on a one-time basis, or they may be identified as a regular contributor or resource for the committee.

IACUC members may also consult with colleagues or consultants about questions related to a protocol; however, members are expected to observe confidentiality requirements associated with the review of unapproved protocols.

IACUC Members: In general, committee members are voting members; however, non-voting members may be appointed as ex-officio members. Members are responsible for executing appropriate duties of the IACUC.

IBC: Institutional Biosafety Committee. The IBC is responsible for review and approval of research and teaching involving biohazardous materials. The IBC is also responsible for review and approval of projects involving transgenic animals, including requirements for individual marking of transgenic animals, following the NIH Guidelines for Research Involving Recombinant DNA.

Institutional Official (IO): The individual with authority to commit resources and make decisions for the Institution regarding the animal care and use program. At ISU, the Vice President for Research and Economic Development (VPRED) is the IO.

LAR Director: The Director of the Office of Laboratory Animal Resources.

Modifications: Modifications are proposed changes to an approved IACUC protocol. All modifications must be reviewed and approved by the IACUC prior to implementation by the investigator. Minor modifications may be reviewed by the IACUC Chair. Major modifications are reviewed in the same manner as new applications.

Office for Responsible Research (ORR): The ORR assists investigators in obtaining the necessary approvals to conduct regulated research, such as research involving humans, animals, biohazards, and radiation. The ORR also provides administrative support for the IACUC.
Pain Category: Categorization of pain and distress determination for animals used in research and teaching programs. ISU is required by federal law to provide this information on pain categories in an annual report to the USDA at the end of the federal fiscal year. The USDA pain categories are as follows:

- Pain Category B—Animals being bred, conditioned, or held for use
- Pain Category C—No or momentary pain and/or distress
- Pain Category D—Alleviated pain and/or distress
- Pain Category E—Unalleviated pain and/or distress

Principal Investigator (PI): The individual who is the primary contact regarding proposed research and who accepts full responsibility for conducting procedures as approved by the IACUC.

RSC: Radiation Safety Committee. Approval must obtained from the RSC before any individual may use radioisotopes or ionizing radiation in experimental or routine procedures.

Research Assurances Monitor (RAM): The individual in the Office for Responsible Research who is responsible for conducting post approval monitoring for research and teaching involving animals and humans.

Stipulations: During proposal review by a designated IACUC member or by the convened committee, there may be questions or clarifications needed. Stipulations are formal requests to the investigator to address those questions or issues. Stipulations must be adequately answered, and, if appropriate, changes must be made to the proposal prior to final proposal approval by the Chair.

Subcommittee Review: At ISU, this term is synonymous with Designated Member Review (DMR). If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those protocols and have the authority to approve, require modifications in (to secure approval), or request full committee review of those protocols. This subcommittee is generally comprised of 2 designated reviewers; however, only one is required to approve proposals. If the only member present is a nonscientist or community member, review will not be held.

Substantive Modifications or Clarifications: Are those that prohibit the IACUC from assessing that the PI has adequately addressed all review criteria based on the Public Health Service (PHS) Policy or Animal Welfare Regulations (AWRs) (e.g., justification for withholding analgesics in a painful procedure, justification for use of animals, many questions in the form are inadequately addressed) and require a response from the PI.

Vice Chair: The Vice Chair of the Institutional Animal Care and Use Committee. The Vice Chair is appointed to lead the committee meetings, reviews IACUC minor applications, and performs the duties of the Chair etc. in the absence of the Chair. The Vice Chair also attends the monthly meetings of the IO, Chair, AV, LAR Director, and DORR and participates in discussions regarding IACUC business such as adverse events, compliance concerns, etc. whenever possible.

3. IACUC Composition: The IACUC is composed of representatives from major administrative units (colleges) of the University that use animals in the animal care and use program, with no more than three members from any one administrative unit. Nominations are solicited by the Vice President for Research and Economic Development or by the Director of the Office for Responsible Research on behalf of the Vice President for Research and Economic Development. Members are appointed in writing by the President (CEO) of ISU. Members are appointed for a three-year period with the possibility of renewal. One term of renewal is approved unless a waiver is granted for extenuating
circumstances (e.g., the Attending Veterinarian, expertise is limited to one individual on campus). Additional members may be appointed based upon statutory requirements, programmatic emphasis, or desired expertise needs.

Service on the IACUC counts towards service requirements for promotion and tenure. IACUC members are not monetarily compensated. Nonaffiliated members are offered parking passes for the parking ramp for parking required for committee meetings. Individuals missing more than half of their responsibilities (i.e., meetings and inspections) in a 12-month time, without an excused absence, may be removed.

Committee membership and specialty participation is subject to adjustment at the discretion of the Vice President for Research with assistance by the Office for Responsible Research. An individual member may represent more than one category of member (i.e., veterinarian and representative of the College of Veterinary Medicine). The basic areas of membership for the committee are listed below:

- Committee Chair
- College of Human Sciences
- College of Veterinary Medicine
- College of Agriculture and Life Sciences
- College of Liberal Arts and Sciences
- Non-affiliated, non animal user (may be nonscientist)
- Attending Veterinarian (may be one of the college members)
- Laboratory Animal Resources
- Nonscientist (may be one of the college members)
- Scientist (may be one of the college members)
- Alternate member (person identified to serve as an alternate at a committee function for a specific committee member).

*Specialty Expertise/Consultants (as available or needed):
- Pain and Distress Management
- Wildlife Studies
- Safety
- Information management/literature search specialist

4. **IACUC Member Training:** IACUC members are provided training through a combination of resources. Each member is required to take the online CITI training entitled “Working with the IACUC” and “IACUC Basics.”

New members are given notebooks containing the following resources:

- Guide for the Care and Use of Laboratory Animals
- Animal Welfare Act and Animal Welfare Regulations
- Public Health Service Policy on Human Care and Use of Laboratory Animals
- Guidelines for Use of Fishes in Field Research
- Guidelines to The Use of Wild Birds in Research
- Guidelines for the Capture, Handling and Care of Mammals
- USDA Animal Care Policy Manual
- Guidelines for the Use of Live Amphibians and Reptiles in Field Research
- AVMA Guidelines on Euthanasia

The IACUC Chair, DORR, and IACUC Administrator meet with all new members to discuss the requirements of the regulations, including criteria for IACUC approval, the process for review, etc. In
addition, each member is given a laminated copy of the regulatory criteria for approval for their use during review of protocols. Laminated copies of the criteria are also brought to the designated review session to guide members during protocol review and to help ensure that each criterion is considered.

IACUC ongoing educational materials include short segments at monthly meeting, workshops, and seminars, emails containing hot topics, IACUC 101 presentations from PRIM&R, etc. meeting.

5. **ORR Staff Training:** All ORR staff working with the IACUC in providing animal care are required to take the CITI online training “Working with the IACUC” and “IACUC Basics.” Staff members also attend the PRIM&R “IACUC 101” training and the annual Institutional Animal Care and Use Committee (IACUC) conference for ongoing education and networking opportunities. IACUC listserves are also utilized as a resource.

6. **ISU Investigator Training:** The IACUC adopted online training in 2006 as the official training resource for investigators. Effective January 1, 2009, all individuals identified as Category 2 personnel in the document “Supervised Staff Training Document” are required to take the CITI online training “Working with the IACUC” before IACUC final determinations or approval will be released.

Individuals defined as Category 1 personnel must read the portions of the Supervised Training document related to “Use of Animals in Research and Teaching.” Upon completion, personnel must then sign the document as certification that they have read the information. The following topics are addressed in relation to research and teaching involving animals: institutional oversight; responsibilities of the IACUC and the Attending Veterinarian; responsibilities of the principal investigator; alternatives to research including replacement, refinement and reduction; reporting concerns involving the care and use of animals; and the occupational medicine program.

Several venues are utilized to provide additional training for investigators such as the following, presented either as an online resource or in an educational seminar format:

- New Faculty Research Orientation Sessions
- Compliance information distributed in orientation packets to new faculty and graduate students
- Departmental seminars
- IACUC Frequently Asked Questions
- Policy and guidance documents:
  - Allocating and Counting Animal Numbers for Protocols
  - Permits Required for Wildlife Research
  - External Protocol Review
- Procedure-specific guidance:
  - Listing Species in Protocols for Wildlife Research and Surveys
  - Determining the Pain Classifications in Wildlife
  - Blood Collection Guidelines
  - How to Search for Alternatives
- Biosafety training videos:
  - Working with Animal Biosafety Levels 1
  - Working with Animal Biosafety Levels 2
  - Working with Animal Biosafety Levels 3
  - Overview of Risk Assessment and Risk Management
- Zoonotic Disease Facts Sheets:
  - Agricultural Worker Respiratory Hazards; Amebiasis; Animal Bites, Scratches, Kicks; Balantidiasis; Brucellosis; Campylobacteriosis; Cat Scratch Disease; Center for Food Security & Public Health Zoonotic Disease Fast Facts; Contagious Ecthyma; Cryptosporidiosis; Dermatophyces; Ebola; Giardiasis; Hantavirus; Herpes B Virus; Human Allergies to Animals; Immunosuppression & Working with Animals; Influenza;
Latex Allergies; Leptospirosis; Lyme Disease; Lymphocytic Choriomeningitis; Marburg Virus; Measles; Monkeypox; Newcastle Disease; Personal Hygiene; Psittacosis; Purposebred Animals; Q-Fever; Rabies Preexposure; Rabies; Rat Bite Fever; Salmonellosis; Sharps; Shigellosis; Sporotrichosis; Toxoplasmosis; Tuberculosis; Yersinia Pestis; Yersinia Pseudo TB.

- Post approval monitoring visits.

The ORR also distributes a newsletter that provides program updates, ongoing educational materials, and current information for investigators. Whenever possible, these resources are supplemented by training from external experts, for example PRIM&R IACUC 101, presentation by USDA inspectors.

7. **Training for Students at the College of Veterinary Medicine:** The College of Veterinary Medicine requires that all students take the CITI on-line training “Working with the IACUC.” Students are required to take the course during the spring semester VDPAM 312 (cross listed as VCS 312) course “Veterinarians in Society II – Introduction to Animal Welfare.” Students must complete the training and provide the instructor with their completion record for a Pass/Fail assignment of grades. The instructor then forwards a copy of the class list to the ORR for documentation purposes.

8. **Relationships to Other Committees:** As part of ISU’s comprehensive system of compliance, the IACUC shares their responsibility for protection of animals and individuals involved in research and teaching programs utilizing animals, as well as compliance with federal, state, and local laws with other committees and offices.

**Institutional Biosafety Committee:** The Institutional Biosafety Committee (IBC) must approve any teaching or research project that involves:

- Use of recombinant DNA, including transgenic animals or plants;
- Use of human, animal or plant pathogens not indigenous to Iowa (e.g., bacteria, viruses, prions, parasites);
- Use of biological toxins;
- Administration of experimental biological products to animals; and
- Field releases of plant pests not indigenous to Iowa or genetically modified organisms.

It is the policy of Iowa State University that all research and teaching involving hazardous biological materials either performed at, or sponsored by, the University be conducted in a manner that does not pose significant risk to the health and safety of ISU personnel, the public, or the environment. Iowa State University will comply with all applicable federal, state, and local regulations governing the conduct of research involving the areas listed above.

In the application for approval, the investigator is responsible for proposing the necessary procedures to protect employees and animals. The IBC subsequently reviews the proposal to determine that the procedures proposed by the investigator are appropriate, including but not limited to, appropriate personnel protective equipment and biosafety level containment practices based upon the committee’s risk assessment during protocol review.

IACUC and IBC approval are held until all compliance requirements have been met for each protocol.

**Radiation Safety Committee:** It is the policy of the University to control and facilitate the use of radioactive materials and radiation-producing devices on campus for purposes of research and teaching. In this process the University is, at the same time, committed to ensuring that all uses of these materials and devices are in compliance with regulatory requirements and that any resulting radiation exposures are as low as is reasonably achievable (ALARA). Toward this end, the University
has established specific administrative entities with responsibilities for controlling the use of radioactive material and radiation-producing devices on campus.

Before an individual may use radioisotopes or ionizing radiation in experimental or routine procedures, approval must be obtained from the Radiation Safety Committee. This must include approval of the following:

1. The project itself on the basis of radiation protection only
2. The facility, for the amounts and types of radioisotopes or other radiation sources which will be used
3. The training and background of the individual to handle the radioactive material or radiation which he or she intends to use

The RSC’s function of assuring safety surveys is implemented by the Department of Environmental Health and Safety. This department provides monitoring services for personnel, receives and handles shipments of radioactive material, collects radioactive waste, and performs other health physics functions.

9. **Occupational Health and Safety of Personnel:** The occupational health and safety program for personnel who work in laboratory animal facilities or have contact with animals is coordinated by Environmental Health and Safety (EH&S). The Occupational Medicine Department provides medical surveillance and assistance to university employees who work with materials and under conditions that have identified and/or regulated risks. The university does not currently require pre-employment medical evaluations. However, each new staff member is required to complete a “Hazard Inventory” form that includes a checklist of potential hazards, which may be encountered on the job.

The Occupational Health section of EH&S helps identify potential occupational health hazards, evaluate the extent of exposure, and then coordinates with the occupational physician to ensure that adequate measures are taken to properly protect employee health and safety. An EH&S representative is also an Ex-Officio member of the IACUC. EH&S also sends notices to the employing department when immunizations, annual physical examinations, and routine monitoring tests (e.g., respirator fit testing) need to be updated.

Formal training programs are offered by EH&S, including courses on nearly 40 different training topics ranging from Autoclave Safety Use to X-ray Safety. EH&S has over 100 titles in their video library available for checkout.

Training courses are open to the Iowa State University community. EH&S provides basic guidelines (Appendix 1) to prevent the spread of infectious agents between animal populations and to protect personnel from zoonotic agents.

10. **IACUC Meetings:** The IACUC generally meets in full committee on the first Wednesday of each month. The meetings will usually be scheduled for 8:30 AM. Meeting times and dates may be altered as needed for special circumstances, to obtain quorum, as committee membership changes. The committee must have a quorum (more than half of the voting members present) to hold a meeting. At the discretion of the Chair, the IACUC may use subcommittees to review and/or recommend approval of animal care and use activities. The IACUC meeting is open to the public, and minutes of the full committee will be recorded.

11. **IACUC Semiannual Review and Inspections:** The committee will conduct semiannual reviews of program and facilities using standardized OLAW checklists designed for that purpose. Semiannual facility inspections will be scheduled every six months. Semiannual program evaluations will be held in March and September.
During facility inspections, at least two voting members of the IACUC will be present. Any member having a conflict of interest during facility inspections shall recuse themselves; the requirement for two voting members remains. IACUC members are given laminated copies of inspection criteria adopted with permission from Kansas State University (see Appendix 2). Findings from facility inspections will be compiled by the IACUC Administrator and forwarded to the individual responsible for management of the area that was inspected, generally within a couple days of the inspection.

The Director for Responsible Research prepares the semiannual report, based upon the IACUC’s comments during the program review and facility inspections, and presents it to the full committee. The full committee will consider the report of the results of the review and inspection and vote on findings and recommendations for the report to the Institutional Official. Any minority or dissenting opinions will be included in the report. All members of the committee present during the final review will sign and date the final report. Results and recommendations will be forwarded to the Institutional Official and maintained for review by appropriate oversight entities.

12. IACUC Reports and Records: The following IACUC records are maintained by the ORR:

   a. Semiannual Review of Program and Inspection of Facilities
   b. Minutes of the IACUC meetings
   c. Protocol records and changes to protocols
   d. Complaints
   e. Suspensions
   f. Annual reviews
   g. Training records
   h. Membership records and qualifications
   i. Correspondence records
   j. Guidelines

13. Animal Care and Use Complaints: It is the statutory responsibility of the IACUC to investigate complaints or concerns about the animal care and use program from any individual(s), including employees or persons in the general community. Signs are posted prominently in animal use areas informing individuals of the mechanisms and contact information to voice concerns or complaints about animal use at ISU.

Complaints may be handled in a confidential or anonymous manner if requested by the originator. The Chair and the DORR, in consultation with the AV, will decide on a case-by-case basis how to proceed, based upon the content and context of the complaint or concern. Regardless, the Chair and DORR will ultimately report to the full committee and the IO any formal complaints and the results of any IACUC investigation. The DORR, on behalf of the IO, will originate required reports to funding agencies, OLAW, or the USDA, as appropriate.

After the Office for Responsible Research has been notified of potential noncompliance or received a complaint, the following process will be used to review the concerns:

   a. The Institutional Official will determine if immediate suspension of the project in question is required while the complaint is being addressed, based upon recommendations of the IACUC Chair, DORR, and AV following discussion with the investigator. If applicable, the sponsor contract or grant award notice will be reviewed to determine requirements for notifying the sponsor. Reports to the sponsor are made by the DORR.
   b. The DORR and IACUC Chair will lead the investigation of the incident with assistance from any combination of the following as appropriate: the Attending Veterinarian, the IACUC Administrator, and members of the IACUC.
c. It may be necessary to perform an audit of study records to determine the level of noncompliance. In that case, the principal investigator will be required to produce all data related to the study projects, applications for approval from the IACUC, and any study-related documentation including monitoring logs, etc.

d. Following completion of the investigation, a meeting will be called of the following individuals to discuss the nature of the situation: the IACUC Chair, the IACUC members, the principal investigator, and the principal investigator’s department chair.

e. The DORR or IACUC Chair will present the matter to the members of the IACUC when a quorum of the full committee is present. The IACUC will determine if (1) suspension is not merited or (2) suspension is merited. In order to suspend a study, a majority of the quorum of members present must vote in favor of the suspension:

   1. **Suspension is not merited:** If suspension is not merited, the issue will be resolved among any combination of the following individuals: DORR, IACUC Chair, Attending Veterinarian, principal investigator, principal investigator’s department chair. These actions will be based on recommendations from the IACUC members and in communication with the Vice President for Research and/or the Associate Vice President. All communications will be documented.

   2. **Suspension is merited:** Notice of suspension effective immediately will be sent to: the principal investigator, co-principal investigators, the department chair, the Office of Sponsored Programs Administration, Sponsored Programs Accounting, the Vice President for Research, the Associate Vice President for Research, and the Office of Laboratory Animal Resources. Notification will be sent to the Office of Laboratory Animal Welfare and the United States Department of Agriculture when applicable.

f. The IACUC makes a determination regarding noncompliance and whether the situation merits a designation of serious or continuing noncompliance:

   1. **Serious or continuing:** If the audit of the study records indicates noncompliance that is serious or continuing, corrective action will be determined by the DORR in consultation with the Vice President and the Associate Vice President for Research. The corrective action will be based on recommendations made by the Chair of the IACUC, the Attending Veterinarian, and members of the IACUC. A copy of the letter will be sent to the principal investigator’s department chair, the dean of the principal investigator’s college, the Provost, and other necessary individuals as determined by the Vice President for Research. The IO will notify the Office of Laboratory Animal Welfare of the final outcome.

   2. **Minor and noncontinuing:** If the incident appears to be isolated and, in essence, is a miscommunication or misunderstanding of a nonserious and noncontinuing nature, a letter from the DORR to the principal investigator describing a summary of the audit will be written. The DORR in communication with the Vice President for Research and Economic Development may determine the appropriate corrective action based on recommendations made by the Chair of the IACUC, the Attending Veterinarian, and members of the IACUC, or require that the principal investigator describe corrective actions. This will be the final step if the incident is considered to be nonserious and noncontinuing. A copy of the letter will be sent to the principal investigator’s department chair and to the Chair of the IACUC.

g. The IACUC is also asked to make recommendations regarding corrective measures. The possible actions that may be taken as corrective measures include:

   - Suspension or termination of Institutional Animal Care and Use Committee approval of protocols that are found to be noncompliant with institutional policies and procedures, state laws, and/or federal laws or regulations, taking into consideration the welfare of animal subjects
   - Compliance audits
   - Letters of reprimand
   - Restrictions on serving as an investigator on animal subjects protocols
- Modification to research protocols
- More frequent continuing review or monitoring
- Data related to noncompliance may be removed from any data collection/pool and not be used for analysis
- Request more information prior to making final decision
- Referral of the issue to other organizational entities such as legal counsel, risk management, or the research integrity officer
- Continuing education
- Other actions as appropriate

The committee’s determinations regarding noncompliance and their recommendations regarding corrective actions are forwarded to the IO for review. The IO may not reverse a committee determination of noncompliance, but the IO may make his or her own determination that a study is in noncompliance.

14. Protocol Submission: All submissions (i.e., new protocols, continuing reviews, or modifications) must be received electronically by the IACUC Administrator. Submissions received by 12:00 noon Wednesday will be reviewed by DMR the following Thursday (some variation due to holidays). The only exceptions will be for those protocols that will lapse prior to the next designated member review. Signed signature pages (department chairs and principal investigator) must be received by the IACUC Administrator prior to full approval being granted. Department chair signatures are required to facilitate review of scientific merit of proposed research, inform chairs of research being conducted by investigators in their department, and to allow chairs to support compliant research.

   a. **Documentation of Informed Consent to Enroll Client-owned Animals in Research:**
   Investigators at the Veterinary Medical Center who wish to involve client-owned animals in research must obtain informed consent from the owner prior to enrollment of the animal in a research project. A sample “Consent to Assess Clinical Outcomes in the Course of New Veterinary Treatments” is provided on the ORR website and the College of Veterinary Medicine website. Investigators should submit a copy of the consent document with the application for IACUC approval, for documentation purposes in the IACUC file. The form is to be used in conjunction with the ISU Veterinary Medical Center “Consent to Treatment and/or Operation.”

   b. **Permits.** Any protocol requiring that permits be obtained (i.e., wildlife research) must have the permits on file with the IACUC Administrator prior to approval being released. It is understood that in certain cases, IACUC approval is needed prior to the granting of permits, and in these cases, the IACUC Administrator will work with PIs to facilitate these needs.

15. Investigator Qualifications: To be eligible to serve as the principal investigator of an IACUC research proposal, the individual must be either a tenured or tenured-track faculty member, or a Professional and Scientific employee on a continuous appointment at a level of P17 or higher. All others require VPRED approval. Unaffiliated investigators must meet the same qualifications as affiliated investigators. Unaffiliated investigators must complete an unaffiliated investigator’s agreement provided by the ORR prior to research proposals being reviewed. A complete version of the VPRED’s policy can be found at: [http://www.vpresearch.iastate.edu/policy/pi-eligibility.html](http://www.vpresearch.iastate.edu/policy/pi-eligibility.html).

16. IACUC Review: All IACUC members receive all animal care and use proposals for preliminary review prior to the scheduled meeting via WebCT. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those protocols and have the authority to approve, table (for clarification), or request full committee review of those protocols. All IACUC members are given the opportunity to pose questions for all proposals, regardless of Designated Member Review (DMR) assignments. Those members conducting the DMR should consider all questions brought forward by other IACUC
members and ask for further clarification from the investigators where appropriate. In addition, each member is given a laminated copy of the regulatory criteria for approval for their use during preliminary review of protocols. Laminated copies of the criteria (a copy for each member) are brought to the designated review session to serve as a guide during protocol review and to ensure that each criterion is considered.

The DMR can either approve, table, or refer a protocol to full committee. All members present must vote affirmatively in order for a protocol to be approved; if one member disapproves or abstains from the vote, the study is forwarded to the full committee for review. The decision to disapprove a protocol can only be made by the full committee. The IO may not approve a protocol that has been disapproved by the full committee; however the IO may disapprove a protocol that has been approved by the IACUC.

When a request for IACUC approval is reviewed by the full committee and require 
contingencies, the IACUC Chair or IACUC/IBC Administrator may review the investigators response for concurrence with the Committees requirements. If the investigator declines to accept the contingencies, the investigator’s response will be scheduled for FCR.

If substantive modifications or clarifications are needed, a quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR. If one member does not agree with DMR, the investigator’s response and the protocol must continue to be reviewed by FCR. More information about this process is provided in the IACUC standard operating procedure entitled “Designated Member Review Subsequent to Full Committee Review When Modifications or Clarifications Are Needed to Secure Approval.”

Meeting minutes are not required by the regulations for designated review. However, controverted issues and their resolution are recorded in meeting “notes” to help with development of communication to the PI and for historical purposes. The format of the “notes” is the same as required by the regulations for full committee meeting minutes. Animal numbers are recorded in the “notes” for documentation purposes to ensure that the IACUC protocols and the LAR records for approved animal numbers agree.

17. Changes to Protocols/Activities: The Chair or their designee will make the determination whether a proposed change to an activity or protocol is minor or major.

a. **Major Modifications:** The PI must submit information that completely explains the proposed changes to the approved animal care and use activity. The proposed major modification will be reviewed by DMR unless it is referred to the full IACUC committee. If the IACUC determines the proposed changes are significant enough, it may require submission of a new protocol.

Those modifications considered major include:

1. Changing the principal investigator
2. Applying the protocol to a new species (However, PRFs in which several species are already studied are exempt [i.e., survey studies].)
3. Changing the number or age of animals used on the study
4. Changing the humane use category
5. Changing when an intervention will be administered to an animal on trial
6. Changing the duration, frequency, or number of procedures to be performed on an animal
7. Changing from terminal to survival or repeat surgery
8. Changing to a different surgical approach or medical treatment
9. Changing the dosage or dose of hazardous agent or an infectious or biohazardous material already in the protocol
10. Addition of a new hazardous agent (e.g., betamercaptoethanol)
11. Addition of a new biohazardous material or new infection protocol (e.g., adenovirus vs. lentivirus)
12. Changing or adding objectives to the study
13. Changing the anesthetic agent(s) or the use or withholding of analgesics (PIs should give an acceptable range so that a modification is not needed.)
14. Changing the method of euthanasia

b. Minor Modifications: Modifications that are determined to be minor can be approved by the IACUC Chair.

Those modifications considered minor include:
1. Changes in personnel other than the principal investigator (When adding personnel, list their role/duties on the project and list their training.)
2. Changing the sex of animals used on a protocol
3. Changing the supply source of animals
4. Changing the campus housing location
5. Changing the disposal of animals
6. Changing the amount of blood drawn, if within guidelines
7. Changing the person monitoring anesthesia (if person is properly trained)
8. Applying the protocol to a new strain or changing a strain of species.

18. Annual Review of Protocols: The IACUC will perform a formal review of ongoing activities at least annually. The review will be coordinated by the ORR and use a formal annual review form. Animal care and use activities are approved for a period of three years. Activities cannot be extended past the one-year or three-year expiration date. If the activity is not completed by the end of the period, the PI must submit a new Protocol Review Form, which will be reviewed in the same way as a new proposal.

19. Suspension of Activities: The IO has statutory authority to suspend animal care and use activities. Any suspension of animal care and use activities would necessarily be coordinated between the ORR, AV, and the IACUC following the noncompliance review process. This action represents a serious step that requires formal reporting to appropriate regulatory authorities and funding agencies. Animals on suspended protocols are moved to the LAR holding protocol and are the responsibility of the AV following the procedures set in the policy on Management of Animals on Lapsed Protocols.

20. Meetings: The full committee will meet the first Wednesday of each month if there is new business or compelling old business. IACUC meeting dates, times, and proposal submission deadlines are provided on the IACUC website.

Order of business for convened meetings will generally proceed as follows:

a. The Chair convenes the meeting
b. Administrative announcements
c. Review of minutes
d. Review of proposals
e. Old business
f. New business
g. Other items for discussion
h. Chair asks for motion to adjourn
i. Meeting adjourns
All meetings are open to the public, and investigators are welcome to attend. Investigators whose protocol will be reviewed at the full committee meeting are specifically invited to attend.

21. Special Subcommittees: In some instances, it may be appropriate to utilize special subcommittees of the IACUC. Examples where subcommittee might be useful include investigation of animal care and use complaints, evaluation of complex or problematic proposals or issues, or review of proposed activities that need expedited review because of unusual time constraints or circumstances, etc. The use of subcommittees for IACUC business will be at the discretion of the Chair. If appropriate, the Chair may use a consultant to assist the subcommittee in technical or specialized review, deliberations, or investigations. Consultants cannot vote on an activity unless they have formally appointed as a voting member of the committee. No IACUC members will be purposely excluded from special subcommittees, and when feasible, all members will be invited to participate in activities of special subcommittees.

22. Use of Telecommunications for IACUC Meetings: The traditional convened meeting, physically attended by IACUC members, provides the optimal forum in which to conduct full committee review of proposals and consider suspensions. Introduction and integration of new members to the Committee is also most effectively accomplished during physically-convened meetings. However, OLAW recognizes that some forms of telecommunications facilitate the conduct of business, reduce regulatory burden, are standard practices in many forums, and enhance flexibility without compromising the quality of deliberation and interaction. The IACUC chairperson, as the appointed leader of the committee, bears some responsibility for holding committee meetings in a manner that encourages participation and facilitates interaction among members. Methods of telecommunications (e.g., telephone or video conferencing) are acceptable for the conduct of official IACUC business requiring a quorum, provided the following criteria are met:

1. All members are given notice of the meeting.
2. Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
3. All members have access to the documents and the necessary technology to fully participate.
4. A quorum of voting members is convened when required by PHS Policy.
5. The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
6. If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
7. Opinions of absent members that are transmitted by mail, telephone, fax, or email may be considered by the convened IACUC members but may not be counted as votes or considered as part of the quorum.
8. Written minutes of the meeting are maintained in accord with PHS Policy, IV.E.1.b.

23. Program Veterinary Care Surveillance: The ISU has adopted a formal veterinary care surveillance program providing for visits to animal care and use facilities on campus. During veterinary care visits, animal health and well-being, husbandry, sanitation, and other pertinent aspects of animal care and use will be monitored. The frequency of visits to individual animal care and use areas will be based on animal use activity and need but will usually occur once a month.

Specific components of the program of adequate veterinary care include (9 CFR 2.31):

1. Ensuring the availability of appropriate facilities, personnel, equipment, and services to comply with the regulations;
2. Implementing appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and assure the availability of emergency, weekend, and holiday care;
3. Assuring daily observation of all animals to assess their health and well-being;
4. Providing guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and
5. Ensuring adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

24. Scientific Review: Scientific review of research proposals is conducted at the departmental level, and the signature of the department chair signifies that the proposed research has scientific merit. The signature of the department chair also represents a departmental assurance that the research will be conducted in compliance with the IACUC-approved protocol. Scientific review may also be conducted through the peer-review process by various funding agencies.

Although the IACUC is not intended to conduct peer review of research proposals, the federal regulations include language such as “consistent with sound research design,” “rationale for involving animals or humans,” and “scientifically valuable research,” which requires that the committees consider in their review the general scientific relevance of a research study. Proposals that do not meet these basic tests are not justifiable and cannot be approved. If a compliance review committee(s) has concerns about the scientific merit of a project, and if the project was not competitively funded and peer reviewed, or was funded by corporate sponsors, the project may be referred to a scientific review committee. The scientific review committee will be ad hoc and will consist of ISU faculty and outside experts as needed. If this situation arises, the PI will be contacted and given the option of agreeing that a consultant may be contacted or withdrawing the proposal from consideration.

25. Reporting of Adverse Events: Principal investigators are required to promptly report any happenings not consistent with routine expected outcomes that results in any unexpected and/or significant animal welfare issues (e.g., death, disease, or distress) or human health risks (zoonotic diseases or injuries) using the “Adverse Event/Unanticipated Problem Form”. Upon receipt of an adverse event forms/notifications by the ORR the DORR will confer with the IACUC Chairs(s) and/or Attending Veterinarian, or ISU Biosafety Officer in the event of human health risks, to determine if immediate review is required. If no immediate concerns or welfare issues are present, the adverse event will be forwarded to the committee for: 1) their review at a subsequent meeting, or 2) their information. The committee will determine if any adverse events forwarded for their review require changes or modification to the protocol in order for IACUC approval to continue. Any member may request review of an adverse sent to the committee for their information at any time.
Appendix 1

Animals on Campus

The spread of infectious agents between animal populations can be prevented, and humans can be protected from zoonotic agents by adhering to the following basic guidelines. IACUC members should be particularly careful to follow these guidelines when conducting inspections:

- Foot baths must be used (when provided) upon entering and leaving an animal room.
- All animal room doors must remain closed at all times, except for entering and exiting.
- Disposable gloves must be worn when handling animals, bedding, or soiled cages.
- Disposable or washable outer garments (such as lab coats, gowns, coveralls) protect your personal clothing from contamination when working with animals.
- Eating, drinking, smoking, applying cosmetics, and handling contact lenses in animal rooms and procedure rooms is prohibited.
- Hand contact with your nose, eyes, or mouth is strongly discouraged when working with animals.
- Hands must be washed with soap and water immediately after handling any animals or animal equipment and before leaving the animal facility or laboratory.
- Extra caution must be taken with needles or other sharp equipment used with animals. Needles shall remain capped until ready to use and then, disposed of promptly and properly. The Sharps and Biohazardous Waste Policy details proper disposal procedures.
- Handling only those species for which proper handling training has been provided can prevent injury.
- Any bites or other wounds must be washed immediately with soap and water, reported to your supervisor, and attended to by appropriate medical personnel.
- Unauthorized persons are prohibited from entering animal rooms.

Additional requirements may be specified for certain research studies.

Animals in the Field

Fieldwork involving wild animals requires adapting the basic animal infection control guidelines to the particular situation in the field. One of the major concerns with fieldwork is exposure to wild rodents that might carry Hantavirus or other zoonotic diseases. Personnel working in areas where they are likely to be exposed to wild rodents or their nesting areas must follow the Guidelines for Experiments with Wild Rodents. <Link to website>
Appendix 2
Facility Inspection Checklist for
Animal Housing and Support Areas

Location: animal areas separate from personnel areas, separation of species, and separation of disease status

Construction: corridors, doors, windows, floors, drainage, walls, ceilings, HVAC, power and lighting, noise

Room/cage: temperature, humidity, ventilation, illumination, noise control

Cage/run: sanitation, cleaning tools, food/water access, security, size, safety; allows undisturbed observation; rationale for Guide/USDA exceptions; meets physiologic, behavioral, social needs

Sheltered or outdoor housing (barns, corrals, pastures, islands): weather protection, ventilation & sanitation of shelters (no waste/moisture build-up), animal acclimation, social compatibility, roundup/restraint procedures, security

Behavioral management: environmental enrichment, social grouping, animal activity

Food: feeding schedule and procedures, contamination, vendor quality control, storage in sealed containers, expiration date labeling, vermin control, rotation of stocks

Water: ad libitum unless justified, QC procedures

Bedding: species-appropriate, keeps animals dry, QC procedures, minimizes scientific variables

Sanitation: frequency of bedding change (note Guide exceptions), cleaning and disinfection, monitoring

Waste disposal: procedures for collection, storage and disposal of waste; hazardous waste; animal carcasses

Pest control: regularly scheduled, documented program including control of rodent pests and insecticide use

Emergency, weekend, and holiday animal care: provision for, accessible contact information, monitoring of backup systems, veterinary care

Animal identification and records: cage/rack cards contain required information, clinical records accessible and appropriate

Genetics and nomenclature: appropriate genetic records and monitoring procedures, use of standardized nomenclature

Storage: food and bedding, supplies, drug and biologics, waste material, hazardous material, carcasses

Personnel: locker rooms, administration and training

Specialized space: Receiving, quarantine, isolation, necropsy, radiology, diet preparation
Cagewash

Construction: doors, windows, floors, drainage, walls, ceiling (see Guide)
- convenient to animal areas/waste disposal
- ease of access (including door size) facilitates use
- sufficient space for workload
- safety precautions/clothing/equipment used for bedding disposal/prewash/acid wash
- traffic flow: clean to dirty, with no contamination of clean equipment by dirty equipment
- insulation and/or sound attenuation present as needed
- utilities are appropriate
- ventilation meets heat and humidity load and Guide requirements
- safety features (SOPs, warning signs, eyewash station) are in use
- cagewash temperatures are monitored and records are available
- appropriate clean cage storage

Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries

General concerns: drug storage, control, and expiration dates
- sharps disposal
- anesthetic monitoring
- gas cylinders immobilized
- scavenging of anesthetic gases
- warning signs
- carcass disposal

Additional concerns for survival surgery (rodent or minor procedures only)
- rodent survival surgery clean and uncluttered, not used for anything else during surgery
- records of perioperative care
- aseptic procedures
- autoclave monitoring procedures
- storage of autoclaved materials
- cold sterilization procedures are appropriate
Aseptic Surgery

General considerations:
- location minimizes traffic/contamination
- functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) according to the Guide
- appropriate drug storage, control, expiration date monitoring
- safe sharps disposal system
- adequate records of anesthesia and perioperative care
- aseptic procedures in use for all survival surgery

Operating room:
- effective contamination control procedures
- effective cleaning procedures/dedicated tools
- interior surfaces smooth and imperious to moisture
- HVAC system meets Guide requirements
- lighting safe and appropriate
- outlets safe and appropriate
- scavenging of anesthetic gases implemented
- warning signs posted where needed
- fixed equipment is sanitizable

Surgical support:
- facility for washing, sterilizing, storing instruments and supplies
- autoclave monitoring procedures are implemented
- storage of autoclaved materials maintains sterility
- cold sterilization procedures are appropriate

Animal preparation: contains large sink to facilitate cleaning of animal and operative sites

Surgeon scrub: outside operating room, non-hand operated sink

Postoperative recovery:
- allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury

Dressing area: place for personnel to change
## Semiannual Facility Evaluation

*M = minor deficiency  S = significant deficiency*

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