LOUISIANA STATE UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
POLICY MANUAL

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POLICY #A-1

Title: New IACUC Member Recruitment

Purpose: To describe the procedure and schedule for recruiting new members to the LSU IACUC.

Background:

Members will be sought to retain a balanced representation of animal users from the SVM and main campus, and to represent the spectrum of animal species utilized at LSU. This will give all sectors of the campus the opportunity to have input into animal use policies and will ensure a broad range of expertise.

Policy:

1.1 The LSU IACUC consists of 9-11 members. IACUC members shall serve for a term of three years. The Attending Veterinarian, or his named alternate, serves permanently.

1.2 Members may commit to an additional three-year term at the end of three years. The member should not serve more than two consecutive terms.

1.3 The IACUC will nominate and discuss prospective new members.

1.4 In accordance with federal regulations, no more than 3 members will be from the same administrative unit. An administrative unit is defined as a department.

1.5 The IACUC will recommend prospective new members to the Institutional Official, who will ask these persons to serve.

1.6 The IACUC Manager shall notify OLAW of changes in the composition of the committee each year at the time of filing of the annual report.

Date last reviewed: July 11, 2023
Date last amended: July 11, 2023

POLICY #A-2

Title: Training of New IACUC Members

Purpose: To ensure adequate training of IACUC members.

Background:

It is essential that new IACUC members receive training regarding the purpose, composition, and operation of the IACUC. It is also imperative that committee members receive on-the-job training

Policy:

1.1 Within three months of appointment to the committee, new IACUC members shall attend a training meeting with a member of the DLAM staff. New members will be introduced to the purpose and function of the IACUC through a review of the "*Guide for the Care and Use of Laboratory Animals"*, the "Animal Welfare Act", the "Report of the AVMA Panel on Euthanasia", the semiannual facility inspection and programmatic review checklists provided by OLAW, the "*Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching"*, "*Biosafety in Microbiological and Biomedical Laboratories", "Occupational Health and Safety in the Care and Use of Research Animals*", the "PHS Policy", the series of guidelines developed by various associations covering the humane use of specific animal species in field studies, and the LSU IACUC policies. New IACUC members will be instructed on how to access these and other IACUC resources on the internet, and will be made aware of opportunities to attend training meetings and workshops.

1.2 If they have not done so already, new members will also be instructed to register with the AALAS Learning Library and complete the modules titled, "Working with the IACUC at LSU" and "Essentials for IACUC Members".

1.3 New member training will be documented through notes placed in the IACUC meeting minutes.

1.4 Opportunities for continuing, on-the-job training will be provided to the IACUC by the DLAM Director, Associate Director, or IACUC Manager; and will include notification of web-based materials, journal articles, etc. as relevant to the oversight of an animal use program and facility.

Date last reviewed: June 13, 2023
Date last amended: June 13, 2023

Policy #A-3

Title: Performance Criteria for IACUC Members

Purpose: To establish a policy regarding performance criteria for IACUC members, including preparation for and attendance at convened monthly IACUC meetings, and participation in semiannual facility inspections and programmatic reviews.

Background:

1.1 Federal regulations, including the 8th edition of the *Guide for the Care and Use of Laboratory Animals (2011)* prescribe the membership, roles, and responsibilities of the IACUC. The *Guide* also states that a quorum of the voting members must be in attendance for the IACUC to conduct business. Alternate members may attend and vote if such persons have been identified as alternate members in the annual report to the OLAW. There is no accommodation for "proxy" voting in the absence of a regular member.

1.2 On occasion, IACUC members are unable to attend or fully participate in IACUC activities because of teaching responsibilities or other professional or personal commitments. Because the committee cannot legally conduct business without a quorum of members, problems arise when individual members consistently fail to attend meetings. Additionally, members attending IACUC meetings who have failed to adequately prepare negate the benefits of multiple committee members, compromise the quality of discussions and decisions which can be made by the remaining members, and may transfer to other members their share of the burden of protocol review.

1.3 The IACUC Handbook (2nd Ed) states:

"*Most organizations agree that… poor attendance at or participation in IACUC activities, or repeated inadequate preparation for assigned IACUC duties might constitute sufficient reason to seek the removal of a member. Ideally, these broad areas would be included in the bylaws developed for the IACUC, and the IACUC members would be informed during their initial IACUC training of the general performance criteria for committee members. The IACUC Chair or IO should inquire whether there are any mitigating circumstances for those members who cannot regularly attend two-thirds of the IACUC meetings held annually and consider the replacement of these individuals if better attendance is not forthcoming*."

Policy:

2.1 The IACUC Manager will notify the IACUC Chair when an individual committee member has missed sufficient convened IACUC meetings as to put the member on track to miss more than one-half (approximately 6) of the IACUC meetings to be held annually. Similarly, the IACUC Manager will notify the IACUC Chair when the Manager observes that a committee member consistently fails to diligently review protocols or amendments or fails to contribute in meaningful ways to the activities of the committee.

2.2 When an IACUC member is identified as not meeting the expected performance criteria, the committee Chair will contact the member to determine the reasons for non-performance/attendance.

2.3 Following inquiry by the Chair, the Chair will determine whether to keep the member on the IACUC or to replace the member with a person likely to better fulfill the responsibilities of the position. If the Chair determines that a member should be removed from the committee, the Chair will write a letter of dismissal to the member. At the next convened meeting of the IACUC, the Chair will have placed on the meeting agenda, a discussion about replacement of the member.

Date last reviewed: July 11, 2023
Date last amended: July 11, 2023

Policy #A-4

Title: Annual Review of IACUC Policies

Purpose: To ensure regular review and revision of IACUC policies.

Background:

1.1 The LSU IACUC has developed a series of policies regarding animal care, IACUC activities, occupational health and safety, and other topics. These policies have proven useful for ensuring continuity of the LSU animal program.

1.2 A policy is needed to ensure regularly scheduled review and revision of IACUC policies so that all active policies remain up to date.

Policy:

2.1 The IACUC will conduct review of all IACUC policies ensuring each policy is reviewed every one to three years. Policies found to be out-of-date will be amended.

2.2 At least two policies will be reviewed at each monthly meeting of the IACUC. The following review will start over again following the same order.

Date last reviewed: July 11, 2023
Date last amended: July 11, 2023

POLICY #A-5

Title: Investigators Appearing Before the IACUC

Purpose: To establish a policy that will stipulate conditions under which investigators may appear before the IACUC.

Background:

The IACUC recognizes that there may be occasions when investigators desire to appear before the committee to express concerns or grievances, or to state their position on noncompliance issues, etc. Likewise, there are times when the IACUC may desire that an investigator attend in order to provide clarification or explanation on matters related to protocols or other issues.

Policy:

1.1 Investigators may request to be placed on the IACUC agenda to address concerns, state grievances, or state their position on noncompliance issues. Likewise, the Chair of the IACUC may place an investigator's name on the agenda so that the committee can request clarification or explanation on matters related to protocols or other issues.

1.2 Investigators will be scheduled to appear before the IACUC at the beginning of the meeting. Investigators requesting an audience with the IACUC will be allowed up to 10 minutes to communicate concerns, etc. to the committee. The IACUC Chair will then ask the investigator to exit the room while their position is discussed.

Date last reviewed: August 21, 2023
Date last amended: December 8, 2011

POLICY #A-6

Title: GeauxGrants Proposal Tracking Approvals

Purpose: To establish a policy that stipulates conditions under which a representative of the IACUC enters a recommendation of approval in GeauxGrants in the Tracking Approvals section.

Policy:

1.1 The following persons are authorized to enter a recommendation of approval in GeauxGrants for an investigator's grant proposal: IACUC Manager and Attending Veterinarian.

1.2 No approval in GeauxGrants is to be entered unless an animal care and use protocol has been approved by the IACUC and the protocol and grant proposal have been found to be congruent.

Date last reviewed: August 21, 2023
Date last amended: August 21, 2023

POLICY #A-7

Title: Facility inspections and programmatic review: Frequency and timing

Purpose: To ensure the semiannual inspection of animal facilities and review of the LSU animal program in accordance with federal requirements.

Policy:

1.1 In accordance with federal regulations, the IACUC shall inspect the LSU animal facility and review the LSU program for animal use. These reviews will occur semiannually, with no more than six months elapsing between reviews.

1.2 Facility inspections and programmatic reviews will occur in April and October of each year, unless the IACUC agrees upon a permanent schedule change and no more than six months elapse since the last review.

1.3 In accordance with federal policies, a triennial AAALAC site visit may substitute for a semiannual facility inspection and programmatic review by the IACUC.

Date last reviewed: September 12, 2023
Date last amended: September 12, 2023

Policy #A-8

Title: Principal Investigator Criteria and Responsibilities

Purpose: To define the criteria for permitting individuals to fulfill the roles and responsibilities of a Principal Investigator (PI)

Background:

The PI is responsible for assuming compliance with applicable IACUC policies and procedures, the Animal Welfare Act (AWA), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and The National Research Council (NRC) *Guide for the Care and Use of Laboratory Animals*. Although the PI may delegate tasks to members of their research team, the PI retains ultimate responsibility for the conduct of the study.

Policy:

1.1 Since the PI responsibilities involve direct interaction and supervision of the research team, the PI must be current faculty of the University. Per the LSU Board of Supervisor's Rules and Regulations manual, faculty includes full-time members of the academic staff on the various campuses with the rank of Instructor or above and equivalent ranks.

1.2 In order to ensure the project is conducted by those who have the requisite skills, training, and ability to uphold LSU's institutional commitments, the following individuals may serve as PI:

1.2.1 Tenure-track or Clinical-track Professors (Full Professors, Associate Professors or Assistant Professors)

1.2.2 Research Professors, Associate Research Professors, or Assistant Research Professors

1.2.3. Senior Research Scientists or Research Scientist

1.2.4 Senior Research Engineers or Research Engineers

1.2.5 Emeritus Faculty

1.2.6 Instructors

2.3 Anyone holding the title of Curator, Associate Curator and Assistant Curator can serve as a PI on an animal care and use protocol (Protocol). Per the LSU Board of Supervisor's Rules and Regulations manual, the ranks of Curator, Associate Curator and Assistant Curator shall be equivalent to those of Professor, Associate Professor and Assistant Professor, respectively.

2.4 Anyone in the position of Emeritus Faculty or an Instructor are required to provide the IACUC with an approval letter from their Departmental Chair/Head, Dean, etc. The approval of the Protocol shall not exceed the life of their

employment at LSU or for 3 years, whichever comes first.

2.4 Student employees (graduate assistants, students, interns/residents) may not serve as a PI for an IACUC protocol, even if the protocol is for their own research projects. Student employees cannot submit a Protocol.

2.5 Adjunct Professors may not serve as PI for research projects and cannot submit a Protocol.

2.6 Qualified co-investigators and research staff may perform tasks as delegated by the PI, but they do not accept primary responsibility for the research study. Research conducted by non-faculty, academic support staff, post-doctoral fellows, staff appointments, graduate students or undergraduate students must be under the direction of a faculty member, as outlined in 1.2.

2.6 The PI may delegate the performance of any or all components of the research to non-faculty if they certify to the IACUC that the individual(s) are sufficiently trained to perform the functions assigned.

2.7 By submitting a Protocol to the IACUC for review, the PI is certifying the following:

2.7.1 The PI and all participants on the Protocol agree to abide by the Policy for the Care and Use of Animals of Louisiana State University. Projects will be in accordance with the NRC *"Guide for the Care and Use of Laboratory Animals"*, and the Louisiana State University Animal Welfare Assurance on file with the U.S. Public Health Service.

2.7.2 All participants on the Protocol will abide by all federal, state, and local laws and regulations governing the use of animals in teaching and research.

2.7.3 All participants on the Protocol are adequately trained to perform the research techniques required in the Protocol.

2.7.4 The fewest number of animals required to produce valid results are being used in the research study.

2.7.5 The PI understands it is his/her responsibility to ensure that all personnel involved in the care and use of animal who are participating on a protocol must participate in the Occupational Health and Safety Program.

Date reviewed: September 12, 2023
Date last amended: September 12, 2023

POLICY #B-1

Title: Animal Use Protocol Amendments: Administrative Handling of Changes to Approved Protocols

Purpose: To provide guidance to the LSU-IACUC and investigators on how amendments to approved protocols will be processed and reviewed in accordance with federal guidelines.

1.1 OLAW provides guidance on "Significant Changes to Animal Activities." This guidance defines the process the LSU IACUC will use to process PI requests to amend an approved protocol. The process is listed here in sections 1.1 to 1.5. Significant changes that will require **Full Committee Review (FCR) or Designated Member Review (DMR)** include the following:

1.1.1 Changes in study objectives.
1.1.2 Changes in procedural invasiveness, or in the distress or pain experienced by an animal.
1.1.3 Changes from non-survival to survival surgery.
1.1.4 Changes in the species of animals used.
1.1.5 Change in principal investigator.
1.1.6 Changes that impact personnel safety.
1.1.7 Changes in housing and/or the use of animals in a location that is not part of the animal program overseen by the IACUC.
1.1.8 Addition of a new procedure.
1.1.9 Note: The IACUC may determine a new protocol is required depending on how complex the proposed protocol changes are or based on the number of changes that have been made through the amendment process from the original protocol.

1.2 Significant changes that will be handled administratively by the IACUC Chair in documented **consultation** with the Attending Veterinarian (AV) or another veterinarian designated by the AV, include:
1.2.1 Changes in anesthesia, analgesia, sedation, or experimental substance administration.
1.2.2 Changes in the route of substance administration.
1.2.3 Changes in duration, frequency, or the number of approved procedures to be performed on an animal.
1.2.4 Changes in the sex of animals to be used.
1.2.5 Changes in the strain of animal.
1.2.6 Adding an undergraduate, graduate, or professional course to an approved protocol.
1.2.7 Changes in the housing and or the use of animals in a location that is part of the animal program overseen by the IACUC. Rooms should be approved prior to an amendment request.
1.2.8 An increase in animal numbers greater than 10% of the previously approved animal numbers (*See 1.3.1 for explanation*)
1.2.9 Change in adjuvant.
1.2.10 Need to repeat an experiment.
1.2.11 Changes in euthanasia method to any method of euthanasia approved by the AVMA Guidelines for Euthanasia of Animals (2020).

1.2.12 References for the above changes (if needed) include, but are not limited to, Plumbs Veterinary Drug Handbook, Formulary for Laboratory Animals by Hawke and Leary, Exotic Animal Formulary by Carpenter, Laboratory Animal Anesthesia by Flecknell, Comparative Medicine, JAALAS, ACLAM Formulary, all IACUC policies, etc.

1.2.13 Any other significant changes that do not fall into section 1.2 above or 1.3 below.

1.3 Significant and minor changes identified in protocol amendments that may be **handled administratively** by the IACUC Chair, without additional consultation, include:

1.3.1 Changes involving an increase in animal numbers equal to or less than 10% of the originally approved animal numbers. This 10% in animal number is based on recommendations listed in The IACUC Handbook, 3rd edition (pp. 189-190) by Silverman et al.

1.3.2 Changes involving the transfer of animals from one approved protocol to another.

1.4 Other changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:

1.4.1 Correction of typographical errors.

1.4.2 Correction of grammar.

1.4.3 Contact information updates.

1.4.4 Changes in personnel, other than the PI.

1.5 Notes regarding animal use signature authority, include:

1.5.1 All communications between animal users and the IACUC must be submitted by the principal investigator.

1.5.2 Electronic signatures are acceptable.

1.5.3 Scientific, clinical, or instructional staff cannot submit or sign amendments, wet lab exemption requests, or protocols on behalf of the principal investigator.

1.5.4 If, as a result of a request by the IACUC, the principal investigator modifies an amendment request or protocol so as to significantly alter the assigned tasks or responsibilities of other persons participating in the animal activities, the principal investigator must re-obtain signatures from other participants.

Date last reviewed: February 20, 2024
Date last amended: February 20, 2024

POLICY #B-2

Title: Processing Protocols or Amendments after Full Committee Review

Purpose: To describe the method used by the LSU IACUC for processing protocols and amendments following full committee review when modifications are required to secure approval.

Background:

1.1 Often information is lacking from a protocol or amendment, or the committee may have questions requiring a response from the Principal Investigator (PI). These may preclude final approval by the IACUC in a convened meeting of the committee.

Policy:

2.1.1 When information is lacking from a protocol or amendment or when the committee has questions requiring a response from the PI, all members of the IACUC agree to the following procedures.

2.1.2 The IACUC will refer to policy B1 and use it as a guideline for processing the protocol moving forward.

2.1.3 The committee may choose to not approve the protocol, send the protocol to Designated Member Review (DMR), send the protocol for administrative approval with the IACUC Chair and Attending Veterinarian, or administrative approval with the IACUC Chair, or administrative approval with the IACUC manager alone.

2.1.4 If protocols or amendments are sent to DMR, subsequent options allowable to designated member reviewers include approval, requesting further changes to achieve approval, or sending the protocol back to the full committee for further review. A protocol sent to DMR cannot be rejected but must return to Full Committee Review (FCR).

2.1.5 Protocols may be deferred until the next regularly scheduled meeting if large amounts of information are needed to bring the protocol into compliance before approval.

2.1.6 Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

Date last reviewed: March 12, 2024
Date last amended: March 12, 2024

Policy #B-3

Title: Alternative Protocol Approval Mechanism

Purpose: To establish an alternative mechanism for protocol approval due to lack of a quorum at a regularly scheduled IACUC meeting, or in the event of extenuating circumstances.

Background:

1.1 Occasionally the LSU-IACUC fails to make quorum required for protocol approval at a regularly scheduled meeting. Rarely, a quorum is met but one member has a conflicting interest resulting in lack of a quorum and the ability to vote on a given protocol. Rarer still are occasions in which protocol review is requested prior to regularly scheduled meetings.

1.2 The IACUC recognizes the importance of prompt protocol approval such that research can proceed in a timely manner. However, rescheduling meetings may be impossible due to personal or work related conflicts with many of the IACUC members. Delaying protocol review to the following regularly scheduled meeting may result in a chain reaction of delays depending upon the time available for meetings.

1.3 The IACUC established an alternative mechanism for protocol approval to minimize delays or additional work for IACUC members while following the letter and the spirit of applicable laws.

Policy:

2.1 In the event a quorum is not met at a regularly scheduled meeting, or if IACUC approval is needed prior to a regularly scheduled meeting the IACUC chair may elect to proceed as follows.

2.2 All IACUC members must be asked if they would like the protocol or protocols in question reviewed by the full committee.

2.2.1 If IACUC members have not seen a copy of the protocol, access to the protocol will be provided on the shared drive (OneDrive) or via the online portal in GeauxGrants to each member by the IACUC Manager.

2.2.2 The PI is responsible for filing the IACUC Protocol in the online portal in GeauxGrants or, if this system is not available, sending an electronic copy to the IACUC's designated email address in the event the IACUC Manager cannot provide members with an electronic copy.

2.2.3. The PI must also submit justification for their request to have their protocol reviewed prior to the next regularly scheduled IACUC meeting.

2.2.4 IACUC members should be given a minimum of 5 days to respond from receipt of the protocol.

2.3 If any member requests full committee review for a given protocol it will have to be discussed at the next scheduled meeting. Otherwise, the IACUC Chair may proceed as follows.

2.4 The IACUC Chair may assign a committee member as the designated reviewer to review a given protocol. The IACUC chair must not assign him or herself as the designated reviewer.

2.5 The designated reviewer may proceed with one of the following three options.

2.5.1 Approve the protocol as is

2.5.2 Require modifications for approval

2.5.3 Request full committee review

2.6 The designated reviewer cannot disapprove a protocol.

Date last reviewed: January 9, 2024
Date last amended: June 17, 2021

Policy #B-4

Title: Animal Use Protocol Distribution

Purpose: To establish who should receive and maintain copies of approved IACUC protocols for reference, other than investigators.

The IACUC removed this policy as it is no longer needed since we have the electronic database system (GeauxGrants) available to review protocols.

Date last reviewed: March 12, 2024

POLICY #B-5

Title: Granting Reciprocity for Protocols Approved by other IACUCs collaborations

Purpose: To establish a formal written understanding between LSU and collaborating institutions regarding the responsibilities and oversight of animal care and use.

Background:

1.1 Occasionally, funds pass through LSU in the form of subcontracts or sub-awards to allow LSU faculty to conduct portions of sponsored research at other institutions (performance site). In these cases, work involving animals is approved by the IACUC at the performance site.

1.2 Occasionally, LSU protocols require temporary housing in other facilities before transfer to LSU. The facilities where animals are temporarily housed before transfer to LSU are deemed the performance site.

1.3 The IACUC recognizes that a formal written understanding and system should be in place for recognizing animal care and use protocols approved by the IACUC of the performance site, for establishing animal ownership, and for assigning responsibility to ensure appropriate animal care and welfare.

Policy:

2.1 The procedure for LSU IACUC to recognize animal care and use protocols approved by the IACUC of the performance site, establish animal ownership, and assign responsibility to ensure appropriate animal care and welfare will be as follows:

2.1.1 The principal investigator submits a cover letter requesting LSU IACUC recognition of approval by the IACUC of the performance site. The letter must indicate whether the performance site: a) has an approved Assurance Statement on file with OLAW, b) is registered with the USDA as a research facility, c) is accredited by AAALAC International, and, d) must state that the performance site institution owns any research animals involved in the approved project and accepts full responsibility to provide oversight of animal care and use in a manner consistent with the *Guide* (the "Guide") *for the Care and Use of Laboratory Animals*, the *Animal Welfare Act*, and if applicable, the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (the "Ag Guide").

2.1.2 The investigator must provide a copy of the approved protocol and a copy of the approval letter from the IACUC at the performance site.

2.1.3 At the time of submission of the required material, the IACUC Secretary

will assign the protocol an LSU protocol number.

2.1.4 The IACUC Chairperson will review the submitted material and make a determination whether to honor the approval of the IACUC at the performance site. A letter so stating will be sent to the investigator and to the person at the performance site who signed their approval letter.

2.1.5 If the performance site is not AAALAC-accredited, representatives of the IACUC will visit and inspect the site for compliance with applicable animal care standards, including the "Guide", the "Ag Guide" and the Animal Welfare Act; or the IACUC will request video or photographic images of the performance site to ensure that the site is compliant with these standards. If the performance site is AAALAC-accredited, the LSU IACUC will accept such accreditation as assurance that the IACUC of the performance site institution is conducting semi-annual inspections and programmatic reviews in compliance with the standards listed above.

2.2 It should be noted that under the above arrangement, the performance site retains full ownership and responsibility for ensuring that animals used in their institution are cared for according to all applicable standards as listed above. This responsibility is to be clearly indicated in the approval letter sent to the investigator and to the IACUC of the performance site.

2.3 Clinical research protocols should refer to IACUC Policy #C-12 for guidance.

Date last reviewed: March 12, 2024
Date last amended: March 12, 2024

POLICY #B-6

Title: Submission of Late Protocols

Purpose: To establish conditions under which late protocol submissions will be accepted by the IACUC.

Background:

1.1 The IACUC has established a reasonable schedule for submission of animal care and use protocols and amendments that facilitates review of protocols in a timely manner.

1.2 Occasionally, investigators attempt to submit protocols or amendments after the deadline for consideration at the next IACUC meeting.

1.3 Federal regulations require that all IACUC members have the opportunity to review at least the titles of all protocols and amendments prior to a regularly convened monthly meeting. Accepting protocols/amendments after the protocol and agenda have been distributed to the IACUC make it difficult to provide the late-submitted protocol/amendment and/or title to all members of the committee prior to the monthly meeting. Late submission of the protocol/amendment does not allow members adequate time to review, will preclude review by absent members, and creates a hardship for the IACUC Manager.

Policy:

2.1 Protocols or amendments must be submitted before the end of the day, 8 days before the regularly convened monthly IACUC meeting. Late protocol/amendment submissions will not be accepted for consideration without the permission of the IACUC Chairperson.

2.2 With the approval of the IACUC Chairperson, it will be the responsibility of the submitting investigator to submit the protocol in the online portal in GeauxGrants or, if this system is not available, sending an electronic copy to the IACUC's designated email address. The IACUC Manager will notify the IACUC of the protocol submission prior to the monthly meeting.

2.3 Protocols that are received too late for consideration may be considered for DMR review according to procedures outlined in LSU IACUC policy #B3.

Date last reviewed: March 12, 2024
Date last amended: March 12, 2024

POLICY #B-7

Title: Type B, C, D, and E Protocol Assignments

Purpose: To define the conditions under which experiments or teaching exercises involving animals are classified as type B, C, D, or E.

The USDA requires annual reporting of the numbers of covered animals involved in experimentation, teaching, or testing, according to the level of pain or distress those animals experience in the course of the covered activities.

Policy:

1.1 Type B projects are those in which animals will be bred, conditioned, or held for use in teaching or research. (e.g., a breeding colony of mice from which animals will be transferred to experimental protocols).

1.2 Type C projects are those in which pain or distress is not induced, or in which animals experience "no more than slight or momentary pain or distress", or are simply humanely euthanized using methods outlined in the AVMA Guidelines for the Euthanasia of Animals (2020). See www.avma.org for additional information. Examples of methods causing no more than slight or momentary pain or distress include: compound injection, blood collection (other than by ear punch, tattoo, microchip implantation, and retro-orbital bleeding), urine or fecal collection; gastric gavage; toe clipping (≤ 7 days for mice or rats) or tail snips (pre-weaning only).

1.3 Type D projects are those in which pain or distress is likely to be produced but is prevented or relieved by appropriate therapy. Thus, all protocols that use anesthetics, or analgesics, or sedatives are Type D. Examples of procedures expected to cause pain or distress include: toe clipping (> 7 days for mice or rats); tail snips (at or after weaning); most other minor surgical procedures; and all major surgical procedures. In addition, due consideration is to be given to the emotional distress that may accompany non-painful procedures.

1.4 Type E projects are those projects in which pain or distress is likely to be produced but cannot be prevented or alleviated by therapy because to do so would invalidate the experiment. In these cases, the investigator must clearly justify for scientific reasons using the available scientific literature or based on professional experience, the need to disallow pharmacological intervention or euthanasia.

1.5 A procedure is considered painful or distressful in an animal species based on whether the procedure is likely to be painful or distressful in humans.

1.6 Protocols with mixed category types must select the highest category type performed.

Date last reviewed: March 12, 2024
Date last amended: March 12, 2024

POLICY #B-8

Title: Terrestrial Vertebrate Eggs in Research

Purpose: To establish that projects utilizing unhatched terrestrial vertebrate embryos at or after 80% of mean incubation period, require IACUC approval.

Background:

1.1 The NIH/OLAW has issued the following interpretation of PHS Policy for research involving avian embryos,

> "*The PHS Policy is applicable to proposed activities that involve live vertebrate animals. While embryonal stages of avian species develop vertebrae at a stage in their development prior to hatching, OPRR (now OLAW) has interpreted "live vertebrate animal" to apply to avians (e.g., chick embryos) only after hatching*."

1.2 In "The IACUC Handbook," the authors add the following,

> "... *However, the risk of eggs hatching and producing chicks (requiring food, water, proper housing, and veterinary care and placing them under the purview of PHS Policy) dictates that IACUCs consider developing policies for different aged avian embryos, newly hatched birds, and the point at which bird embryos are considered vertebrate animals. For chickens, the last 3 days of incubation (incubation days 18 to 21) represent the last stage of embryo development and coincide with the chick drawing the yolk sac into the body and having sufficient pulmonary maturation to handle oxygen and carbon dioxide exchange. During this period of time, some chicks may hatch normally and some prematurely hatched chicks could survive outside of the egg with little additional care*."

Policy:

In consideration of the above, the IACUC requires submission of an animal use protocol for projects utilizing pre-hatched terrestrial vertebrates at or after 80% of mean incubation period has been reached. An IACUC protocol shall be in place if the 80% of mean incubation period will be achieved during the course of study.

Date last reviewed: May 14, 2024
Date last amended: May 14, 2024

POLICY #B-9

Title: Fish Embryos and Larvae in Research

Overall Purpose: The purpose of this policy is to provide guidance for evaluating and submitting animal care and use protocols involving research with embryonic and larval fish.

Section 1.0: Fish larvae in research

Purpose: The purpose of this document is to provide guidance regarding the inclusion of fish under the Public Health Service Policy (PHS) on Humane Care and Use of Laboratory Animals. This document will describe requirements for housing fish in IACUC-accredited fish holding facilities, as well as the stage at which the use of larval fish of oviparous species must be covered by an approved animal care and use protocol.

Background & Policy:

1.1.1 Fish are considered embryos before hatch, and larvae after hatch.

1.1.2 PHS policy does not apply to fish embryos; their use does not need to be covered by an approved protocol.

1.1.3 The NIH Office of Laboratory Animal Welfare (OLAW) considers fish species live vertebrae animals at hatch. Time to hatch depends on species, but typically occurs 3 days post-fertilization for zebrafish and by 14 days post-fertilization for Gulf killifish.

1.1.4 Fish develop backbones before hatch. Current OLAW interpretation of PHS policy views aquatic species as "live, vertebrate animals" at hatch.

1.1.5 Post-hatch, all fish (larvae, fry, adults) must be housed in an IACUC-accredited facility and covered on an approved animal care and use protocol.

1.1.6 Post-hatch, fish larvae are not nutritionally independent, and will obtain sustenance from their yolk for up to several days. The time to nutritional independence correlates with neurologic development to pain perception.

1.1.7 For purposes of pain management and euthanasia, the time to nutritional independence can serve as a transition point from embryo to larvae. For zebrafish, the transition point is 5 days post-hatch. At and beyond 5 days post-hatch, zebrafish larvae must be treated as adult fish and be provided with appropriate pharmaceuticals for pain management and humane euthanasia.

1.1.8 The pain management and euthanasia transition point for other fish species will also be set at 5 days post hatch, unless the investigator familiar with the biology of the particular species can justify a different age post-hatch.

Section 2.0: Field studies involving fish

Purpose: To ensure that I.A.C.U.C. and field researchers utilize sound scientific and professional guidelines in evaluating and submitting animal use protocols for field investigations involving fish and to promote the principle of humane euthanasia of fish involved in field studies.

Background:

2.1.1 American Fisheries Society (AFS) has produced Guidelines for the Use of Fishes in Research (2014).

2.1.2 The LSU IACUC supports the policies in this guideline regarding collecting methods, live capture techniques, field restraint (anesthesia and other chemical restraint), handling and transport, physical facilities for temporary holding and maintenance, field acclimation, collection of blood and other tissues, and marking and tagging and field euthanasia.

Policy:

2.2.1 Protocols should adhere to the procedures outlined in the AFS guidelines to the extent possible within the constraints of the scientific investigation or field survey. Protocols should also state their adherence to these guidelines.

2.2.2 In instances where the proposal does not adhere to AFS guidelines, the protocol shall provide scientific justification for the proposed variance.

2.2.3 In instances where field manipulations of fish are not covered by policies in the AFS guideline, the investigator shall provide background information/references that support the proposed methods of handling and manipulating fish.

2.2.4 Investigators collecting fish in the field are encouraged to anesthetize fish with MS222 or other suitable anesthetics as in the guidelines prior to euthanasia. The committee recognizes that this may be unfeasible when working with larger specimens or in remote locales. For small fishes, immediate immersion in an ice slurry may be substituted. For larger specimens, the investigator must provide scientific justification for not anesthetizing fish prior to euthanasia.

2.2.5 Fish anesthetized with MS222 cannot be released into natural waters for 21 days in accordance with EPA rules to prevent human consumption of previously anesthetized fish.

Section 3.0: Laboratory studies involving fish

Purpose: To ensure that IACUC and laboratory researchers utilize sound scientific and professional guidelines in evaluating and submitting animal use protocols for laboratory investigations involving fish and to ensure the humane euthanasia of fish.

Background:

3.1.1 American Fisheries Society has produced Guidelines for the Use of Fishes in Research (2004).

3.1.2 The LSU IACUC supports the policies in this guideline with regard to acclimation to laboratory conditions, physical facilities, density of animals, feeds and feeding, water quality assurance, restraint and anesthesia, and euthanasia.

Policy:

3.2.1 Protocols shall adhere to the procedures outlined in the AFS guidelines to the extent possible within the constraints of the scientific investigation.

3.2.2 In instances where the proposal would not adhere to AFS guidelines the protocol shall provide scientific justification for variance from these guidelines.

3.2.3 In instances where laboratory manipulations of fishes are not covered by policies in the AFS guideline, the investigator shall provide background information/references that support the proposed manipulations of fishes.

3.2.4 Hypochlorite can be used to euthanize unhatched and hatched zebrafish up to 7 days post-fertilization. Rapid chilling and MS222 are unreliable euthanasia methods in embryos.

3.2.5 Rapid chilling to 2-4 °C is a suitable in zebrafish >7 days post-fertilization. This may be a suitable euthanasia method for other fish species.

3.2.6 Buffered MS222 may be utilized, unless another method can be justified for scientific reasons. If another form of chemical anesthesia will be proposed, suitable scientific background information should be provided in the protocol or consultation with the attending veterinarian should be described.

Date last amended: May 14, 2024
Date last reviewed: May 14, 2024

POLICY #B-10

Title: Blood Withdrawal Restrictions

Purpose: To protect animal well-being by establishing limits to the volume, frequency, and site of blood collection from animals used on approved teaching and research protocols.

Background:

1.1 Most vertebrates contain 6-7ml blood/100 gm body weight. Studies have shown that hemodynamic changes result from losses >25% of total blood volume. Smaller percentages, while safe for the animal, may alter normal physiologic functions and impact study results. Care should be taken when serial blood sampling is utilized.

1.2 Studies in rats, dogs, and horses have shown that when erythrocytes are returned and plasma replaced, up to 33% of blood volume may be removed weekly for several months without causing harm to the animal.

1.3 Recent advances in the humane care of laboratory animals have included recommendations that blood be removed from the facial artery of mice ("submandibular" bleeding), as a humane alternative to retro-orbital sinus bleeding, which is considered more stressful to mice, and has the potential to result in greater tissue damage and pain versus submandibular bleeding.

Policy:

2.1 The maximum volume of blood that can be safely collected from an animal is that volume which represents 1.5% of the animals body weight over the course of two weeks. This figure was derived as follows: Blood volume = 6% of body weight; 25% of blood volume can be safely removed from an animal each two weeks. Blood collection in excess of 1.5% of body weight in a two week period may be approved by the IACUC if scientific justification is provided by the investigator.

2.2 The 1.5% value above is established for the safety of the animal. However, best study practices suggest that blood withdrawal not exceed 0.6% to 0.9% of body weight every two (2) weeks to minimize, if not eliminate, volume loss impacts on study results. (Diehl et al, J. Appl. Toxicol., 21, 15-23, 2001) Where blood volume is known for a given species, that value should be utilized to calculate blood withdrawal volumes.

2.2 When erythrocytes are returned to the animal, up to 33% of total blood volume (2.2% of body weight) may be removed weekly. Plasma should be replaced with an equal volume of lactated Ringer's solution, normal saline, or suitable volume expander.

2.3 For mice, acceptable sites of blood collection include the facial artery (submandibular bleeding), saphenous vein, heart (under anesthesia), or tail artery. In other species, retro-orbital bleeding (under anesthesia) may only be performed by trained personnel when justified for scientific reasons and when approved by the IACUC.

Date last reviewed: June 11, 2024
Date last amended: June 11, 2024

Policy #B-11

Title: Rodent Cumulative Tumor Burden

Purpose: To extend guidance for investigators and prevent undue distress or suffering of research animals while providing physiologically stable biologic models for cancer research.

Background:

1.1 Tumor (cancer) implantation in research animals is a critically important experimental activity which also requires consideration of the effect of the tumor on the animal. Outcomes of tumor studies, including death as an endpoint, vary depending on the species and strain of animals, the route of injection for transplantable tumors and the subsequent chemotherapy or other modality in cancer treatment studies. At all times during this process, the well being of the research animals must be balanced against requirements of the study. Cancer studies can broadly be divided into two categories, biology and treatment:

1.1.1 Cancer biology is the study of how tumors grow and behave. This policy is intended to limit the tumor burden an animal experiences to that which does not cause excessive pain or distress, but achieves the research goal.

1.1.2 Cancer treatment is the study of the response of tumors to chemical, radiologic or immunologic therapy. In this class of study, not only must the tumor burden be considered, but the effect of the treatment modality must also be evaluated. The purpose of all cancer treatments, whether radiologic, immunologic or chemical, is to destroy or disable the cancer cells while minimizing damage to healthy tissues. The success of a treatment becomes a balance between cancer destruction and reduction of side effects.

Policy:

2.1 This policy is for cumulative tumor burden per animal. If multiple tumors occur (an unusual situation), the total tumor burden cannot exceed the parameters noted below.

2.2 Animals showing any of the signs below will be euthanized, unless an exemption is granted by the IACUC:

2.2.1 Overall visible tumor dimensions in any one location on the body exceeding:

2.2.1.1 Mice: 2 cm in diameter.

2.2.1.2 Rats: 5 cm in diameter.

2.2.2 Tumors that are ulcerated AND appear painful and/or infected. If an exemption is provided for this condition, the affected animals are required to be single housed (may require protocol amendment and/or alternate environmental enrichment or medical treatment),

2.2.3 Tumors where the animals chew on the lesion or pay undue attention to the ulcer,

2.2.4 Tumors that interfere with 'normal' animal functions (e.g., eating, drinking, defecating, or ambulating).

2.3 Animals showing other clinical signs that require veterinary intervention or are suggestive of tumor related disease, such as metastases or ascites:

2.3.1 Significant abdominal distension, especially when it begins to compromise respiratory ability of animal.

2.3.2 Hunched posture with easily visible vertebral bodies.

2.3.3 Failure to eat or drink.

2.3.4 Absence (or abnormal) of fecal or urine output.

2.3.5 Rough hair coat.

2.3.6 Reluctance to move or abnormal gait.

2.3.7 Discharges or hemorrhage.

2.3.8 Abnormal behavior or vocalizations.

Date last reviewed: June 11, 2024
Date last amended: August 13, 2019

POLICY #B-12

Title: Feed/Water Restriction

Purpose: To provide for the humane care of animals used in teaching and research by ensuring that feed and water restrictions are of appropriate degree and duration so as not to compromise the health or well-being of the animals involved.

Policy:

1.1 Investigators are encouraged to fast dogs, cats, and other large, non-ruminant species overnight in preparation for anesthesia. Water restriction should be limited to the day of the procedure in all animal species larger than a rabbit.

1.2 There is no need to fast or water deprive rodents or rabbits prior to anesthesia. Neither rodents nor rabbits can vomit stomach contents, and rabbits can store a gastric food bolus for up to 12 days.

1.3 Adult ruminants should be fasted for one to two days.

1.4 For experimental studies, short-term withholding of food or water is allowed when specified in an approved animal use protocol. A description of monitoring procedures must be included. Short-term feed and/or water deprivation means deprivation for up to 16 hours in non-ruminants, and 48 hours in ruminants, since these periods are equivalent to those adopted for pre-anesthetic preparation. Feed and/or water restriction beyond these limits must be justified for scientific reasons.

1.5 It should be noted that some species (e.g. rats), feed primarily in the dark phase of their photoperiod. Therefore, withholding food overnight results in a fast that includes the period of the previous day, roughly an additional 10 hours.

1.6. Other species not specifically identified will be considered on a case-by-case basis as described in the approved animal care and use protocol.

Date last reviewed: November 9, 2021
Date last amended: January 29, 2020

Policy #B-13

Title: Use of Analgesia

Purpose: To ensure that adequate care and analgesia be provided as a matter of course for laboratory animals undergoing potentially painful treatments or procedures.

Background:

1.1 The *Guide for the Care and Use of Laboratory Animals* requires that adequate analgesia be provided for laboratory animals undergoing painful treatments or procedures.

1.2 Pain management strategies described with language such as; "*analgesia will be administered on an as needed basis*", are open-ended and lead to the possibility that no analgesic will be administered following painful treatments or procedures.

1.3 Many animals are stoic or purposefully hide signs of pain or illness such as that exhibited by most prey species.

Policy:

2.1 If it is determined by the PI or the IACUC that animals are likely to experience more than slight or momentary pain during the course of a procedure or experiment, then a detailed pain management strategy must be included in the protocol.

2.1.1 The pain management strategy must provide demonstrable triggers indicating when analgesics will be administered or additional analgesics provided.

2.1.2 Investigators are encouraged to err on the side of extending analgesic therapy at least 24 hours after clinical signs of pain have abated.

2.2 Post-surgical pain management after major survival surgery must include a minimum of 24 hours of analgesic coverage even if outward signs of pain are not exhibited by the animal. Use of terminology such as "*as needed*" will not be acceptable without specific scientific justification during the first 24 hours.

2.3 An individual qualified to recognize signs of pain, distress, and other abnormalities must be responsible for the administration of analgesics.

2.4 Medical records must be maintained and include the date, time, dose, and route of pain medication provided for all species

Date last reviewed: March 15, 2022
Date last amended: March 9, 2022

POLICY #B-14

Title: Justification of Animal Numbers

Purpose: To provide guidance on acceptable means of determining appropriate numbers of animals to be used in research protocols.

Background:

1.1 Both the *Guide* and the Animal Welfare Act require the IACUC to evaluate the approximate number of animals to be used, as well as the rationale ... for the appropriateness of the ... numbers used".

Policy:

2.1 Investigators must provide a rationale for the numbers of animals to be used. Analysis should be based on power analysis, or the rationale can be based on past full experiments, either the investigators or others (published information), or pilot experiments. Where statistical comparisons are not performed, for example in teaching laboratories or descriptive experiments, animal numbers should be supported by the investigators thoughtful estimation of procedural needs.

2.2 Investigators are encouraged to perform power analysis or sample size estimation to determine the number of animals needed to demonstrate treatment effects. Several websites have been created which guide investigators through the performance of a power analysis, using formulae embedded in the sites. The IACUC should inform investigators of the availability of these resources, through posting web addresses on the DLAM website.

Date last reviewed: December 14,2021
Date last amended: December 14, 2021

POLICY #B-15

Title: Counting Animals on Approved Animal Care & Use Protocols

Purpose: To clearly explain the procedures for counting animals on approved animal care & use protocols, as well as clarifying animal use and procedures.

Background:

1.1 Historically, counting animals used on a protocol has been problematic for both teaching and holding protocols, where animals are transferred back and forth between the two. Uncommonly, counting animals on research protocols can also be a problem when animal transfer is involved. An animal can only be on one protocol at one time.

1.2 In the past, each time an animal was used on a protocol it was counted, even though the animal may have been transferred to and from the protocol multiple times. This method easily tracks animal use. However, it overestimates the actual number of animals used.

1.3 Recently, a system was developed to track horse use by tracking procedures. This system counts the number of procedures performed on an individual animal and only counts the animal once on any protocol that it is transferred to or held on. This system accurately reflects the total number of animals used on a given protocol and tracks the number of procedures performed on a given animal. The number of times an animal has been used can be derived from the recorded information.

Policy:

2.1 In consideration of the information above, the following policy is in effect.

2.2 An individual animal will only be counted once on any particular protocol, even if the animal moves onto and off of that protocol multiple times during the life of the protocol.

2.3 Animal Use and Procedures: The number of times a procedure can be performed during any one "animal use" or over time (weekly, yearly, during the animal's life) must be defined. User groups will define maximum limits for animal use/procedures with approval of the attending veterinarian and subsequently the IACUC. Maximum limits will be maintained in an SOP format.

2.3.1 Animal use must be tracked and recorded. An "animal use" is defined as an animal's use over a given time (e.g., a teaching laboratory) on a single protocol. Any time an animal is brought up for a lab, it is considered an animal use no matter how benign the procedure (e.g., external anatomy demonstration). An animal can be "used" more than once on a protocol. How often an animal can be used (daily, weekly, monthly, etc.) shall be considered in advance and will likely depend on the procedures planned as well as animal temperament. Preventive,

routine, or emergency medical care is not considered animal use. Medical care must be recorded in the animal's medical records.

2.3.2 Animal procedures must be recorded. Procedures may vary from benign (anatomy demonstration, halter placement, ophthalmic exam, etc.) to more invasive (blood collection, biopsy, nasal swab, transtracheal wash, vaginal swab, restraint, sedation, anesthesia, etc.) All procedures must have been approved in the associated protocol.

Date last reviewed: January 11, 2022
Date last amended: January 11, 2022

POLICY #B-16

Title: Assessment of Grant and Protocol Congruency

Purpose: To describe the method used by the LSU IACUC for assessing congruency between grants and animal care and use protocols.

Background:

1.2 The PHS Office of Laboratory Animal Welfare (OLAW) requires that work described in grants awarded for the conduct of animal research, must be performed under the auspices of an IACUC-approved animal care and use protocol.

1.3 According to NIH Grants Policy Statement (NIHGPS Part II, A, 4.1.1.2), "*It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC*". Thus, the IACUC must conduct a congruency assessment to verify that all animal-related work described in a grant narrative is described in an approved animal care and use protocol. As a result of LSU's approved Assurance Statement with OLAW, congruency checks will be performed for all grants regardless of funding source.

Policy:

2.1.1 Persons qualified to perform congruency assessments include: IACUC staff, Sponsored Projects staff, and/or compliance oversight personnel. The LSU IACUC has opted to have congruency assessments performed by the laboratory animal veterinarian currently serving on the IACUC.

2.1.2 The institution (via the Institutional Official for Animal Care) and the Principal Investigator (PI) are responsible for notifying the funding agency of a change in scope to an award or to IACUC required modifications to an animal care and use protocol.

2.1.3 Protocol and grant congruency ensures that any details of animal research, including techniques and procedures, proposed within a funded grant, are approved within relevant IACUC protocol(s).

During a typical congruency check, animal procedures and treatments, etc., in a grant are reviewed first. Once the grant review is completed, the protocol (protocols) provided by the PI is/are reviewed to determine if the animals and their related procedures, treatments, etc. are approved. The referenced IACUC protocol may contain additional animals, procedures, treatments, etc. over and above that described in the grant, which will not adversely affect congruency.

2.1.4 If a procedure described in a grant is not similarly described in an IACUC-approved animal care and use protocol, the PI must amend the protocol to be congruent with the grant or inform the funding agency if procedures will not be conducted as originally proposed.

2.1.5 If a procedure described in a protocol is not similarly described in a grant, the PI should be asked for clarification regarding potential change in scope to the grant and if so, must notify the funding agency of such change in scope. NIHGPS Part II: Subpart A: 8.1.2.5 states, "*The grantee (PI) must make the initial determination of the significance of a change and should consult with the Grants Management Officer of the NIH funding component as necessary*".

2.1.6 Indicators of a change in scope to a grant include: a) change in the specific aims approved at the time of award, b) substitution of one animal model for another, c) change from the approved use of vertebrate animals, and, d) shift of the research emphasis from one disease area to another (NIHGPS Part II: Subpart A: 8.1.2.5).

2.1.7 Items that require clarification and which may or may not represent a change in scope include changes in: a) animal numbers, b) performance site, c) administration of agents, and, d) species.

2.1.8 Components of grant and protocol which should be congruent in a side-by-side comparison include: a) general scope of the work, b) experimental procedures and endpoints, c) experimental and therapeutic agents to be administered, d) species (including strain(s) if the conduct of the proposed study or disease model is dependent on strain), e) approximate numbers of animals, and, f) euthanasia method.

2.1.9 A reasonable matching description of the six areas identified in 2.1.8 above will be regarded as congruent.

2.1.10 Where the IACUC protocol covers only the first three years of a five-year award, the PI should provide a brief description, without experimental details and procedures, of the studies planned for the 4^{th} and 5^{th} years of the award. The 4^{th} and 5^{th} year studies must be addressed in more detail at the time of protocol renewal.

2.1.11 Where the IACUC protocol does not include alternative approaches described in the grant application, the PI will be asked to provide a brief description, without experimental details and procedures, for review and approval. The PI must amend the protocol to include alternatives if it is determined that these are to be used.

2.1.12 If vertebrate animal studies are to be performed off-site by collaborators, the PI must provide documentation sufficient to allow for a congruency assessment, or documentation stating that the performance site IACUC has conducted a congruency assessment for the work to be done at their site. This requirement is in addition to those described in LSU IACUC Policy B-5 ("*Granting Reciprocity for Protocols Approved by other IACUCs*").

2.1.13 If reagents (i.e., antibodies, serum, etc.) described in a grant application are to be produced by a vendor, that vendor must be registered with the USDA, be accredited by AAALAC Int., and must have on file with OLAW, an approved Animal Welfare Assurance.

2.1.14 Where training grants support training only (e.g., salaries for postdoctoral fellows) and provide no funds for animal care and use, no congruence review is necessary.

Date last reviewed: February 15, 2022
Date last amended: January 15, 2022

POLICY #C-1

Title: Reporting Animal Welfare Concerns

Purpose: To establish methods for investigating animal welfare concerns, to make persons at the university aware of the importance of and mechanisms for reporting animal welfare concerns, and to ensure that persons reporting concerns are not subject to unlawful discrimination or reprisal.

Background:

1.1 The *Guide for the Care and Use of Laboratory Animals* requires research institutions to establish methods for reporting and investigating animal welfare concerns and making persons at the university aware of the importance of reporting animal welfare concerns.

1.2 Valid concerns which should be reported include observing a procedure that is not covered under an approved animal care and use protocol or that appears to cause pain or distress; observing an animal in need of care; hearing an animal vocalize in a manner suggestive of pain or distress, or being notified by a third party of any of the above.

1.3 Federal law offers protection from discrimination or reprisals against persons who report animal welfare concerns.

Policy:

2.1 Procedure for Reporting and Handling Concerns.

2.1.1 The concerned individual should notify any of the following officials, or use the "Ethics & Integrity Hotline" system, regarding valid concerns such as those described above:

DLAM Director and Attending Veterinarian- Dr. Rhett Stout
LSU IACUC Chair- Dr. Fernando Galvez (or Current Chairperson)
LSU Institutional Official for Animal Care & Use- Dean Oliver Garden
LSU Ethics & Integrity Hotline- www.lsu.ethicspoint.com

2.1.2 Upon notification of one of the above, the concern will be reported to the Attending Veterinarian who will investigate the concern. If the identity of the concerned person is known, the Attending Veterinarian will report his findings to that person.

2.1.3 Most issues are resolved by the Attending Veterinarian. Unresolved issues will be forwarded to the IACUC for discussion and action at the next regularly scheduled IACUC meeting, or in an emergency meeting at the discretion of the IACUC Chair.

2.1.4 The IACUC will address the issue and determine an appropriate response up to and including suspension of the animal care and use protocol followed by notification of the Federal Office of Laboratory Animal

Welfare (OLAW), the USDA, and any associated funding agency.

2.1.5 To maintain anonymity, at no time will the reporting individual's name be included in any communication with the person(s) responsible for the animal(s) in question or in IACUC correspondence.

2.2 Posting of reporting instructions.

The above instructions for reporting animal welfare concerns will be posted in several locations covering all areas of the university housing research animals or where large numbers of potentially concerned personnel congregate. These areas will include bulletin boards outside all three student classrooms, livestock barns, the SVM vivarium, and the Life Sciences vivarium. It is the responsibility of the DLAM Director to maintain the postings.

Date last reviewed: February 15, 2022
Date last amended: October 6, 2023

POLICY #C-2

Title: Assessing and Reporting of Adverse Events

Purpose: To establish a Policy for assessing and reporting adverse events and animal welfare concerns.

Background:

1.1 LSU is committed to the health and wellness of animals held and used in approved IACUC protocols.

1.2 The *Guide for the Care and Use of Laboratory Animals* (the *Guide*) requires research institutions to establish methods for reporting and investigating animal welfare concerns. AAALAC International requests a specific IACUC policy of the IACUC in the form of an appendix Assessing and Reporting of Advert Events impacting animal welfare.

1.3 The term "adverse" is only used 11 times in the current edition of the *Guide* (8th Edition). The term is not defined in the context of the *Guide* but appears to focus on unexpected experimental outcomes. No specific reporting requirements are requested, yet it charges the IACUC to review "adverse or unexpected experimental outcomes."

1.4 Adverse Events include the illness or death of animals outside of what would be normally expected for an approved protocol or in the routine care of animals. The causes of adverse events include power outages, HVAC issues, transportation mishaps, etc., which may cause an unexpected illness or death of animals. This list is not exhaustive but only serves as examples. Adverse Events may or may not be due to non-compliance with an approved protocol.

1.5 A review of OLAW reporting requirements found the following notice number NOT-OD-05-034 with the title of "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals." Content has not been finalized; however, the current working information can be found on OLAW's website. Thus, this can be accessed for reference as needed.

Policy:

2.1 IACUC procedures to address adverse events and animal welfare concerns.

2.1.1 All adverse events or animal welfare concerns should be brought to the attention of the IACUC Chair, IACUC Manager, or Attending Veterinarian (AV).

2.1.1.a. Self-reporting of your own IACUC protocols is required by law.

2.1.1.b Reporting associated with the IACUC protocols of others can be made in person or anonymously. These are specifically addressed in Policy C1.

2.1.2 Regardless of the issue type, the AV and IACUC Chair will start an

investigation. If acute action is required, the AV will stop the procedure/ action on behalf of the animal/animals to investigate the cause of the adverse event.

2.1.3 Following a full investigation, information will be brought to the IACUC (in an emergency meeting if needed), and a determination will be made concerning the need to report the issue. This may include a temporary halt of work or protocol suspension. If an event requires immediate reporting to any authorities, a preliminary report will be sent to the appropriate agencies (OLAW, USDA, AAALAC International, etc.), notifying the entire IACUC and the Institutional Official.

2.1.4 If the issue is reportable, reports will be sent to the appropriate regulatory, accreditation, and funding agencies. At a minimum, this would include OLAW and AAALAC International.

2.2 If the adverse event is due to non-compliance of an IACUC protocol, additional corrective measures may be required. See Policy C-1 for additional details on non-compliance.

Date last approved: December 12, 2023 (New Policy)
Date last amended:

POLICY #C-3

Title: Policy Statement on IACUC Protocol Noncompliance and Animal Mistreatment

Purpose: To ensure the humane care and use of animals in research and outline the procedures for addressing noncompliance and animal mistreatment.

Background:

1.1. LSU is committed to the health and wellness of animals held and used for research and teaching within approved IACUC protocols.

1.2. LSU has procedures, including policy C1, for reporting issues of IACUC protocol noncompliance and animal mistreatment.

1.3. The Animal Welfare Act Regulations (AWAR) and PHS require a quorum of the IACUC to review all complaints, regardless of the source of the complaint.

1.4. The PHS Policy, section IV.F.3., requires that "the IACUC, through the Institutional Official, promptly provide OLAW with a full explanation of the circumstances and actions taken concerning any serious or continuing noncompliance with this [PHS] Policy or any serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals*, or any suspension of an activity by the IACUC."

1.5. OLAW issued a Guidance Notice in 2005 [NOT–OD-05-034], which provided numerous examples of reportable situations. Serious or continuing noncompliance with PHS Policy can constitute a number of things, such as performing animal research that has not received prior approval from the IACUC, failure by investigators to follow the approved protocol, failure of animal care and use staff to follow IACUC-approved institutional policies or procedures, or a failure of the institution to correct deficiencies identified during the semiannual evaluation in a timely manner.

Policy:

2.1. Reporting Noncompliance and Mistreatment: Any individual who observes or suspects noncompliance or mistreatment of animals must report the incident immediately to the IACUC. Reports can be made anonymously and kept confidential to the extent possible.

2.2. Upon receipt of a report, the Attending Veterinarian, the IACUC Chair, or a subcommittee of the IACUC can promptly investigate the allegation.

2.3. The Attending Veterinarian may choose to put a halt to part or all of the animal work on an IACUC protocol during the investigation phase, if it is deemed necessary for the protection of animals.

2.3. Any allegation of noncompliance directed towards the IACUC chair should be handled by the acting chair of the IACUC, the Attending Veterinarian, or the Institutional Official.

2.3. If noncompliance or mistreatment is confirmed, the IACUC will determine appropriate corrective actions, which may include: retraining of personnel, modification of protocols, suspension of activities, and reporting to regulatory

agencies.

2.4. Serious noncompliance or deviation from the *Guide for the Care and Use of Laboratory Animals* must be reported.

2.5. When the IACUC suspends a PHS-supported project, a direct report must also be made to the PHS funding component. No charges for research activities with animals are to be made to the grant during the suspension period.

Date approved: June 11, 2024 (New Policy)
Date amended:

POLICY #C-4

Title: LSU Owned Herd: Oversight

Purpose: To establish a policy that will ensure optimal care and oversight of animal herds owned by LSU.

Background:

The University owns herds of cattle and horses. These animals are used in teaching laboratories, breeding programs, and research projects.

Policy:

1.1 It shall be the responsibility of the faculty user groups to maintain accurate health records on all university owned livestock. These records will be available at all times, for inspection by the Attending Veterinarian and other members of the IACUC, and any representative of AAALAC, the OLAW, or APHIS.

1.2 Records must be retained for a period of not less than 3 years from the termination or expiration of the protocol, or the death of the animal, whichever is longer.

1.3 Health records should include animal identification number, medical procedures performed, and information concerning animal use in approved protocols.

1.4 Health records will be reviewed by the Attending Veterinarian semiannually.

Date last reviewed: March 15, 2022
Date last amended: September 9, 2014

POLICY #C-5

Title: Housing of Animals from Other Institutions

Purpose: To establish a policy that will stipulate the conditions under which animals owned by other research institutions may be housed in LSU facilities.

Background:

1.1 The IACUC recognizes that shortage of space, specialized facilities, or pathogen status may occasionally result in faculty of other institutions requesting that animals be housed in LSU animal facilities.

1.2 The LSU IACUC must ensure that research involving animals housed at LSU, regardless of the institution owning the animals, will be conducted in accordance with accepted standards of animal care and use, including the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the Animals Welfare Act (AWA), and the 2020 AVMA Panel on Euthanasia.

Policy:

2.1 Animals from other institutions may be housed in LSU animal facilities following approval by the Director of the DLAM, and following receipt, review, and approval by the Chair of the LSU IACUC, of a copy of an approved animal use protocol and a letter of protocol approval issued by the IACUC of the guest institution.

2.2 Where zoonotic or human pathogens are to be used, housing of animals from other institutions in DLAM facilities also requires approval of the LSU Inter-institutional Biological and Recombinant DNA Safety Committee (IBRDSC). Following IBRDSC approval, the investigator must provide DLAM with an approved animal room door posting, describing pathogen containment procedures.

Date last reviewed: May 10, 2022
Date last amended: May 10, 2022

Policy #C-6

Title: Transfer of Animals between Approved Protocols or Institutions

Date last reviewed: August 9, 2022

The IACUC reviewed and determined this policy was no longer needed. Transfer of animals between approved protocols or institutions is covered in Policy B-1.

Policy #C-7

Title: Use of Animal Shelter Subjects in Teaching Protocols

Purpose: To ensure accurate and timely order, receipt, housing and tracking of animals obtained from Animal Shelters for use in teaching protocols.

Background:

1.1 Adoptable animals obtained from Louisiana animal shelters will undergo recovery spay or neuter to provide live-animal surgical experiences for the School of Veterinary Medicine (SVM) students. These animals will then be returned to their respective shelters for future adoption. Live animals, scheduled for humane euthanasia at various Animal Shelters, will rarely be obtained for terminal surgical teaching procedures.

1.2 The LSU SVM and the LSU IACUC recognize the value of utilizing these animals for teaching purposes and wish to do everything possible to maintain local Animal Shelters as a source of adoptable animals for spay or neuter, while maintaining compliance with federal, state, and local animal laws.

Policy:

2.1 The junior surgery supervisor will place orders for random source animals directly to local animal shelters and rescue organizations.

2.2 Medical records for these animals will be maintained in the junior surgery suite.

2.3 Spreadsheets containing the following information on the animals will be forwarded to the DLAM facility supervisor after each lab.

2.3.1 IACUC protocol number.

2.3.2 Date of use.

2.3.3 Sex.

2.3.4 Description or ID (Name).

2.3.5 Source.

2.3.6 Terminal or Recovery Surgery.

2.4 Separate IACUC protocols will be submitted for the Junior Surgery, 4th year Surgery, and Educational Commission for Foreign Veterinary Graduates (ECFVG) Laboratories to ensure accuracy of tracking animal numbers used for each lab.

2.5 Selection of animals for recovery or terminal surgeries will be determined by the source institution (i.e. Animal Shelters, rescue organizations, etc). Under no circumstances will LSU personnel deviate from the approved final animal

disposition indicated by the source institution.

2.6 Animals used in terminal surgeries are not recovered from surgery, but while anesthetized, are euthanatized at the completion of the surgical procedure.

2.7 These policies do not apply to animals received for LSU-ASAP (Animal Sterilization Assistance Program) which are not covered by approved LSU protocols. The LSU-ASAP program is considered to be a doctor/client/patient relationship with the university which is not under the authority of the LSU IACUC.

Date last reviewed: July 12, 2022
Date last amended: July 12, 2022

Policy #C-8

Title: Post-Approval Monitoring

Purpose: To establish a policy regarding post-approval monitoring of animal activities to ensure that animal procedures are performed in accordance with approved animal care and use protocols.

Background:

1.1 Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Post-approval monitoring (PAM) consists of all types of protocol monitoring after initial protocol approval.

1.2 PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures.

1.3 Methods include continuing protocol review; laboratory inspections (conducted either during regular semi-annual facility inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; external regulatory inspections and assessments; and IACUC review of annual updates provided by investigators.

Policy:

2.1 Methods of PAM will include but not be limited to:

- 2.1.1 Documented daily animal observation by the caretaker or scientific staff.
- 2.1.2 At the request of the IACUC, a DLAM veterinarian and/or committee member will observe procedures with potential to cause serious adverse effects to the animal, or to verify the proficiency of newly hired personnel or of established personnel performing new procedures.
- 2.1.3 Semi-annual facility and programmatic review by the IACUC.
- 2.1.4 Annual questionnaire sent to investigators to give opportunity to describe any unanticipated adverse events or effects, and updates of relevant aspects of work in progress.
- 2.1.5 Inquiry by the Attending Veterinarian or other DLAM veterinary staff, of issues or concerns raised by the public; or by any LSU personnel including students, staff, or faculty.

Date last reviewed: August 9, 2022
Date last amended: June 13, 2013

Policy #C-9

Title: Minimizing Research Animal Use

Purpose: To facilitate the use of minimal, yet sufficient, numbers of research animals by investigators.

Background:

Federal guidelines for research animal use stipulate that investigators should seek to refine, replace, and reduce animal use ("The 3 Rs"). Reduction refers to the use of the minimum but sufficient number of animals needed to yield statistically meaningful results. Similarly, federal guidelines require the IACUC to evaluate the "appropriateness" of the numbers of animals to be used. The IACUC recognizes that not all investigators are familiar with steps needed to arrive at the minimum number of animals needed.

Policy:

1.1 Investigators should seek to use the fewest animals necessary to yield statistically meaningful results. It is not the purpose of the IACUC to prescribe the method by which investigators arrive at the minimum number of animals needed for a research project. The number of animals to be used may be derived from citations of relevant literature, past experimental findings of the investigator, recommendations of sponsors, or through a power analysis.

1.2 Investigators must clearly state in their protocol or protocol amendment how they arrived at the number of animals requested.

1.3 Investigators opting to perform a power analysis may benefit from using power analysis algorithms available on-line.

Date last reviewed: August 9, 2022
Date last amended: May 14, 2013

Policy #C-10

Title: Daily Animal Observations

Purpose: To ensure daily animal observation as required by the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) and the Animal Welfare Act (AWA)

Background:

1.1 Federal regulations and guidelines require daily observation of all animals used in teaching and research. This function is carried out as part of standard operating procedure for all animals under the care of the Division of Laboratory Animal Medicine (DLAM).

1.2 Unless posted in a conspicuous location in or near an animal room or other housing location, there is no evidence that daily animal observations occur. In fact, it has come to the attention of the IACUC that some animals, particularly those cared for by investigators, are not observed daily. Lack of daily observation places the institution out of compliance with federal animal care regulations as well as with expectations by our AAALAC accreditation.

Policy:

2.1 Evidence of daily observation of animals must be posted in or near animal rooms or other housing sites such that DLAM or other personnel can easily verify that daily observations are occurring.

2.2 Daily observation records should include, but are not limited to, check of all animals as well as:

2.2.1 Fish or other non-air breathers: Room temperature, water temperature, and verification that air supply is operational.

2.2.2 All other species: Room temperature and humidity.

2.3 Failure to record daily observations of all animals may result in protocol suspension.

Date last reviewed: August 9, 2022
Date last amended: July 14, 2011

Policy #C-11

Title: Social Housing of Animals

Purpose: To establish a policy regarding social housing of animals in accordance with standards of the *Guide*, the *Ag Guide*, and AAALAC Int. expectations.

Background:

1.1 Federal regulations, including the 2011 edition of the *Guide for the Care and Use of Laboratory Animals* strongly suggest that social species be group housed whenever possible. Recently, accrediting bodies such as AAALAC Int. have been placing more emphasis on this issue.

1.2 Group housing of social species has been an unwritten policy of the DLAM. AAALAC Int. strongly suggests that the IACUC have a written policy to address this issue.

Policy:

2.1 Rodents: With the exception of hamsters, group housing of rodents shall be the default husbandry practice for the DLAM. Hamsters are generally pugnacious and may be cannibalistic unless group housed from an early age.

2.2 Other social species: Whenever possible other social species will be group housed. When not housed socially, conspecifics will have visual, auditory, and/or olfactory contact. Animals may be individually housed away from conspecifics for medical treatment with oversight from the DLAM veterinary staff.

2.3 Requests for single housing of normally social species must be scientifically justified in the animal care and use protocol or amendment and approved by the LSU IACUC.

Date last reviewed: September 13, 2022
Date last amended: March 8, 2012

POLICY #C-12

Title: Field Research: Safety and Training

Purpose: To address changes in the 8th Edition of the *Guide for Care and Use of Laboratory Animals* (the *Guide*), which specifically call for risk assessment of hazards encountered in field research. See policy C-12 for the definition of Field Research versus Field Study.

Background:

1.1 Previous editions of the *Guide* primarily focused on hazards and risk assessment in the laboratory, where animals are involved, in relation to an institution's OHSP (Occupational Health and Safety Program).

1.2 In the 8th Edition of the *Guide*, the council (NRC) increased its focus on OHSP and specifically addressed the need for hazard and risk assessment for field research.

1.3 To address this increased focus, as it relates to field research, the LSU IACUC convened a subcommittee of IACUC members, LSU safety personnel, and LSU field researchers to devise a mechanism to identify hazards and estimate the risk to promote safety for personnel involved in these endeavors. This mechanism addresses hazards directly associated with a given animal species and the modes of travel, local weather, safety training, and first aid to mention a few.

Policy:

2.1 Prior to using animals in field research, investigators must fill out and turn in a "Field Research Safety Plan". This document must be submitted, to the IACUC, along with their animal care and use proposal.

2.2 A safety plan is needed for each research lab participating in field research and must be submitted by the PI of each lab. A new plan is not needed for each protocol submission.

2.2.1 The plan shall be amended, as needed, for each new protocol submitted.

2.2.2 The plan shall be reviewed with all personnel in the lab

2.2.3 The Primary Investigator shall utilize the "Field Research Safety Guidelines, 1st edition, to help with safety plan preparation.

2.3 The safety plan submitted will be reviewed to ensure it addresses the potential risks associated with the protocol. If the safety plan does not generally address the risks associated with the protocol, modifications to the safety plan will be requested.

2.4 Final protocol approval will be withheld if the safety plan is not in place.

Date last reviewed: December 13, 2022
Date last amended: December 13, 2022

POLICY #C-13

Title: Field Research with Birds

Overall Purpose: To provide the LSU IACUC and bird researchers with information and guidelines for evaluating and submitting Animal Care and Use Protocols involving field research with birds. See policy C-12 for the definition of Field Research versus Field Study.

Background:

1.1.1 Occasionally, investigators need to conduct experiments using birds in the wild.

1.1.2 These studies may be observational only or may include tissue or whole specimen collection.

1.1.3 Historically the LSU IACUC has used a combination of traditional guidelines as well as class specific guidelines such as the "Guidelines to the Use of Wild Birds in Research" by the Ornithological Council for guidance.

1.1.3 The AVMA Guidelines for the Euthanasia of Animals: 2013 Edition changed their position regarding bird euthanasia via thoracic compression from conditionally acceptable to unacceptable. Their stated reasons are based on opinions with no scientific basis and there are no provisions for situations when acceptable methods of euthanasia may not be practical. The AVMA's citations were reviewed on 5/26/2014.

1.1.5 To address the change in position regarding thoracic compression by the AVMA, the LSU IACUC promulgated the following policy for future guidance concerning field research with birds.

Policy:

2.1.1 Protocols should adhere to the procedures outlined in the Ornithological Council guidelines to the extent possible within the constraints of the scientific investigation or field survey, and protocols should state their adherence to these guidelines.

2.2.2 In instances where the proposal would not adhere to Ornithological Council guidelines the protocol should provide scientific justification for the proposed variance.

2.2.3 In instances where AVMA approved euthanasia methods are not feasible (for example when thoracic compression is required), the protocol should provide clear justification for the proposed variance. This justification must be scientifically based. The limitations for practical application of various euthanasia methods will also be considered by the committee.

Date last reviewed: January 10, 2023
Date last amended: January 10, 2023

POLICY #C-14

Title: Criteria for Exemption from IACUC Approval for Field Studies

Purpose: Approved animal care and use protocols are generally, but not always, required. This policy clarifies those field situations when a protocol is not required.

Background:

1.4 The USDA definitions of Field Study vs. Field Research are used to determine the need for an IACUC protocol during fieldwork involving vertebrate animals.

- Field Study: Observation/data collection without impacting the animal(s).
- Field Research: Observation/data collection requiring the capture, redirection, behavior modification, sedation, etc.
- Either a "field study" or "field research" only applies to free-living wild animals.

Policy:

2.1 Field studies of free-living, wild vertebrate animals in their natural environment that satisfy all the following criteria may be exempt from IACUC approval:

- Field studies that do not "involve an invasive procedure, harm, or materially alter the behavior of an animal under study." (9 CFR 1.1 – Animal Welfare Regulation).
- Field studies that do not involve the capture, handling, housing, transportation, treatment, or euthanasia of animals.
- Field studies that do not cause excessive disturbances of animals due to study activities. Excessive disturbance would include visits to nest sites or breeding areas, close approach to animals during sensitive phases of their life cycles, or experimental techniques that might elicit disturbance (e.g., tape playbacks of calls or presentation of models).

2.2 To apply for exempt status, the Principal Investigator (PI) shall submit in writing a detailed description of the study to the IACUC via email at IACUC@lsu.edu. The description should sufficiently demonstrate that the criteria for exemption from the IACUC approval have been met. If any federal, state, or local permits are required to conduct the study, it should be noted.

2.3 Exemption requests are reviewed by the IACUC Chair and Attending Veterinarian (Reviewers). A full committee review may take place if requested by one or both of the Reviewers. The PI must obtain IACUC approval or an exemption letter prior to engaging in the proposed activities. A determination will be sent to the PI via letter. Although a Field Research Safety Plan is only required for Field Research studies, it is highly recommended that the PI have a Field Research Safety Plan in place for Field Studies too which the IACUC will review if requested.

2.4 If IACUC approval of a study is required by the funding agency, an exemption cannot be granted. Field studies assigned exempt status may be subject to

reevaluation by the IACUC for conditions including, but not limited to, changes in federal, state, local or institutional policy or changes in funding source.

Policy Approved: December 13, 2022
Date last reviewed: December 13, 2022

POLICY #C-15

Title: Clinical Research: Regulatory Oversight

Purpose: To describe the extent to which the LSU IACUC oversees the care and use of privately owned animals used in clinical research studies.

Background:

1.1 The School of Veterinary Medicine (SVM), Veterinary Teaching Hospital (VTH), has established a committee to oversee the care and use of privately owned animals used in clinical research studies and housed at their normal residence or in the VTH. This committee functions in a manner similar to that of the IACUC, except that housing conditions and daily care of the privately owned animals are not monitored by the IACUC.

1.2 Previously, the IACUC assumed no jurisdiction or oversight responsibilities due to the lack of control by LSU over housing and treatment of privately owned animals away from campus.

1.3 Recently, the Office of Laboratory Animal Welfare released a position statement (1) indicating clinical studies must have IACUC oversight if funds for the study come from the PHS.

1.4 LSU's federal assurance statement indicates all animal research protocols will be reviewed and treated the same regardless of funding source. Therefore, the following policy is in effect.

Policy:

2.1 The LSU IACUC will review all clinical research protocols in a manner consistent with other LSU research protocols.

2.2 Clinical research protocols will be reviewed by the IACUC after the VTH Clinical Protocol Committee (CPC) has reviewed and approved the protocol.

2.3 To streamline the process for investigators a modified, dual-use protocol was approved by the IACUC and the CPC in January 2010. Beginning in February 2021, the animal care and use protocol form in the GeauxGrants system was approved to be used for the LSU Protocol for Clinical Studies. The Principal Investigator (PI) completes the protocol form in GeauxGrants and saves the document as an Adobe file. The saved file is then submitted to the CPC via email by the PI. Once the CPC approves the clinical study, an approval letter is provided to the PI. The PI uploads the approval letter in the GeauxGrants protocol form and submits the document to the IACUC for review and approval. Any amendments to the clinical study must be reviewed by the CPC prior to the IACUC.

2.4 The LSU IACUC does not need to inspect clinical facilities at the LSU SVM nor at other institutions engaged in the practice of clinical veterinary medicine.

(1) Brown P, Gipson C, Response to Protocol Review Scenario: A word from OLAW and the USDA, Lab Animal, 38, 6, 2009.

Date last reviewed: November 15, 2022
Date last amended: December 13, 2022

POLICY #C-16

Title: Non-Pharmaceutical Grade Compound Use

Purpose: To provide the LSU IACUC and researchers with guidelines for non-pharmaceutical grade drug use.

Background:

1.1 The 8th edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) provides guidance on the use of non-pharmaceutical grade compounds (NPGC). (1)

1.2 Specifically, pharmaceutical grade compounds (PGC) should be used when available. Use of NPGC should be described and justified. The NIH follows the same standard but substitutes the word "must" for "should".

1.3 What constitutes a pharmaceutical grade drug or compound?

1.3.1 Any active or inactive drug, biologic, or reagent for which a chemical purity standard has been established by a regional or national pharmacopeia (eg.: U.S. Pharmacopeia, British Pharmacopeia, National Formulary, Japanese Pharmacopeia, etc.)

1.3.2 Commercial availability does not mean a compound is pharmaceutical grade.

Policy:

2.1 PGCs (active or inactive) must be used in animals when available, including terminal procedures. These include drugs, reagents, or biologics.

2.2 The use of NPGCs must be justified within the animal use protocol.

2.3 Examples where non-pharmaceutical grade compounds may be justified include, but are not limited to, the following:

2.3.1 The non-pharmaceutical grade compound is required to achieve the research project objectives.

2.3.2 The PGC available must be diluted, concentrated, or altered for use by the investigator to meet research project objectives.

2.3.3 The PGC does not meet the non-toxic vehicle requirements for the specified route of administration.

2.3.4 A PGC is available but to compare with previous studies, a NPGC is required.

2.3.5 An appropriate vehicle control is unavailable for the PGC.

2.4 Requirements for use of non-pharmaceutical grade compounds:

2.4.1 Vials or other containers with compounds, drug combinations, or drug mixtures must properly labeled. Label information must include all component solutions, concentrations, and expiration date (soonest).

2.4.2 The PGC available must be diluted, concentrated, or altered for use by the investigator to meet research project objectives.

2.4.3. When mixing compounds, investigators must ensure the sterility of compounds to be used in animals. Investigators are encouraged to use sterile vials, and/or, to employ methods that ensure sterility, such as autoclaving or filter sterilizing of prepared compounds.

2.4.4 Investigators should follow established protocols for mixing and storing anesthetic and other compounds highly susceptible to degradation, such as 2,2,2-Tribromoethanol ("Avertin"). Such compounds may be harmful to animals if administered in a degraded condition.

References:

1. 8th Edition of the Guide for the Care and Use of Laboratory Animals
2. https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/b14_pharmaceutical_compounds.pdf, Guidelines for the Use of Non-pharmaceutical grade compounds in laboratory animals.

Date last reviewed: December 13, 2022
Date last amended: December 13, 2022

POLICY #C-17

Title: Animal Transportation Outside the Vivaria

Purpose: To facilitate the safe transportation of animals outside of the vivaria.

Background:

1.1 Occasionally, there is a need to transport animals from the vivarium to a research or teaching laboratory; or from one vivarium to another.

1.2 It is essential that animals are transported in such a manner that safeguards their own health and well-being, as well as the safety of personnel.

Policy:

2.1 Dogs may be walked on a leash, from the vivarium to the teaching laboratory; or walked between their kennel and the SVM vivarium. Dogs and cats transported to campus must be in a suitable carrier, and transported in the covered bed of the DLAM truck. Transportation should occur at such times as to minimize exposure to heat, transported in a safe but expeditious manner, and removed from the truck upon arrival. If multiple animals are transported, carriers must not be stacked.

2.2 Rodents and other animals must be transported in their normal caging fitted with a filter cover. Cages must be moved within the building on carts provided by DLAM.

2.3 For transportation between vivaria, or from the vivarium to a laboratory outside of the home building, cages must be transported in the covered bed of the DLAM truck, or in the cab of a vehicle. If transported by truck, animals should be transported at such times as to minimize exposure to heat, transported in a safe but expeditious manner, and removed from the truck promptly upon arrival at their destination. If multiple cages are transported, they must not be stacked to prevent tipping.

2.4 Cages transported in the cab of any vehicle must be positioned in such a manner as to avoid tipping, and exposure of personnel to animal allergens. At no time are animals of any species to be transported in the trunk of a car or on a golf cart, "four wheeler", or other similar vehicle.

2.5 During transportation of rodents, water bottles must be positioned upright to avoid wetting of animals; and then returned to the operating position upon arrival at the destination.

2.6 When animal cages are moved between a transport vehicle and a building, they must be covered such that it is not obvious that the cages contain animals.

2.7 When animal cages are moved between buildings from the Life Sciences ABSL2 lab to the SVM ABSL3 lab, they will be transported in a secondary container

with a hole on top. Filter top will remain during the transport and individual cages will be secured. Secured cages will be placed inside the secondary container. Empty spaces in the container will be filled to secure to avoid movement of cages. The top of the container will also be secured. Animals will be transported using personal vehicle. The container containing the animals will be placed in the cargo area. Upon arrival to SVM, animals will be unloaded on the freight dock area and moved to the ABSL3 facility using the elevator near the facility.

Date last reviewed: December 13, 2022
Date last amended: December 13, 2022

POLICY #C-18

Title: Storage of Schedule IV drugs

Purpose: To provide the LSU IACUC and researchers with guidelines for the safe storage of Schedule IV drugs.

Background:

1.1 The Federal government does not require that Schedule IV drugs, including Isoflurane, be stored behind two locks, as required for higher schedule drugs.

1.2 However, the IACUC recognizes the theft and abuse potential for Schedule IV drugs.

Policy:

2.1 Schedule IV drugs, including Isoflurane, must be stored in a locked container, such as a cabinet, desk or safe within an office, laboratory or procedure room.

2.4 The office, laboratory or procedural room door locks do not, by themselves, constitute secure storage and thus cannot replace storage in a cabinet, desk or safe described above.

Date last reviewed: January 10, 2023
Date last amended: January 10, 2023

POLICY #D-1

Title: Authority of the Attending Veterinarian

Purpose: To establish that the Attending Veterinarian and his/her designees have the authority to provide and oversee all aspects of animal care to university-owned animals used in teaching and research.

Background:

1.1 The *Guide for the Care and Use of Laboratory Animals*- 8th Ed. (p.14) states:

> "The Attending Veterinarian (AV) is responsible for the health and well-being of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. The AV should oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the Program complies with the *Guide*.@

1.2 The *Guide for the Care and Use of Laboratory Animals*- 8th Ed. (p.114) further states:

> "… In the case of a pressing health problem, if the responsible person (e.g. investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian must have the authority, delegated by senior administration … and the IACUC, to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary."

1.3 With the adoption of the 8th edition of the *Guide for the Care and Use of Laboratory Animals*, AAALAC's new Program Description form for accreditation specifically asks what authority the Attending Veterinarian has for handling animal emergencies (*JAALAS* 51(3):p.325). Thus, it is appropriate for the IACUC to promulgate a policy which specifies the authority of the AV.

Policy:

2.1 In the absence of the Attending Veterinarian (AV), authority for animal care as described below is designated to the Alternate AV (currently the DLAM Associate Director) and in his/her absence, to the laboratory animal medicine resident veterinarian on duty. Collectively, these are referred to as "veterinarians".

2.2 The Attending Veterinarian (AV) is responsible for the health and well-being of all laboratory animals used at this institution. The veterinarian has the authority to examine all animals at all times. Further, the veterinarian has the authority to oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the Program complies with the *Guide*.

2.3 In the event of an animal health emergency, or when the principal investigator is available but does not agree with the veterinarian on the appropriate treatment, the veterinarian is authorized to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia.

Date last reviewed: February 14, 2023
Date last amended: February 14, 2023

POLICY #D2

Title: Personal Hygiene and Personal Protective Equipment

Purpose: To establish a policy regarding personal hygiene and personal protective equipment use in animal rooms and laboratories where animals are taken.

Background:

1.1 The *Guide for the Care and Use of Laboratory Animals*- 8th Ed. (p.20) states:

"Appropriate policies should be established and enforced…" (regarding personal hygiene), and; "…Personnel should not be permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in room and laboratories where animals are housed or used…"

Policy:

2.1 Signage shall be posted and maintained instructing personnel not to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in room and laboratories where animals are housed or used. Posting signage in the vivaria will be the responsibility of the DLAM. Posting signage in laboratories where animals are taken for procedures will be the responsibility of the principal investigator in charge of each laboratory.

2.2 Personal lab coats must not be worn in vivarium animal rooms. Persons entering animal rooms must wear DLAM-provided isolation gowns and gloves. All personnel must wear closed-toed shoes. Gloves and gowns must be discarded in the biohazard trash upon exiting the room. Hearing protection must be worn in areas of high decibel noise levels (dogs, psittacine birds, etc). Additional protection may be required in toxicology rodent rooms, cage washing areas, bioclean rodent rooms, ABSL2 rooms, and ABSL3 rooms; including disposable bouffant, shoe covers, Tyvek suits, footbath, and/or N95 respirators and PAPR (see DLAM Husbandry SOP 8.9).

2.3 Persons working in laboratories with animals must wear a lab coat, gloves, and close-toed footwear. The principal investigator should establish appropriate systems for disposing of contaminated PPE and laundering lab coats to prevent the ingress and egress of pathogens into and out of the laboratory (respectively).

2.4 Personnel should wash and/or disinfect their hands and change clothing as often as necessary to maintain good personal hygiene.

Date last reviewed: February 14, 2023
Date last amended: February 14, 2023

POLICY #D-3

Title: Wet Lab Training & Exemptions

Purpose: Wet lab training is required before any procedures involving live animals are performed. The Attending Veterinarian and IACUC will evaluate the qualifications of persons performing procedures with animals, including surgery and other invasive procedures under IACUC-approved animal care and use protocols.

Background:

1.1 The Federal Animal Welfare Act, the *Guide for the Care and Use of Laboratory Animals*, as well as other regulations, require that persons working with laboratory animals must be trained and experienced. For example, the *Guide* 8th Ed. (p.15) states:

> "All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being."

1.2 The IACUC has determined that a "wet lab" represents an effective venue for the training of individuals on animal protocols to humanely perform surgery and other procedures on live animals.

1.3 The IACUC has determined that the Attending Veterinarian is qualified to evaluate on behalf of the IACUC, the training and experience of persons proposing to conduct procedures on live animals.

Policy:

2.1 Each Principal Investigator will indicate on the animal care and use protocol (Section 10) that personnel to be working with animals have or have not been trained in the assigned procedures and the date of that training. Participating personnel will be named on the protocol.

2.2 Prior to commencement of the project, personnel to perform procedures on live animals will schedule a wet lab with the DLAM Chief Clinical Veterinarian. Procedures will be taught utilizing the type of animal named in the protocol, and will include basic handling and restraint techniques, compound injection, blood collection, anesthesia, and other procedures as stipulated in the approved protocol. Personnel requiring training in surgical or other invasive procedures will also be trained in those procedures as necessary.

2.3 The wet lab will be conducted by a DLAM faculty or resident veterinarian or by an expert outside of DLAM with particular proficiency with the animal and procedure to be used. Following successful completion of the wet lab, as determined by the instructor and Attending Veterinarian, the IACUC Manager will be notified that the employee may carry out their assigned protocol tasks.

2.4 Principal Investigators may request exemption from wet lab training based on previous training and experience, as indicated on the animal care and use protocol.

2.5 Investigators requesting exemption from wet lab training will submit in writing to the IACUC Manager, a signed request for exemption, describing in narrative format the training and experience of persons to be exempted.

2.6 All requests for exemption will be reviewed and a recommendation made to the IACUC by the Attending Veterinarian.

Date last reviewed: March 21, 2023
Date last amended: March 21, 2023

POLICY #D-4

Title: Rules and Regulations Course: Failure to Complete training

Purpose: To establish a consistent policy to address noncompliance with the LSU triennial animal regulatory training requirement.

Background:

Federal regulations require that all persons using animals in research or teaching be "appropriately trained". The LSU IACUC has determined that appropriate training includes training not only in the procedures to be used, but also in the principles of animal use. The IACUC has determined that triennial testing via the AALAS Learning Library class "Working with the IACUC at LSU" provides the teaching and research staff with adequate training in the principles of humane animal use. Individuals on the IACUC are exempt from the requirements of the training requirement while they are on the committee.

Policy:

1.1 New Protocols

1.1.1 All persons listed in the Investigator's Training section of the LSU Animal Use Protocol, as well as the principal investigator, must take and pass the online class "Working with the IACUC at LSU".

1.1.2 A new protocol will not be approved until all personnel listed on the protocol have successfully completed the online training requirements.

2.1 Active Protocols

2.1.1 Failure of personnel to renew certification for a class, where triennial requirement has expired during the life of the protocol, will result in removal of the noncompliant person from the research protocol in question, and/or suspension of the protocol in question. If deemed necessary, a protocol could be suspended, causing a temporary or permanent stoppage of all animal work on the protocol in question.

2.1.2 Any vote to suspend a protocol will occur during a regularly convened IACUC meeting. If a protocol is suspended, the IACUC will notify, through the Institutional Official, the agency funding the research covered by the suspended protocol as well as the USDA and the OLAW.

2.1.3 Future protocols involving the noncompliant person will not be approved until the person has completed the on-line training course and is once again in compliance.

Date last reviewed: March 21, 2023
Date last amended: March 21, 2023

Policy #E-1

Title: Occupational Health and Safety Program (OHSP) for Animal Users

Purpose: To ensure adequate health monitoring, disease prevention, and employee education are in place for personnel involved in the care and use of animals.

Background:

1.1 The *Guide for the Care and Use of Laboratory Animals* requires an occupational health and safety program, and it "must" be part of the overall animal care and use program.

1.2 Organisms infectious to humans are classified by the U.S. Department of Health and Human Services (PHS) into 4 risk groups based generally on human infection potential, the severity of disease, availability of treatments, and route of infection. Classification is further extended to these agents when found in or used in animal research. Classifications and guidelines are found in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition.

1.3 Organisms in animals that are required to be handled in ABSL3 facilities are typically indigenous or exotic diseases that cause serious and potentially lethal diseases, and are often transmitted by the aerosol route. These organisms are divided into risk groups, and typically, Risk Group 3 organisms are studied in animals housed in ABSL3 facilities.

1.4 With the current infectious disease focus at the LSU School of Veterinary Medicine and the use of higher risk organisms, the IACUC needs to ensure that all personnel are adequately monitored and protected.

Policy:

2.1 Participation in this program is **mandatory** for all personnel working with LSU-owned and field-based animals utilized in teaching, research, and testing, as well as for personnel who may be exposed to chemical or infectious animal waste. Program participants include facility services personnel, animal caretakers, principal investigators, scientific-technical staff, graduate students, student workers, and post-doctoral and visiting scientists.

2.2 An Initial Risk Assessment Questionnaire is required to be completed and submitted to the OH&S Physician at the LSU Student Health Center by all personnel involved in the care and use of animals from 2.1. Based on the assigned risk level, the OH&S physician may request additional medical information through the completion of a medical health questionnaire, and consultation with the program participant, and may perform a physical examination, diagnostic tests, and/or administer immunizations.

2.3 Should personnel choose to utilize their private physician, the LSU OHSP Medical Questionnaire must be completed and presented to the private physician prior to or at the time of the office visit. Confirmation of the office

visit, immunizations administered, and recommendations for work restrictions are to be sent to the LSU Student Health Center for review.

2.4 When the use of infected animals requires them to be housed in ABSL3 facilities, then all personnel working with the animals must complete the medical questionnaire and schedule a physical examination with the OH&S Physician at the LSU Student Health Center.

2.5 Final approval of the protocol will be withheld until all personnel listed on the protocol are enrolled in the OHSP and notification has been received by the IACUC Manager from the OH&S Physician of the LSU Student Health Center regarding completion of the program requirements, as well as clearance of the program participant(s) to perform their assigned animal-related duties. As such, the OHSP process should be started well in advance of the time animal use will begin.

2.6 Continued approval of any animal care and use protocol that is considered in Risk Group 3, for animals housed in ASBL3 facilities is contingent upon yearly medical reevaluation of all participants.

2.7 Continued approval of any animal care and use protocol that is **not** considered in Risk Group 3, is contingent upon the protocol participants submitting a risk assessment annually to the OH&S Physician during the three-year protocol approval period.

2.8 The entire OHSP process must be completed annually by all participants listed on an approved IACUC protocol.

Date last reviewed: May 9, 2023
Date last amended: May 9, 2023

POLICY #E-2

Title: Approval of Studies Involving Zoonotic Agents & Human Pathogens in Animal Rooms

Purpose: To facilitate the safe use of known zoonotic agents and human pathogens in the animal rooms.

Background:

1.1 Zoonotic agents are those organisms that can be transmitted from animals to humans.

1.2 Federal regulations require that the institutional biosafety committee evaluate and approve the use of zoonotic agents and human pathogens and other potentially infectious materials such as certain tissues and body fluids with potential for causing ecologic or commercial harm.

1.3 LSU has established an Inter-institutional Biological and Recombinant DNA Safety Committee (IBRDSC) to review and approve activities involving biohazardous agents.

Policy:

2.1 The IACUC requires that before approval of an animal use protocol involving a zoonotic agent is granted, the investigator must discuss the study with the DLAM Director or Associate Director to confirm that the DLAM can accommodate the study. The investigator will then complete a full application to, and receive approval from, the campus IBRDSC. This application will include completion of the DLAM "Precautions in Animal Rooms" form.

2.2 Before animals infected/infested with a human pathogen can be housed in the animal rooms, the investigator must provide DLAM with a completed and signed "Precautions in Animal Rooms" form, complete with Biohazard emblem, for posting on the animal room door.

2.3 For projects involving BSL3 agents to be housed in the SVM ABSL3 facility, the IACUC requires investigators to have also received approval from the BSL-3 Containment Advisory Committee (BCAC).

2.4 Animal work cannot begin on an approved animal care and use protocol for studies involving zoonotic agents and human pathogens in animal rooms until approval has been received from the IBRDSC.

Date last reviewed: May 9, 2023
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