Institutional Animal Care and Use Policy and Procedures Manual

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PURPOSE

It is the purpose of this document to enumerate the specific requirements, roles and responsibilities for the use of live vertebrate animals in research, experimentation, biological testing, teaching, or for related purposes, hereinafter referred to as "Activities", in order to assure that any use of animals conforms to the ethical and humane standards for animal care and use, federa*l statutes and regulations, policies and guidelines; and applicable University* policies and procedures.

BACKGROUND

All activities performed by, or under the direction of, UL Lafayette personnel in the course and scope of University duties, or which use University resources, must comply with applicable UL Lafayette policies and procedures, regardless of funding and whether performed in UL Lafayette facilities or at offsite locations. The University of Louisiana at Lafayette policies on live vertebrate animal use in research and teaching are based on the federal regulations, US Government Principles, PHS Policy, and professional standards of practice. A selection of these references is listed here:

1. Animal Welfare Act, 1966 [USC Title 7, Sections 2131 to 2156] as amended in 1970, 1976, 1985 and 1990.
2. Animal Welfare Regulations [Title 9 CFR, Subchapter A, Animal Welfare, Parts 1, 2 and 3]
3. Health Research Extension Act, 1985 [Public Law 99-158, November 20, 1985, Section 495]
4. US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 1985
5. PHS Policy on Humane Care and Use of Laboratory Animals, 1986
6. NIH Grants Policy Statement (12/03), Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General -- Part 2 of 7
7. Guide for the Care and Use of Laboratory Animals (*Guide*) [8th Ed., 2010]
8. AVMA Guidelines on Euthanasia 2013
9. University of Louisiana at Lafayette Policy on the Use of Animals in Research and Teaching
10. University of Louisiana at Lafayette Animal Welfare Assurance of Compliance (A3029-01)

APPLICABILITY

Any activities involving the use of live vertebrate animals performed by or for UL Lafayette are covered under this policy, if it satisfies any of the following criteria:

1. It is conducted by or under the direction of UL Lafayette personnel in connection with his or her UL Lafayette responsibilities;

2. It uses UL Lafayette property, facilities or resources to support or carry out research or teaching;

3. The name of the University of Louisiana at Lafayette is used in applying for funds (intra or extramural);

4. The investigator plans to use his/her University of Louisiana at Lafayette association in any publication or public presentation resulting from the research.

POLICIES

In order to demonstrate appropriate oversight of animal care and use activities and to comply with federal regulatory agency requirements, no vertebrate animal care or use activities shall be initiated by UL Lafayette personnel prior to obtaining Institutional Animal Care and Use Committee (IACUC) review and approval.

The UL Lafayette IACUC has the authority to approve animal care and use activities that are proposed to occur in UL Lafayette facilities, use UL Lafayette resources, or are performed at or in collaboration with offsite locations. When an IACUC approved policy or Standard Operating Procedure does not exist governing a particular type of animal use, such as toe-clipping, genetically modified animals, or food and fluid restrictions, it is the policy of the IACUC to require a full description of the procedure in the Animal Procedure Statement, where the IACUC will evaluate the effect of the procedure on animal welfare for the animal model selected.

Any other applicable regulatory committee approvals (e.g., IRB, IBC, RSC) and completion and/or receipt of all other necessary documentation is required prior to the initiation of any animal activity.

Animals shall not be purchased, collected, or transported to any division of UL Lafayette until an Animal Procedure Statement either for holding the animals or the procedures involved has been approved by the IACUC.

Additionally, contract research requires an agreement between the University and the contracting entity. If UL Lafayette will receive compensation for conducting or directing a research activity, a contract must be established through UL Lafayette Sponsored Programs Finance Administration & Compliance. When contracts or other agreements are required, the language is to be developed and negotiated by UL Lafayette Sponsored Programs Finance Administration & Compliance and the New Iberia Research Center staff to document UL Lafayette's responsibilities for the conduct of the specific project.

POLICY ON THE USE OF ANIMALS IN RESEARCH AND TEACHING

PREAMBLE

The University of Louisiana at Lafayette recognizes the importance of the use of animals in its research and teaching programs. Animals are vital both for understanding basic biological processes and in developing treatment for human and animal diseases.

The University, committed to maintaining high standards for the care and use of animals in research and teaching, therefore adopts as its own principles the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training".

The University, including its investigators and researchers, accepts responsibility for determining that research and teaching involving the use of animals fulfill these principles.

POLICY ON APPLICABILITY OF THE FEDERAL GUIDELINES AND REGULATIONS

It is University policy that University practices for the procurement, housing, care, and use of animals should conform to the Guide for the Care and Use of Laboratory Animals in Research, 1996 or succeeding editions, all requirements of the United States Department of Agriculture (USDA) and all regulations issued by the USDA implementing the Animal Welfare Act (P.L. 89-544) as amended. The President, Vice President for Research, Innovation and Economic Development, Institutional Official or Director of the Office of Research and Sponsored Programs shall take appropriate action to meet such standards. The policy applies to all research and teaching irrespective of whether the research is funded from extramural or internal sources.

RESPONSIBILITY FOR COMPLIANCE

The Vice President for Research, Innovation and Economic Development, Institutional Official and Director of the Office of Research and Sponsored Programs are responsible for compliance with this policy in the institution. They are

authorized to take appropriate action for those activities under their jurisdiction to implement regulations required by all funding and regulatory agencies on the care and use of animals in research and teaching. The Vice President for Research, Innovation and Economic Development shall establish and implement procedures, including appointment of an animal care and use committee to assure adequate review of animal facilities, procedures, research, and teaching protocols.

The committee shall consist of no fewer than five members with varying backgrounds. At least one member shall be a licensed doctor of veterinary medicine and at least one member shall be a person whose-primary vocation is in a nonscientific area. One member shall be unaffiliated with the institution.

ACCREDITATION

Non-human primate facilities shall be fully accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) or the Vice President for Research, Innovation and Economic Development shall be taking appropriate action to achieve such accreditation.

RESPONSIBILITY IN OFFICE OF THE VICE PRESIDENT FOR RESEARCH, INNOVATION AND ECONOMIC DEVELOPMENT

The Vice President for Research, Innovation and Economic Development is responsible, on behalf of the President, for assuring University compliance with the policy and for developing any modifications or exceptions to policy as appropriate.

U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING, RESEARCH, AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.*

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results.

Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

*For guidance throughout these Principles, the reader is referred to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences. (Note from OLAW)

POLICY FOR REPORTING ANIMAL ISSUES

INTRODUCTION

In accordance with the Office of Laboratory Animal Welfare (OLAW) guidance on prompt reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animal (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html), which state that "*conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanisms failures, resulting in actual harm or deaths to animals, is an example of a situation that is reportable to OLAW*", the IACUC has developed this policy to provide guidance on the process of reporting.

POLICIES/PROCEDURES

1. Animals supported by PHS or NSF funds will be monitored and cared for in accordance with the contract or grant statements of work, UL Lafayette NIRC Standard Operating Procedures, the Animal Welfare Act, PHS Policy and the Guide for the Care and Use of Laboratory Animals.

2. In the event facility or handling failures result in serious injury or death, the incident will be reported to the IACUC for further investigation and subsequent reporting the IO. Reporting to OLAW will be accomplished in the form of a letter from the IO.

3. All other cases of death or serious injury will be reported to the IACUC, OLAW and the funding agency in a monthly report. In the event of a traumatic injury resulting from conspecific aggression leading to subsequent death of the animal, the PI (or designate) of the program will communicate the details of the incident by phone to OLAW. When a detailed written report is required by OLAW, the facts of the incident (accident) will be verified, and a final written report will be submitted to OLAW by way of a letter from the IO.

4. In the event that the veterinarian or IACUC notes a trend in deaths resulting from conspecific aggression, the IACUC will initiate an investigation. Assessment of possible trends may be done by the program assigned veterinarian and subsequently reported to the IACUC or will be done by the IACUC via assessment of mortality and morbidity reports reviewed during the meeting. Once the IACUC completes the investigation, the IACUC will submit a written report to the IO. The IO will submit a report in the form of a letter to OLAW describing in detail the events and plans for remediation of the problem if applicable.

OLAW: Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Dr.
Bethesda, Maryland 20817
Ph. (301) 496-7163 Fax (301) 402-7065

(Reviewed and approved August 15, 2017)

REPORTING CONCERNS INVOLVING THE CARE AND USE OF ANIMALS

HANDLING OF COMPLAINTS

Statement

Principal Investigators, animal caretakers, or anyone else responsible for or concerned with the health and welfare of the animals used in research and teaching at the University of Louisiana at Lafayette and any of its facilities who are aware of instances of possible non-compliance with the policies, rules, regulations and laws regarding the humane care and use of animals, should report such concerns to a member of the Institutional Animal Care and Use Committee (IACUC) or to a designated member of University administration.

All allegations of animal mistreatment will be taken seriously and investigated. In accordance with Federal laws and the Institution's Assurance statement to the Public Health Service (PHS), individuals reporting such concerns may do so without fear of discrimination or reprisal.

Procedures

A. Complaint Requirements

1. Any complaint regarding possible inappropriate care or handling of animals should be made to a member of the IACUC, the Institutional Official, or the Vice President for Research, Innovation and Economic Development. Contact information is provided on the IACUC website.

2. A verbal or written complaint is acceptable. Whatever the mode of communication employed, the complaint should include a factual description, time, location, animal species, numbers and identification of animals, specific care or handling concerns, and any other relevant details to the extent this information is known.

3. Anonymous complaints are acceptable if sufficient detail is provided to allow investigation of the charges.

4. The identity of a complainant will be kept confidential, when so requested by the complainant, to the extent allowed by law or court order.

B. Internal Routing of Complaint and Investigation

1. The person specified in A.1 who initially received the complaint shall forward it to the IACUC Chair as soon as possible and in no event more than 1 business day after receiving the complaint.

2. When a verbal complaint is received by a person specified in A.1, that person is responsible for providing a written, summary report to the IACUC Chair.

3. The IACUC Chair shall review the complaint, notify the Institutional Official

(IO) that a complaint was made, and schedule a meeting of a subcommittee of the IACUC to review the complaint within ten (10) business days.

4. The IACUC Chair will notify the alleged involved individual(s) and the person(s)' supervisor(s) that a complaint was received, and afford them 24 hours to respond.

5. If the preliminary investigation by the subcommittee indicates that the complaint is unsupported, the complaint and all relevant information will be presented at the next meeting of the IACUC and recorded in the minutes. The IACUC Chair will notify the IO, all involved individuals and associated administrators of the IACUC's determination.

6. If the preliminary investigation reveals that further investigation of the incident is warranted, the relevant information will be presented for discussion at the next convened meeting of the IACUC. Involved individuals will be invited to the meeting to respond to the complaint and questions from the IACUC in person. Once the investigation is concluded, the IACUC will make recommendations for any corrective action. The IACUC Chair will notify the IO of the findings of the IACUC and recommended actions. The IO will notify the involved individuals and appropriate institutional administrators or departmental leaders in writing of corrective action to be taken as recommended by the IACUC.

7. In cases where significant problems are identified which are not satisfactorily resolved between the IACUC and the involved individuals, the IACUC may make recommendations to the IO for immediate action.

8. The IACUC will be responsible for maintaining a file documenting complaints, committee reviews and actions taken or recommended to rectify the problems identified, including any minority views expressed by any committee member.

9. Significant violations will be reported in writing to the appropriate Federal Agencies by the IO and will include a summary of the IACUC's investigation and information about corrective actions taken.

REPORTING OF NEGATIVE INCIDENTS

"Negative incidents" is defined as occurrences that harm, appear to harm, or cause the death of animals under the care of the University or occurrences that are deviations from standard operating procedures or generally accepted animal care practices that could endanger the welfare of the animals under the care of the University.

In instances when negative incidents occur involving animals under the care of the University or any campus facility, center or division; the director, department head or other relevant authoritative administrative personnel shall provide the IACUC Chair a description of the incident along with a description of any actions taken to remedy the situation within twenty-four hours of the time when the incident was first discovered.

The IACUC Chair shall provide the information related to the incident and any steps taken towards its resolution to the Institutional Official within 24 hours of receipt. The IACUC Chair shall review the information provided and present it to the IACUC in a timely manner. The IACUC shall review the incident and its resolution at the next scheduled meeting or before, if necessary, to be certain the matter is satisfactorily resolved. Should the IACUC have any recommendations for further corrective action, the IACUC Chair will forward a summary to the IO for presentation to the appropriate facility authority.

(Revised: November 22, 2013)

FACILITY INSPECTION POLICY

In compliance with 9 CFR 2.31 (c) (2), the IACUC will inspect at least once every six months, all of the research facility's animal facilities, including animal study areas.

Additionally, in compliance with 9CFR 2.31 (c)(6), the IACUC will assure appropriate living conditions that contribute to the health and comfort of the animals by inspecting, prior to housing animals, all new facilities or facilities that have undergone renovation that involved construction of walls, addition of permanent electrical fixtures or major changes in plumbing or HVAC systems.

Persons expecting to house animals in renovated or newly constructed animal facilities should contact the IACUC Chair to determine if the facility requires inspection prior to housing animals. Please allow 2 weeks for the inspection to occur.

Following the initial inspection, the facility will be included in the semiannual fall and spring inspections.

Facilities housing animals seasonally or periodically (i.e. clinics and surgery suites) will be inspected during the semiannual fall and spring inspections, even if animals are not present. Notations of deficiencies will be provided to allow repair and modifications to be made prior to moving animals into the facility.

(Revised: November 7, 2014)

POLICY ON SEPARATION BY SPECIES, SOURCE, AND HEALTH STATUS

Introduction

Physical separation of species housed at the University is important and necessary in most cases; however, special consideration should be given to species where psychological well-being is a factor. Interspecies aggression can cause anxiety and physiological changes. Additionally some species may carry infectious disease agents that could cause severe disease or death in other species. Control of infectious disease in laboratory animals requires that populations that may vary in microbial status be segregated. In this regard, it is effective to separate animals according to species, source, and health status. This document describes the IACUC policy for separation of animals by these criteria. Fish, reptiles and amphibians can be exempted from this policy following IACUC approval.

Policy rules:

1. Animals may not be housed with those from another species, except on a case by case basis to benefit animal welfare. For these exceptions, animals may be housed with other species following attending vet review ensuring adherence to rules on separation by pathogen status and behavioral compatibility. When exceptions are made, the IACUC must be notified about the number and species of animals and the concerns that were addressed by the housing adjustments.

2. Animals of the same species obtained from different sources and vendors, or via different shipments, may not be housed together unless they have completed a quarantine period and have the same health status as the other animals in the room. Rodents from separate vendors may be housed in the same room when ventilated racks are used. Preferably, one rack will be designated for quarantine use (to protect non-quarantine animals in the event of a ventilation failure).

3. Animals of different microbial or pathogen status may not be housed in the same room.

(Approved for use: November 7, 2014; Revised November 8, 2018)

POLICY AND GUIDELINES FOR THE USE OF NON-PHARMACEUTICAL GRADE COMPOUNDS IN LABORATORY ANIMALS

INTRODUCTION

Study Directors and Investigators are expected to use pharmaceutical grade compounds whenever possible. This policy is based on guidelines presented by

OLAW, USDA, and AAALAC International. A pharmaceutical-grade compound is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia, eg. US Pharmacopeia (USP) or equivalent (Note: Everything produced by Sigma/Aldrich is non-pharmaceutical grade). The Food and Drug Administration (FDA) maintains a database listing of FDA approved commercial formulations for both human and veterinary drugs. It is important to note that investigational test articles by definition are non-pharmaceutical grade compounds, as these are non-clinical materials manufactured for research purposes. Furthermore, these investigational compounds are not intended for use in humans, until human clinical trials are initiated. Investigational drugs do not have a pharmaceutical grade substitute unless it is a marketed drug used as a control.

STUDY DIRECTOR/INVESTIGATOR GUIDELINES

When compounds are used for the clinical treatment of animals or to prevent or reduce/eliminate animal pain or distress, pharmaceutical grade compounds must be used whenever possible. Although it is preferred that Pharmaceutical Grade Compounds are used in experimental investigation when available, the use of Non-Pharmaceutical Grade may be appropriate to accomplish scientific aims. When Non-Pharmaceutical Grade Compounds are required for study, the compound must be described and a scientific justification must be provided in the Animal Procedure Statement (APS) for review by the IACUC. The IACUC will use the following factors in its review:

1) Scientific justification is provided, such as:
    a) A pharmaceutical grade compound is not available.
    b) A pharmaceutical grade compound is not available in the appropriate concentration or formulation or the appropriate vehicle control is unavailable;
    c) The non-pharmaceutical grade compound is required to generate data that are part of an ongoing study or to generate data that are comparable to previous work.
2) The chemical properties of the compound are appropriate for the study and the route of administration (e.g., the purity, grade, stability in and out of solution, solution vehicle properties, pH, osmolality, and compatibility of the solvent and other components of final preparation). In some cases the reagent-grade of the compound may be as or more pure than the pharmaceutical-grade; and
3) The method of preparation, labeling (i.e., preparation and use-by dates), administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality (i.e., to

prevent inadvertent co-administration of infectious agents or contaminants).

In all cases, principal investigators and study directors will be expected to use professional judgment to determine the appropriate test material and to ensure use of an agent with the least likelihood for causing adverse effects.

(Approved for use: June 19, 2014)

POLICY ON FISH EUTHANASIA

The IACUC encourages all investigators to utilize euthanasia methods approved by the AVMA and detailed in the current edition of the AVMA Guidelines for the Euthanasia of Animals.

Of the methods outlined in the AVMA, immersion in a buffered solution of MS-222 of at least 250 mg/L[1] for 10 minutes following the loss of rhythmic opercular movement is sufficient for most finfish regardless of size and geographic origin.

For subtropical to tropical finfish, 1 inch or less in length, ice water may be used, as long as the fish do not contact the ice. The fish should be immersed in the ice water for 5 minutes following the loss of rhythmic opercular movement to ensure death.

However, it is possible that certain research situations or requirements will make it necessary to utilize alternative methods. The IACUC will consider these methods, when appropriate literature is provided.

1 – Wilson et al. 2009. Journal of American Association for Laboratory Animal Science.

(Approved for use: December 13, 2016)

DESIGNATED MEMBER REVIEW FOLLOWING FULL COMMITTEE REVIEW POLICY

Purpose: This policy specifies the review procedures that are permissible when an Animal Procedure Statement has undergone full committee review and requires additional information.

In the event that an Animal Procedure Statement, having undergone review by a quorum of the full committee, requires additional information, the committee will vote to determine if a majority of the committee present feel the required revisions are substantive. When the revisions are not substantive, the APS will be reviewed by a designated member. When the revisions are substantive, the revised APS will be circulated to the committee for polling to determine either full committee or

designated member review. The Chair chooses the designated member for the review.

(Approved for use: November 22, 2013)

POLICY FOR HANDLING CHANGES TO AN IACUC-REVIEWED AND -APPROVED ANIMAL PROCEDURE STATEMENT

The UL Lafayette IACUC understands that modifications to an approved animal procedure statement may need to be made during the conduct of the research. To facilitate timely modification of active IACUC approvals and to minimize delays in research, the IACUC has set the following guidance to assist with expeditious review of the necessary changes.

SIGNIFICANT CHANGES TO ANIMAL ACTIVITIES PREVIOUSLY APPROVED BY THE IACUC

1. Significant changes that must be **approved** by either Full Committee Review or Designated Member Review, includes changes:
   a. from non-survival to survival surgery;
   b. resulting in greater pain, distress, or degree of invasiveness;
   c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
   d. in species;
   e. an increase of >10% in the number of animals (or a second increase during a single approval period);
   f. in study objectives;
   g. in Principal Investigator (PI); and
   h. that impact personnel safety.

   These changes should be submitted as an addendum and will undergo the normal review process.

2. Veterinary Verification and Consultation (VVC). Specific significant changes may be **handled administratively** in **consultation with a clinical veterinarian** at the New Iberia Research Center. The IACUC authorizes all New Iberia Research Center clinical veterinarians to act in this capacity. In the event that a clinical veterinarian is not available to perform the VVC, a study director with veterinarian credentials may perform the review, as long as, it is not for the study that they are overseeing. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify the requested change is consistent with current standards

of veterinary practice or specifically addressed in IACUC-approved policy (the IACUC Coordinator maintains a list of IACUC-approved policies that may be provided to any PI, Study Director or IACUC member, as needed) and will have no negative impact on the welfare of the animals. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. Modifications that may be reviewed via Veterinarian Verification and Consultation (VVC) include changes in:

a. anesthesia, analgesia, sedation, or experimental substances (within the same class);
b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
c. duration, frequency, type, or number of procedures performed on an animal;
d. addition of a non-invasive sampling method, determined at veterinary discretion, such as swabs of any orifice, collection of excrement or body fluid secretions, hair or skin scraping;
e. modification of a procedure that does not increase the degree of invasiveness.

These changes should be submitted as an addendum. The box for administrative handling should be checked, as well as, the one for the type(s) of change, and the relevant IACUC approved SOP(s) or guidance listed. The Coordinator will verify that the appropriate SOP or guidance has been referenced and IACUC approval is within the last 3 years prior to the consultation with the clinical veterinarian.

3. Specific significant changes that may be **handled administratively without additional consultation or notification**:

   a. A single increase of 10% or less in the IACUC-reviewed and -approved animal numbers.

   This change should also be submitted as an addendum. An explanation for the need of additional animals must be included. The box for administrative handling should be checked. The IACUC Office will confirm that the request is only for an increase (of 10% or less) in numbers and that this is the first such increase for this APS.

OTHER CHANGES

1. Changes that may be **handled administratively without IACUC-approved policies, consultations, or notifications** include:

   a. correction of typographical errors;

b. correction of grammar;
c. contact information updates; and
d. The addition of referenced IACUC approved SOP may be added to the APS if in fact the procedure will be conducted in accordance with the SOP; alternatively, the procedure must be fully described in an addendum if not included in the original prose submitted as the APS (Subsequent review process is required for all addenda)
e. Additional selection of Animal impact statements may be allowed when the intent is to reconcile a described procedure and provide consistency within the APS; and
f. change in personnel, other than the PI. **Note** - There will be administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

These changes may be communicated via email.

2. Investigators may use fewer animals than approved and do not need to communicate this to the IACUC prior to the decision.

(Approved for use: October 31, 2014; Revised May 18, 2021; October 18, 2023)

ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

INSTITUTIONAL OFFICIAL

The UL Lafayette President has delegated the responsibility for compliance with applicable federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal care and use activities to the Vice President for Research, Innovation and Economic Development.

The Vice President for Research, Innovation and Economic Development is the designated Institutional Official (IO) and is assisted in the discharge of this responsibility by the Institutional Animal Care and Use Committee (IACUC), the Attending Veterinarian, and staff in the Office of Research and Sponsored Programs (ORSP). The IO supports, facilitates, and promotes ethical and humane use of animals by demonstrating institutional commitment to uphold the standards set forth in the federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities.

The IO has the authority to establish campus policy for the use of animals and to disapprove, suspend or terminate Institutional Animal Care and Use Committee (IACUC) approved protocols. However, only the IACUC has the authority to approve animal care and use protocols or animal procedure statements.

The IACUC reports, through its Chair, directly to the Institutional Official. Nominations for membership on the IACUC are submitted to the Vice President for Research, Innovation and Economic Development, who reviews the qualifications of the nominees and makes the appointments.

The Attending Veterinarian reports directly to the Institutional Official regarding animal program issues.

The Institutional Official designated the ORSP as the office of record for the UL Lafayette animal care and use program. All records maintained by ORSP are stored for three years following the end of the project.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

The IACUC is the institutional body with responsibility for review and oversight of UL Lafayette's program for the humane care and use of animals. The IACUC supports, facilitates, and promotes ethical and humane use of animals by upholding the standards set forth in the federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities.

The IACUC is authorized to investigate and resolve concerns involving the care and use of animals brought to the attention of the committee by veterinarians, researchers, animal caretakers, students or others.

In accordance with the PHS Policy, the Committee must consist of no fewer than five members, including a Veterinarian with direct or delegated program responsibility for activities involving animals, one practicing scientist experienced in research involving animals, one member whose primary vocation is in a non-scientific area, and one member unaffiliated with the institution. In accordance with animal welfare regulations, not more than three members of the Committee shall be from the same administrative unit.

The IACUC oversees UL Lafayette's animal welfare program, facilities and procedures, and provides comprehensive reviews of activities involving animals. The IACUC's specific responsibilities are to:

1. Review at least once every six months UL Lafayette's animal care and use program.
2. Inspect at least once every six months UL Lafayette's animal facilities, laboratories, and other areas where animals are used.
3. Prepare and submit reports of IACUC program evaluations and facility inspections to the Institutional Official.

4. Review and approve, require modifications in (to secure approval) or withhold approval of proposed and continuing animal activities described in animal procedure statements (APS). Note – Any IACUC member submitting or listed on an Animal Procedure Statement as a researcher (veterinarians advocating for animal welfare are excluded) must recuse themselves from the review and approval process.
5. Review and approve, require modifications in (to secure approval) or withhold approval of all proposed changes (modifications) to approved animal activities. Note – Any IACUC member submitting or listed on an Animal Procedure Statement as a researcher (veterinarians advocating for animal welfare are excluded) must recuse themselves from the review and approval process.
6. Notify investigators in writing of its decision to approve, require modifications in (to secure approval) or withhold approval of proposed animal activities.
7. Review, and, if warranted, investigate concerns involving the care and use of animals in accordance with UL Lafayette's Policy and Procedures for Reporting Concerns of Animal Use and Abuse.
8. Suspend animal activities that are not being conducted in accordance with applicable federal statutes and regulations, policies and guidelines, and applicable University policies and procedures.
9. Make written recommendations to the Institutional Official regarding any aspect of the UL Lafayette animal care and use program.

IACUC Chair

The IACUC Chair is appointed by the Vice President for Research, Innovation and Economic Development and is responsible for ensuring the IACUC performs its functions as outlined in the Animal Welfare Act, PHS Policy, and the University's Animal Welfare Assurance. The Chair also acts as liaison with the IO on behalf of the IACUC.

The Chair has the authority, on behalf of the IACUC, to halt any animal activity if the safety or welfare of an animal appears to be at risk, if the work being performed on a project is not in accordance with the approved protocol, or if the research, has not been reviewed and approved by the IACUC. The Chair also has the responsibility to address, in a timely fashion, any serious or repeated problems, concerns, complaints or allegations regarding the care and use of animals.

ATTENDING VETERINARIAN

The Attending Veterinarian (AV) serves as a voting member of the IACUC and is the Chair of the Division of Veterinary Medicine at the New Iberia Research Center (NIRC). The AV is responsible for veterinary services at the NIRC, as well as, the main University campus.

The primary responsibility of the Attending Veterinarian is to assure that adequate veterinary care is provided to all animals. Adequate veterinary care includes programs of disease detection and surveillance, prevention, diagnosis, treatment, and resolution.

The Attending Veterinarian (or designee) is authorized to enter any UL Lafayette facility to conduct inspections of animal facilities and animals to ensure that animal husbandry, sanitation practices, and animal health and procedures are in compliance with federal statutes and regulations, policies and guidelines; and applicable University policies and procedures.

The Attending Veterinarian's (or designee's) specific responsibilities are to:

1. Monitor the care and use of animals in UL Lafayette facilities.
2. Provide technical assistance and training to all UL Lafayette personnel involved in animal activities, including selection and procurement of animals, husbandry and care, handling and restraint, identification and records, animal health and welfare, employee safety and health concerns, specific experimental and surgical techniques and euthanasia.
3. Assist investigators with protocol preparation pertaining to animal housing, requirements for surgery, proper use of anesthetics, analgesics, and tranquilizer drugs, methods of euthanasia and other animal health and welfare issues.
4. Halt any animal activity if the safety or welfare of an animal is at risk or if the work being performed is not in accordance with an IACUC approved UL Lafayette Animal Procedure Statement.
5. Report animal welfare concerns and/or possible non-compliance to the IACUC.

IACUC COORDINATOR

The IACUC Coordinator supports and coordinates all of the activities of the IACUC and serves as the liaison between the IACUC and the UL Lafayette research and teaching community. The IACUC Coordinator's specific responsibilities are to:

1. Provide training, education, and consultation services on regulatory requirements.
2. Communicate with other UL Lafayette administrative units and regulatory compliance committees.
3. Conduct administrative audits (Post-approval monitoring) of approved Animal Procedure Statements and animal activities.
4. Coordinate meeting materials, locations and times.
5. Coordinate program review and facility inspections.
6. Monitor regulatory changes and communicate them to the committee.
7. Maintain official files.

IACUC Assistant

The Assistant supports the IACUC by facilitating the review process and maintaining the database of approvals. The IACUC Assistant's specific responsibilities are to:

1. Receive applications for review and approval.
2. Prepare documents for committee review.
3. Prepare files for each application.
4. Communicate to investigators in writing, on the behalf of the IACUC, all committee decisions and actions.
5. Maintain a database of approvals and expirations.
6. Notify investigators of pending expirations.

Principal Investigator / Study Director

Eligibility

Each UL Lafayette faculty is eligible to be a Principal Investigator, unless the privilege of utilizing animals has been revoked by the IACUC or a federal or state entity. Persons filling the positions of Study Director at the New Iberia Research Center are by virtue of their University appointment status eligible to serve as the study director on an Animal Procedure Statement for an offsite Principal Investigator. Professors and Instructors utilizing live vertebrate animals in the classroom should enter their names as the Principal Investigator of an Animal Procedure Statement for classroom activities. Individuals who do not meet the criteria for Principal Investigator may serve as Principal Investigator, if they obtain a Faculty Sponsor for the activity. A Faculty Sponsor must be eligible to be a

Principal Investigator. Graduate students must have a graduate faculty member as a Faculty Sponsor.

Responsibilities

The Principal Investigator, Study Director (and Faculty Sponsor, when required) are responsible for full compliance with all federal and state statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities. This responsibility extends to all aspects of animal care and use, and all co-investigators, research personnel and students who participate in the animal activity. Although the Principal Investigator may choose to delegate aspects of animal care and use to other laboratory personnel or faculty in his/her laboratory, the Principal Investigator retains ultimate responsibility and is accountable for all animal activities performed under their protocol(s).

All IACUC approvals will be granted for periods not to exceed one year. Annual renewal of IACUC approval is the responsibility of the Principal Investigator.

The Principal Investigator's specific responsibilities are to:

1. Apply for IACUC approval (complete and submit the APS form) prior to the commencement of any live vertebrate animal care or use activity and initiate animal care or use activities only after written IACUC approval is provided.
2. Investigators and researchers (other than veterinarians assuring animal welfare), who are IACUC members, must recuse themselves from the review process.
3. Recognize that IACUC approval, in and of itself, does not necessarily constitute permission for implementation of animal use projects. Accordingly, the project should not begin until all required approvals have been obtained. Other approvals may be needed from the Institutional Biosafety Committee, Institutional Review Board or the Radiation Safety Committee.
4. Purchase any non-human primates to be used through the New Iberia Research Center. All non-human primates are subject to health assessment and quarantine by NIRC staff upon arrival at UL Lafayette - NIRC.
5. Species other than non-human primates may be purchased through the University purchasing department. The investigator (or other responsible, trained lab group member) must make arrangements to be available to receive the shipment and arrange for veterinary assessment of health, as needed.
6. Make no changes to the approved protocol without first submitting those

changes for review and approval by the UL Lafayette IACUC.

7. Provide the IACUC with any information requested relative to the care and use of animals.
8. Comply with an IACUC decision to suspend or withdraw its approval for an animal activity
9. Complete annual continuing review form for years 1 and 2 of the approval period. When animal activities will continue beyond the 3 year approval period, IACUC approval must be obtained prior to the expiration date or animal activities must be put on hold until approval is received.
10. File a closing report with the UL Lafayette IACUC at the conclusion of the study.
11. Ensure all personnel having direct live animal contact have been or will be trained in applicable humane and scientifically acceptable procedures for animal handling, administration of therapeutic drugs and euthanasia, as well as the online LATAnet training or appropriate modules of CITI training, prior to beginning any procedures with live animals.
12. Maintain documentation of trainings and make them available to the IACUC upon request.
13. Maintain and make available for inspection by the IACUC, Attending Veterinarian and federal agency inspectors all IACUC Animal Procedure Statements and animal care and use records in accordance with federal regulations, as well as, any controlled substance logs.

ANIMAL PROCEDURE STATEMENT APPROVAL PROCESS

IACUC Review Overview

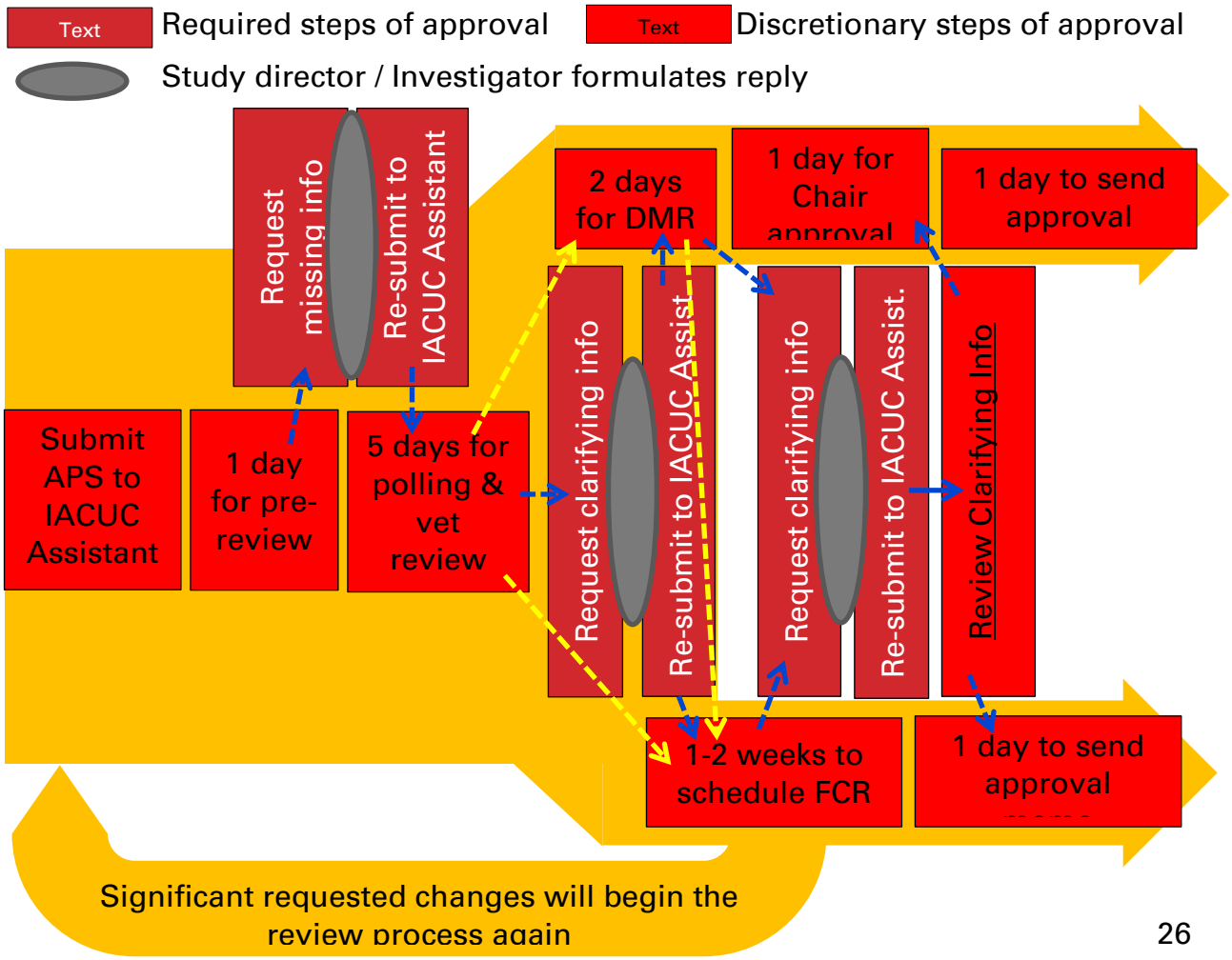
After an initial review for completion, the committee will determine the type of review: designated member review (DMR), full committee review (FCR) or a combination of both.

An APS, undergoing DMR, requiring no revisions, can be approved in about 10 business days (red boxes following the top arrow).

An APS requiring revisions and undergoing DMR may need more than 13 days for approval, dependent on the speed of reply from the study director/investigator (see the blue diversions from the red path along the top arrow).

An APS requiring full committee review with limited revisions, if any, can be approved in about 3 weeks (red boxes following the bottom arrow).

An APS requiring full committee review and revisions can be approved in about 1 month depending on the speed of reply from the study director / investigator (see the blue diversions from the red path along the bottom arrow).



All persons intending to utilize live vertebrate animals in research or teaching must complete an Animal Procedure Statement (APS) and submit it to the IACUC for approval. Persons needing to change the information in an approved APS must complete the Addendum form. The current Animal Procedure Statement and Addendum forms may be obtained from the IACUC website (http://vpresearch.louisiana.edu/research-compliance/institutional-animal-care-and-use-committee. Persons needing assistance with completion of these documents may contact the IACUC Coordinator, Attending Veterinarian or Chair of the committee. Forms are submitted via email as word documents to the IACUC Assistant. Submissions should also include a current CV that documents familiarity or training with the animal model and PDFs of required collecting permits, if applicable.

Review of Animal Procedure Statements and Addenda are continuous, because the IACUC utilizes a designated reviewer format for most reviews. While this tends to expedite the approval process, Investigators/Study Directors should still allow 3-4 weeks for review of an Animal Procedure Statement or addendum. Animal housing facilities not inspected within the last 6 months by the IACUC will be inspected during the review process to ensure that the facilities are prepared to accept and house animals. Annual renewals should be submitted 1 month prior to expiration and may be approved in 2-3 weeks, if there are few changes from the previous year. Significant modifications and renewals undergo the same approval process as new applications with the exception of those that OLAW has determined may be administratively approved in consultation with a veterinarian (NOT-OD-14-126). Please see the Policy for Handling Changes to an IACUC-reviewed and –approved Animal Procedure Statement.

GUIDANCE FOR COMPLETION OF THE ANIMAL PROCEDURE STATEMENT

The current form is an interactive PDF form. When opened in Adobe Reader, there is a purple bar across the top. On the right side of the purple bar, there is a button to highlight the existing fields. You will also note throughout the form buttons to add and remove additional sections, and rows of information in tables. As this is an interactive form answers to some questions will open hidden questions when needed and close others when not needed. Please contact the IACUC office if you have any trouble using the form. Below is an overview the expectations for the various sections.

Section 1 of the APS gathers general information about the Principle Investigators of the project. Professors and Instructors completing this form for a class should place their name as the PI. The graduate assistant, if known at the time of application, can be listed as the Co-PI. Graduate students completing this form

should always include their mentor's information, as well. The IACUC is no longer using LATAnet training. In order to complete the required Animal Welfare Training, please go to the Collaborative Institutional Training Initiative. If you are not registered with CITI and affiliated with ULL, click the register button, provide the required information and affiliate with the University of Louisiana at Lafayette. When answering questions about which courses you would like to take, in question 6, everyone must check the box for "Working with the IACUC Course". Then select the courses relevant to your animal model. These courses must be completed by all animal users listed on the Animal Procedure Statement prior to approval. The IACUC staff will confirm the completion and determine if additional modules are required based on the animal model used.

Section 2 requests the title, funding source(s), start and end dates for the project.

Section 3 allows you to select the type of application and collects data on the previous year's work for annual renewals. This allows the IACUC to fulfill its obligation to provide annual review of continuing projects and monitor the welfare of animals participating in the project.

Section 4 question a) Purpose should be written in everyday language, be understandable by the general public and serve to explain why the use of animals is important to advancing knowledge or human or animal health. This is important as there are non-scientists on the IACUC. The form contains two links to readability testers. If one of these shows a reading level of 10th grade, the purpose is properly written. Contact the IACUC office for assistance, if you have trouble getting down to a 10th grade level. There are also 2 questions to explain why mathematical models and computer simulations cannot be used and how the research does not unnecessarily duplicate. The key word is unnecessarily; explain why your research is necessary or non-duplicative.

Section 5 has some impact statements next to checkboxes or as pulldown lists. Check and select the statements that apply to the research for this project. If additional text boxes open, please provide the requested information.

Section 6 has a table to gather information about the animals to be used. Select the class of animals and a drop-down list of species will become visible. If your species is not listed, please type it in. Additional species may be added by clicking the green Add Row button. The age and weight listed can be ranges. The total number of animals will be calculated from the numbers entered for each pain category. The **P&D cat** labels are buttons that will display the definition for the pain category when clicked. If animals will be screened prior to selection for the activity, these animals should be listed as category B. Please do not "double list" your animals.

For example, if you expect to screen 50 animals to use 30 with the possibility that 10 will euthanized for maximum blood collection, you would enter

Number	
Total 50	
P&D cat. B	20
P&D cat. C	20
P&D cat. D	10
P&D cat. E	0

20 category B, 20 category C and 10 category D, depicting the maximum pain category for each group of animals. While these are approximations, always list the maximum number you intend to use to minimize the number of times you need an addendum to be approved.

Should it appear that the number of animals used will exceed the number approved by the IACUC at any time during the year, an addendum will need to be submitted and approved prior to using more than the maximum number requested on the original APS. If the additional animals are 10% or less of the original approval, the addition may be administratively handled.

Section 7 contains questions to help you justify the species used and the number of animals requested. When animal numbers are listed in category D or E the Consideration of Alternatives section will become visible in Section 7. There are 2 options for fulfilling this requirement; please select one and provide the requested information. For assistance with performing a "consideration of alternatives" please consult the following references:

USDA Policy 12

Animal Welfare Information Center – Literature Searching and Databases

ALT web Search for Alternatives

Section 8 collects information about anything other than sedation or euthanasia agents that will be administered to the animals. This includes chemicals, bacterial and viral exposures and DNA, RNA, protein or other molecules. You have the option of uploading a table from another document or entering your information into a table.

Section 9 has a table to gather information about the samples that will be collected. Again, you have the option of uploading a table from another document or entering your information into a table.

Section 10 collects information about surgical procedures, both major and minor. These are procedures that pierce or open a body cavity.

Section 11 gathers information about sedation and pain relief. This section is independent of the Surgery section, because some animal models and nonsurgical procedures require sedation for the welfare of the animal and the handler.

Section 12 contains checkboxes to allow additional sections to open as needed to gather further information that may pertain to your research.

Section 13 is a description of the procedures; this section should be used to depict the timing and order of the procedures. Specifics about agents administered and samples to be taken do not need to be repeated here if they are described adequately in previous sections. Do not skip this question; there must be a concise description of the animal use. Sequential steps of the animal activity are the easiest to understand. The description may include a timeline or drawings as necessary.

Section 14 for Housing and Husbandry will be visible for animals that are housed in University facilities, when Yes is clicked in question 6.b). When nonstandard housing and/or husbandry procedures are necessary please explain the need. An additional question about enrichment will be visible for USDA regulated species.

Section 15 asks the investigator to consider if Adverse Events are known or expected with the procedures described. When they are expected, the investigator will be given an opportunity to explain how animal welfare will be protected.

Section 16 has a series of questions to gather information the experimental and humane endpoints for the procedures described. Note a euthanasia method appropriate to the animal model and type of research must be provided. The Attending Veterinarian can assist with determining an appropriate method if the AVMA Guide on Euthanasia is not clear. The final disposition of the animals must be declared.

Section 17 allows one to list all the personnel involved and denote the types of procedures they will participate in. If you are utilizing the NIRC animal facility, you will notice a prefilled list of personnel, please delete as necessary. Any further adjustments will need to be entered into the table below the pre-filled table. Check a box to indicate if training is complete or needed and provided any requested information. Training assurance can also be provided by pasting curriculum vitae into Section 18.

Section 18 may be used to paste in any additional information relevant to animal work detailed in the animal procedure statement or curriculum vitae of the investigators.

Section 19 contains the assurance statements that investigator is assuring the IACUC of when they type their name, in lieu of written signature, in Section 20.

Note: If the submit button does not allow your document to be sent to the IACUC, please save a copy and send to IACUC@louisiana.edu.

ADMINISTRATIVE REVIEW

Upon receipt of an APS or an addendum to an approved APS, the Assistant reviews the document for completeness of content and checks for Animal Welfare training completions of the personnel listed. The Investigator/Study Director will be notified of any deficiencies and given the opportunity to revise the document prior to dispersal to the committee.

The IACUC Assistant or Coordinator will solicit the consultation of a veterinarian when the box for "Please consider administrative approval in consultation with a veterinarian," is checked and the changes fit the criteria for review via Veterinarian Verification and Consultation. The animal welfare assessment from the veterinarian will be forwarded to the Chair, who will determine if the addendum can be administratively approved. Addenda that cannot be administratively approved will be forwarded to the committee for review polling and regular approval procedures.

INITIAL REVIEW

The Assistant sends the completed documents to the IACUC for initial review (polling) and a veterinarian, assigned by the Attending Veterinarian, for Veterinary Review. The IACUC has 5 business days to review the APS, record any questions and determine if the APS should be reviewed by a designated reviewer or a full committee. Their determinations are sent to the Assistant. After 5 business days, if no one calls for a full committee review, and a majority of the committee has responded, the assistant collects any questions and concerns from the committee and Veterinary Review and forwards them to the Investigator/Study Director for clarification. The Investigator may provide clarifications to the Assistant either by revising the APS (preferred) or supplying a memo. Upon receipt of the clarifications the Assistant will request the assignment of a designated reviewer by the Chair. The designated reviewer performs the final review of the APS (see below). In the

event the Chair determines the clarifications were significant, the APS will be redistributed to the committee for review determination.

Full Committee Review

If any member of the committee calls for a full committee review, the assistant will forward all comments and questions to the Investigator/Study Director prior to the meeting. The coordinator will schedule a time for a quorum of the committee to meet and discuss the application. The Investigator will be invited to submit a revised document prior to the meeting and to answer questions during the meeting. After the discussion, if the committee is satisfied with the changes and has no further questions or concerns, they may vote to approve the application. If there are remaining questions and concerns, the committee will decide if the revision/clarifications are significant or minor. The Coordinator will summarize the items that need to be clarified and forward a request to the Investigator/Study Director. The Investigator/Study Director may provide clarifications either by revising the APS or supplying a memo, as appropriate. If the changes are significant, the revised document will be sent to the committee for initial review, and the committee will again decide whether the revision should go to a designated reviewer or to the full committee. If the changes are minor, the committee may vote to have Chair choose a designated reviewer to perform the Final Review and confirm the requested changes have been made.

Final Review

The Designated Reviewer will have 2 business days to review the application for compliance with the regulations and policies. He/She may recommend approval, request modifications prior to approval or request a full committee review. If there are modifications needed, the Assistant will send the request to the Investigator/Study Director. The Investigator/Study Director may provide clarifications to the Assistant either by revising the APS or supplying a memo. When the designated reviewer is satisfied that the application meets all the compliance requirements, the Assistant will submit the Review for final approval by the Chair. When the Chair gives final approval, the Assistant will send the approval document to the Investigator/Study Director.

Approval

All APS approvals are for three years. Submission of a continuing review form annually updates the committee on the project progress and number of animals used, and is required to maintain approval for the three years. The continuing review form must be completed near the end of years 1 and 2. Projects going beyond the 3 year approval period will need to resubmit a full application for

approval prior to the end of the third year, in order to obtain additional approval. Modifications or changes do not change the expiration date and must be submitted to the IACUC for approval prior to implementation.

Failure to Approve

Only a majority vote of a quorum of the full committee can determine that an application for animal use cannot be approved. All efforts will be made to identify modifications that will allow an application to be compliant with the guidelines and regulations while still achieving the goal of the animal activity. If approval cannot be granted, the Investigator/Study Director will be notified of the committee's decision and the reasons in writing.

Expirations

All approvals expire three years from the approval date. When work will continue past the expiration date, it is the Investigator/Study Director's responsibility to submit an APS form about 4 weeks prior to the expiration to renew the project (be sure to use the current form). The IACUC assistant may send an expiration notice 4-6 weeks prior to the expiration date as a reminder. Failing to renew the approval prior to the expiration date will require all animal activities under the approval to stop until the renewal has been approved. During such a lapse in approval only feeding, watering and cleaning of cages will be allowed.

Animal Facilities

The University has several facilities available for animal housing: a large non-human primate facility with a variety of housing types; a mouse facility that uses ventilated caging; classic fish tanks or large water tables with flowing water; and naturalized artificial mini-ponds. Please contact the IACUC if you would like more information about housing animals in one of these facilities. If these options are not the type of housing you need, the IACUC will work with you and your department to develop compliant housing for your species prior to their arrival at the University.

Note: All persons accessing the non-human primate facility must show proof of measles immunity or have their titer checked, and receive a semiannual TB test or annual chest X-ray, if serum positive for TB.

Physical Requirements

Each facility is required to provide primary and secondary containment, temperature control, light control, feed and clean water appropriate for the species

being housed. Species specific standards can be found in the federal regulations, the "Guide", and a number of guidelines listed on the IACUC Resources website.

The facility should also provide space for any equipment used to handle, manipulate or euthanize the animals. Additionally, there should be space designated for storage of feed and bedding, personal protective equipment, cleaning supplies, clean and dirty caging (as appropriate) and carcass storage until disposal.

STAFFING REQUIREMENTS

Enough staff should be available to maintain appropriately clean and sanitized housing; appropriate feeding times, fresh water and daily animal health checks. Veterinarian visits and consults should be arranged through the Attending Veterinarian. A consultation early in the project will allow the development of a health check schedule, when necessary.

POLICIES AND PLANS

Each animal facility must be inspected prior to housing animals and every 6 months thereafter, as per the facility inspection policy, have a plan for the care and use of the animals housed there and documentation to record the steps taken in their care and who performed it. This may take the form of single document and checklist or multiple Standard Operating Procedures (SOPs) and logs, depending on the complexity of the facility and requirements for care of the animals.

Policies should be in place to assure proper training of staff prior to handling animals. Note staff handling animals is required to complete the Animal Welfare Training provided by the University, as well as, any species specific modules that apply. See the Training section below.

Contingency plans should describe the steps that will be taken in the event of an electrical outage, HVAC failure, approaching hurricane or tropical storm, the potential need for mass euthanasia and/or saving a few important animals from a fire.

The IACUC will review these documents before they are put into use and whenever a change is made.

TRAINING

IACUC Members

All New IACUC members are required to attend a New Member Orientation where the following materials will be provided: the Guide for the Care and Use of Laboratory Animals, OLAW IACUC Guidebook, Animal Welfare Act and Regulations, USDA Animal Care Policies, PHS Policies on Care and Use of Laboratory animals, and the AVMA Guidelines on Euthanasia. Other documents also reviewed include, but are not limited to: Animal Procedure Statements, review checklists, and Continuing Review forms. IACUC members are given the opportunity to attend webinars, on-line training, workshops, and conferences from various sources i.e. OLAW, NIH, PRIM&R, NABR, and FBR. CITI online training is offered to all IACUC members and completing animal modules pertinent to research at UL Lafayette is encouraged. During IACUC meetings, a current Animal Procedure Statement is reviewed for ongoing continuing education on animal procedures and appropriate review considerations. Documentation of training sessions are kept for each IACUC member.

Animal Procedures

The PI is responsible for ensuring his or her laboratory staff is proficient in the necessary animal techniques. The Principal Investigator (PI) will assure the committee of competence to use the animal model of choice by submitting a current CV with their APS.

Staff at NIRC are required to complete skill certification procedures as indicated by their supervisor to become proficient in all necessary animal procedures and tasks.

CITI

Training on Laboratory Animal Welfare is available through the Collaborative Institutional Training Initiative at the University of Miami (CITI). To access and complete this training:

1. Go to **https://www.citiprogram.org/default.asp**.
2. Click "Register"
3. Under "Participating Institutions" select "University of Louisiana at Lafayette". Leave the other fields blank
4. Click "Continue to Step 2" at the bottom of the page.
5. Complete the personal information section

6. We suggest using your CLID as your user name, create a password and fill in the remaining fields, then press submit.
7. Complete your profile
8. In Step 7 of the registration process, there are questions to determine your course enrollment. Question 6 pertains to the use of animals in research. Please check the first box and boxes next to any species that you will be using.

Review of the required materials and completion of the quizzes will take about 30-35 minutes per topic. Multiple sessions may be used to complete your course. The program will "remember" your progress and a certificate will be generated upon completion. A minimum aggregate score of 80% is required to pass the course.

Upon completion, you will be able to print a course completion certificate. Please print and retain for your records. The IACUC staff can access the completion records so there is no need to send the completion certificate.

POST-APPROVAL MONITORING

Post-approval monitoring is used to gage a project's continuing compliance with the approved APS and satisfy the requirement in 9CFR 2.31(d)(5) for continuing review. Projects are randomly selected for post-approval monitoring. When protocol documents are available for comparison to the APS these will be reviewed. If no documents are available, an interview with a person working on the project will be used to gage compliance. When evaluation of an ongoing project finds evidence of:

- failure to conform to specifications of the approved Animal Procedure Statement
- failure to comply with the Institution's Animal Welfare Assurance
- unjustified morbidity/mortality of animal subjects
- a report of concern involving the care and use of study animals
- noncompliance with the USDA or PHS Policy

1) The investigator will be notified via email by the Coordinator and given an opportunity to respond to or correct the item(s) in writing.

2) The items and the investigator response will be reported to the committee.

3) Items brought into compliance will require no further action.

4) Items not brought into compliance will be reviewed by a subcommittee of the IACUC consisting of volunteers with no conflict of interest and Chair appointees.

5) If the outcome of the review supports suspension of the project, the Chair will inform the IO and the investigator in writing of the possibility of suspension, and call a full IACUC meeting to review the case for suspension. The investigator and IO will be invited to attend and discuss the concerns of the Committee.

6) The Committee in closed session will vote to suspend, or not suspend but request modifications for evaluation prior to implementation in the project. Approval of any modifications to ongoing projects must be made prior to implementation. A majority vote to suspend an activity must be made at a meeting containing a quorum of members. Any minority views will be recorded in the minutes.

7) The vote of the Committee will be reported in writing to the investigator and the IO. If the vote is to suspend the project, a report of the Committee investigation and details of the occurrence, with all supporting documents will be sent to the Office of Laboratory Animal Welfare, Division of Compliance Oversight director and to the funding agency, for Public Health Service funded projects.

Definitions

Addendum – a change to the Animal Procedure Statement outlined on the addendum form that requires IACUC Approval

Adverse event – is not equivalent to a unanticipated event, most are reportable

Amendment – change to the NIRC study protocol that does not require IACUC approval, because the change falls within the frame work of the approved Animal Procedure Statement

Analgesic - drug reduces or eliminates the sensation of pain.

Anesthetic - a drug that eliminates the perception of pain in a small local area, over a region of the body, or over the entire body.

Animal Procedure Statement (APS) - ULL IACUC document that requests specific information about animal activities, involving animals, which allows the committee to assess the welfare of the animals in the activity

B.I.D. – (latin - *bis in die*) dosing twice daily

Blanket APS – This is an animal procedure statement where the same methods will be used repeatedly throughout the year to test chemicals, antibiotics, antivirals, or gather information that requires routine testing methods over multiple study days, sites or groups of animals.

Euthanasia – "good death", used to specify human assisted end of life. Consult the AVMA guide to euthanasia or the Attending Veterinarian for acceptable methods and dosing. Other authorities will be accepted when the AVMA does not have methods determined for the animal model.

Full IACUC meeting – A meeting where a quorum (majority) of members are in attendance. Members with a conflict for any agenda item will not be counted in the quorum and may not participate in the deliberation or vote on that item.

Gavage – sedated animal has oral dose administered via tube to the stomach.

Humane Endpoint – criteria used to end a study early to avoid pain and distress, but still meet study or experimental objectives. ILAR Journal Vol. 41, Issue 2 has multiple articles about humane endpoints.

IM – Intramuscular (in a muscle), usually used to designate a method of dose administration.

Invasive Procedures – procedures that open a body cavity or cause significant impairment for the animal

IV – Intravenous (in a vein), usually used to designate a method of dose administration.

Institutional Animal Care and Use Committee (IACUC) – a University committee appointed by the President's designee, the Vice President for Research, Innovation and Economic Development. According to PHS Policy (IV.A.3), the committee shall have a

minimum of 5 members consisting of at least one veterinarian (Attending Veterinarian), a non-university person, a scientist experienced in research involving animals, and a non-scientific person. One person may fulfill more than one category.

Oral Dosing – animal is administered dose cooperatively via cup or syringe to the mouth. This does **not** equal orogastric intubation or gavage.

Orogastric intubation – alert dosing via a tube inserted through the mouth and esophagus into the stomach to administer compound

Paralytic drug - paralyzes the muscles and prevents a reaction to external stimuli. Pain is perceived but the animal is unable to react. Therefore, paralytic agents **must not be used without anesthetics,** unless specifically approved by the IACUC.

PCV – (packed cell volume) a measure of the cellularity of the blood used after a large volume non-terminal blood collection.

P.O. – (latin - *per os*) dosing via mouth

Sedative - depresses the central nervous system enough to calm and often promotes sleep.

Tranquilizer – creates an indifference to stress or pain (relaxes), however the actual perception of pain is not reduced.

Unanticipated event – is not equivalent to an adverse event. Most are not reportable.