LSUHealthNewOrleans

Institutional Animal Care and Use Program Policies and Procedures Guidebook

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1.0 POLICY ON THE USE OF ANIMALS IN RESEARCH AND TEACHING

1.1 LSUHSC-NO Responsibilities

Louisiana State University Health Sciences Center – New Orleans (LSUHSC-NO) acknowledges and accepts responsibility for the care and use of laboratory animals and will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this policy as well as all other applicable laws and regulations pertaining to the care and use of laboratory animals. To help achieve this goal, the LSUHSC-NO has created the Institutional Animal Care and Use Committee (IACUC) as the ethical oversight body for all of its animal activities. Furthermore, in recognition of these responsibilities, the Office of Research Services (ORS) and the IACUC work in coordination with the Division of Animal Care (DOAC), the Animal Exposure Surveillance Program for Occupational Health and Safety, the Environmental Health and Safety Department (EH&S), the Institutional Biosafety Committee (IBC), the Animal Care Advisory Committee (ACAC), Grants and Contracts, Conflicts of Interest, and the Sponsored Projects Office.

LSUHSC-NO policy for the procurement, housing, care, and use of laboratory animals will conform to all applicable provisions of the Animal Welfare Act and all other federal and state regulations issued and as amended. This policy governs all research, teaching, research training, biological testing, experimentation, and related activities, hereinafter referred to as activities, involving live vertebrate animals when conducted at LSUHSC-NO by LSUHSC-NO faculty, students or staff, or other personnel not affiliated with LSUHSC-NO. This policy also pertains to animal research conducted at facilities outside of LSUHSC-NO when there is a collaborative arrangement.

1.2 Guiding Principles

The LSUHSC-NO policy is guided by the recommendations and ethical principles that were established by the 1996 National Research Council in the "Guide for the Care and Use of Laboratory Animals". In the development of policies and procedures governing activities involving the use of vertebrate animals, LSUHSC–NO adopts as its own the following guidelines from the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training *and other applicable Federal laws, guidelines, and policies.*

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 unanaesthetized 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

1.3 Federal, State, and Regulatory Agency Regulations Related to the IACUC

LSUHSC-NO utilizes the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS) and uses the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for establishing and maintaining an institutional program for activities involving animals. LSUHSC-NO animal care policies comply with all applicable provisions of the *Animal Welfare Act* (AWAR), guidance from the Office of Laboratory Animal Welfare (OLAW), the American Veterinary Medical Association Guidelines on Euthanasia, and all state and local regulations. Along with the PHS Assurance, LSUHSC-NO will maintain a Category 1 accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). LSUHSC-NO conducts its research and IACUC oversight in compliance with federal, state and regulatory agencies. Key references for the development and continuous monitoring of regulatory changes that may affect these policies are as follows:

- *Animal Welfare Act* (AWAR) - Public Law 89-544, 1966, as amended, (P.L. 91- 579,

P.L. 94-279 and P.L. 99-198) 7 U.S.C. 2131 et. seq.
http://www.nal.usda.gov/awic/legislat/awa.htm

- PHS Policy – U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Implements the HREA – Health Research Extension Act of 1985, Public Law 99-158, Section 495.
  http://grants.nih.gov/grants/olaw/references/phspol.htm
- OLAW - Office of Laboratory Animal Welfare, DHHS, NIH office that provides guidance and interpretation of the PHS Policy to ensure the humane care and use of animals in PHS-supported research, testing, and training.
  http://grants.nih.gov/grants/olaw/olaw.htm
- Guide for the Care and Use of Laboratory Animals, (*Guide*), National Research Council, published by the National Academy of the Sciences.
  https://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth
- The USDA – U.S. Department of Agriculture administers APHIS -Animals and Plant Health Inspection Service where implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3 which is available on the World Wide Web at
  https://www.gpo.gov/fdsys/pkg/CFR-2006-title9-vol1/pdf/CFR-2006-title9-vol1.pdf and the Animal Care Policy Manuel- updated version under review
- The AAALAC - Association for Assessment and Accreditation of Laboratory Animal Care http://www.aaalac.org/accreditation/rules.cfm
- The AVMA - American Veterinary Medical Association Guidelines on Euthanasia
  https://www.avma.org/KB/Policies/Documents/euthanasia.pdf
- OLAW Semiannual Program Review and Facility Inspection checklist
  https://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm
- Animal Care Resource, Animal Care Inspection Guide
  https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

2.0 RESPONSIBILITIES AND FUNCTIONS OF THE HEALTH SCIENCES CENTER ADMINISTRATION

2.1 Administration of the IACUC

The LSU Health Sciences Center – New Orleans has delegated to the IACUC the full authority of the Chancellor's Office for the conduct of the program. The Chancellor has appointed the Vice Chancellor for Academic Affairs as the IACUC Institutional Official (IO) to exercise such functions that require official action. The Chancellor will appoint members to the IACUC and designate the Chairperson responsible for the day-to-day conduct of the program, and in cooperation with Grants and Contracts and the Sponsored Projects Office will:

A. Ascertain that all proposals are screened relative to the need for the IACUC evaluation.

B. Assure that the faculty, students and staff are informed as to their responsibilities and the responsibilities of the institution for care and use of animals in research and for the protection of human occupational and environmental safety.

C. Provide the liaison and channeling of appropriate information between faculty, students, staff, the IACUC, the administration, and governmental agencies.

D. Exercise a continuous surveillance of the IACUC program by:

1. Reviewing all grant applications and research agreements to determine that IACUC review has been instituted where required
2. Maintaining permanent files on IACUC actions
3. Reviewing IACUC activities to assure that the guidelines are being implemented

2.2 IACUC Disapproval

IACUC disapproval cannot be overruled by the administration of LSUHSC-NO. However, IACUC approvals may be overruled by the administration. Project directors or principal investigators (PI) may appeal to the IACUC to reconsider disapproval or restrictions on approval. If the PI wishes to further challenge any decisions made by the IACUC, the PI may initiate the process through the Institutional Official (IO).

2.3 Research Funding

Funds for a project may be withheld at the discretion of the administration. A one-to-one correlation shall exist between an IACUC protocol and a research project funded by any federal agency, such as the National Institute of Health or the Department of Defense, or funded by any agency, foundation, organization or commercial company with contractual exclusivity. A new funding source may replace expired funding. Concurrent funding related to one IACUC protocol will be considered on a case-by-case basis.

3.0 THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

3.1 IACUC Authority

The committee is designated as the Institutional Animal Care and Use Committee (IACUC) and is responsible for oversight and evaluation of the LSUHSC-NO program for the humane care and use of animals. The IACUC derives its authority from the Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act and acts in an advisory role to the Institutional Official (IO) on the status of the institution's compliance with the Act and other federal, state and local laws and regulations and guidance. The IACUC makes recommendations to the IO regarding any aspect of the institution's animal program, facilities or personnel training. The IACUC will oversee the institution's animal program, facilities and activities and will perform all reviewing, inspecting and reporting functions.

The IACUC has the authority to gain access to any laboratories or any areas of the facility where animals are used or housed and must be provided any records and other relevant information regarding the use of animals. All activities involving animals must be approved by the IACUC. The IACUC has the authority to approve as well as suspend an activity previously approved.

The IACUC must review and approve a project before the initiation of any animal use and research activity. Any animal research conducted through an award made to or contracted with this institution must also be evaluated and approved by the LSUHSC-NO IACUC regardless of the performance site. The investigator must submit the other institution's approved IACUC protocol, a Memorandum of Understanding (MOU), and an abbreviated LSUHSC-NO IACUC application. The other institution must have a current OLAW Assurance only if the animal research is supported by PHS, HHS, NASA, and NSF funds.

While approval of an IACUC application is given in the principal investigator's name, it will be understood that all investigators and other participants of the study have the responsibility for understanding, meeting and adhering to all of the regulatory requirements and to the policies and procedures of the LSUHSC-NO IACUC during the conduct of the study. All student-conducted research must be supervised by an LSUHSC-NO faculty mentor. Students, including fellows, residents and others in training without a faculty appointment, must submit the IACUC application under the name of the faculty mentor who assumes the role and responsibilities of principal investigator.

3.2 Responsibilities of the IACUC Institutional Official (IO)

The IO will commit institutional resources for the administrative and operational authority of the IACUC to ensure compliance with all policies and regulatory agencies as mandated by the Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act.

A. To comply with both USDA and PHS requirements, the Chancellor through the IO will appoint a minimum of five members to the IACUC. The committee composition will be sufficiently qualified through professional experience, competence, training and diversity to ensure respect for its advice and

decisions. The committee composition must meet the following criteria:

1. Chairperson
2. Doctor of Veterinary Medicine with program authority
3. Non-Affiliated Member who other than to serve on the IACUC has no affiliation with LSUHSC-NO and is not an immediate family member of any person who is affiliated with the LSUHSC-NO. The non-affiliated member will serve to represent the general community interests in the proper care and treatment of animals.
4. Practicing scientist experienced in research involving animals
5. Non-scientist

B. On behalf of the IACUC and Animal Care Program, the IO interacts with all governmental agencies and transmits required reports and assurance statements to federal, state and credentialing agencies.

C. The IO, in consultation with the IACUC, reviews program changes, suspensions or significant deficiencies and ensures appropriate corrective action is taken. As required by federal regulations, the IO promptly reports program changes, suspensions, significant deficiencies or any significant event which may impact the animal care program to OLAW, the USDA/APHIS, and affected federal funding agencies.

D. The Institutional Official may exercise authority to revoke an IACUC approval decision, but cannot overrule an IACUC decision to withhold approval of a protocol.

3.3 Responsibilities of the IACUC Chairperson

The IACUC chairperson has responsibility for the daily management and operation of the IACUC. In addition, the chairperson serves as the advisor for regulatory matters regarding animal care and usage at LSUHSC-NO to the IO and acts as the liaison for channeling appropriate information between the administration, IACUC, faculty, staff and governmental agencies.

A. The chairperson is responsible for preparing all regulatory reports on behalf of the IO and the IACUC.

B. The chairperson schedules and facilitates regularly convened meetings, inspections, and program reviews and, when necessary, convenes the IACUC on an emergency basis.

1. Fulfills all member responsibilities of the IACUC and signs all official notifications from the IACUC.
2. Sets the agenda for monthly or called emergency meetings and provides for

the distribution of the meeting agenda and meeting book that includes all of the study materials to be considered at the meeting.

3. Provides for the taking of minutes, recording of any minority views, and distribution of minutes to IACUC members and the IO in a timely fashion
4. Distributes literature to IACUC members regarding the concerns of the IACUC.
5. Designates a committee member on a rotating basis as the primary reviewer to be responsible for a written review of a submitted application and for leading the discussion during Full Committee Review (FCR).
6. Serves as, or appoints a committee member to serve as, the reviewer for Designated Member Review (DMR) to approve, request modifications to secure approval or request Full Committee Review (FCR) of changes to applications submitted to the IACUC that resulted in a vote of Modification Required to Secure Approval (MRSA), or of amendments and annual reviews where FCR is not requested.
7. May require principal investigators to appear before the IACUC when questions arise about any study.
8. If necessary, invites individuals who are not members to serve as expert consultants for review of selected applications. These consultants shall serve in a non-voting, advisory only capacity.

C. Maintains a file of curriculum vitae for all members of the IACUC.

D. The chairperson coordinates the continuous surveillance of the initial protocol submission, protocol renewal, and amendment review process.

E. The chairperson will make certain that all recommended actions are initiated pursuant to IACUC decisions.

F. The chairperson is responsible for the availability, maintenance and security of all IACUC Policies and Procedures and for keeping an updated file on IACUC correspondences and all studies submitted to the IACUC.

G. The chairperson may designate an IACUC member with appropriate experience to act in his/her behalf on matters related to IACUC activities.

H. The chairperson provides initial and ongoing training for IACUC members and staff. The chairperson coordinates the necessary support services for the IACUC and presents appropriate and ongoing educational opportunities for IACUC staff, committee members, investigators and others, concerning animal use and protection, related to OLAW, AAALAC, federal regulations and IACUC procedures and policies.

I. The chairperson is responsible for the documentation, maintenance and security of all IACUC actions and documents according to institutional, federal, state and regulatory requirements.

3.4 Responsibilities of the IACUC

The IACUC is responsible for reviewing, approving if appropriate, and monitoring all activities involving the use of animals, and for continuous review to assure compliance with all policies and regulations regarding the care and use of animals.

A. The committee will review and approve, require modifications in order to secure approval, or withhold approval of proposed activities related to the care and use of animals. The review process is applicable to initial, annual, third year de novo reviews and any proposed significant changes regarding the care and use of animals in ongoing activities. An initial protocol application will receive Full Committee Review (FCR) during a properly convened meeting. Subsequent review of protocol modifications requested by FCR, annual reviews, and amendments for a significant change utilize the Designated Member Review (DMR) unless FCR is requested. Amendments for a minor change are administratively reviewed and can be approved by the chairperson without utilizing DMR.

B. In preparation for a full committee meeting, each IACUC member will receive in advance, copies of all meeting materials for discussion. The IACUC member assigned as primary reviewer for an action item will prepare a written report and will lead the committee discussion, but all members are expected to contribute to a thorough discussion of all items.

C. Should a conflict of interest exist, the member will notify the chairperson and will be recused from the meeting during the deliberation and voting on that item.

D. The committee will review and approve all Standard Operating Procedures (SOP) established by the Division of Animal Care (DOAC) that relate to activities involving the use of animals under an IACUC protocol. If performed according to the SOP, the PI may reference a specific SOP number in the protocol in lieu of providing a full description of the procedure.

E. The committee monitors approved protocols to ensure that research is conducted as described in the approved protocols.

F. All concerns regarding the care and use of animals at this Institution are considered by the IACUC upon receipt of any such information regardless of the source. Notices are located in the animal facilities, the IACUC webpage, and throughout campus advising individuals how and where to report animal

welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. Any compliance issue, suspected violations of any federal or state laws, or regulations of any LSU policies, may be reported directly or anonymously to any of the DOAC veterinarians, the IACUC, the IACUC Chair, or the IO, either verbally, in writing, electronically, or through the LSUHSC Office of Compliance Program Hotline, at **855-561-4099** or email to ***nocompliance@lsuhsc.edu***. This hotline allows anyone to report animal welfare concerns to the compliance officer anonymously.

Upon notification, the Chair will determine if a concern is a significant or a minor deficiency. Concerns will be investigated by the IACUC using a subcommittee system. However, no member is involuntarily excluded from participating. Where appropriate, investigators must submit written explanations addressing the concerns. The full committee evaluates the concerns as presented by the subcommittee and the responses from investigators to make a final determination of a resolution to the concern.

G. At least once every six months, the committee will review the animal care program and inspect the animal facility and all areas used for research, testing, education and in the care of animals. The committee will prepare and submit reports of its semi-annual evaluations to the IO. The reports shall be signed by a majority of the IACUC members and include any minority views.

H. When necessary, the IACUC submits a written notification to the IO regarding any concerns with the safety and management of animals, personnel, or any aspects of the Animal Care Program. The IACUC also submits written recommendations for improvement in any aspect of the IACUC or the Animal Care Program. The committee's concerns and recommendations are included in the IACUC meeting minutes.

I. Policies and procedures governing the IACUC may be changed at a convened meeting, and require a vote by a majority of the IACUC members present based on a quorum.

J. Members are expected to familiarize themselves through educational opportunities provided by the Institution with regulations and policies and procedures related to IACUC function and with issues surrounding animal use and research. All training will be documented and maintained on file in the IACUC office for three years. The institution also supports the members of the IACUC through the following:

1. Liability coverage for all IACUC members is provided by the Institution
2. Each IACUC member is provided with an electronic copy of the following

documents: (To become familiar with these documents, new IACUC members will be mentored by the Chairperson or by a senior IACUC member.) These documents and other reference materials are available in the IACUC office and in the office of the Division of Animal Care.

a. PHS Policy for the Humane Care and Use of Laboratory Animals

b. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals

c. ARENA/OLAW IACUC Guidebook

d. A copy of the PHS Assurance

3. All members must complete the Collaborative Institutional Training Initiative (CITI) course titled *Essentials for IACUC Members*. Members may complete any of the additional courses related to animal use. Every three years, members must retake the CITI course. A score of 80% is required for successful completion of CITI courses.

4. When available, other educational courses, opportunities and materials related to IACUC functions and animal care and use in research are provided for members.

4.0 IACUC APPLICATION REQUIREMENTS

4.1 Types of IACUC Applications and Forms

The latest version of the IACUC applications and forms, which are posted on the IACUC website, must be used. They must be submitted electronically by the Principal Investigator, or the PI must be included in the electronic submission when made by another on behalf of the PI.

A. Research Protocol Application

https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_ResearchApplication_24Oct2019.docx

B. Abbreviated Research Protocol Form

https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_ResearchApplication_Abbreviated2Feb2020.docx

C. Surgery Addendum

https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_AddendumSurgery_23May2019.docx

D. Breeding Colony Application

https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_BreedingApp_25July2019Final.docx

E. Protocol Amendment Form
https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_Amendment_10Jan2019.docx

F. Change in Personnel Form (CIP)
https://www.lsuhsc.edu/administration/academic/ors/docs/IACUC_CIP_11Jun2019.docx

G. Annual Re-Approval Form (issued by IACUC Office)

H. Expiration Notice Form (issued by IACUC Office)

4.2 Application Requirements for Different Situations

A. Animal research conducted on a LSUHSC-NO campus

For any animal research conducted on LSUHSC-NO campus, regardless of who the awardee/sponsor or performer is, a LSUHSC-NO IACUC application is required.

B. Research conducted at another institution

1. If the research is conducted at another institution, and LSUHSC is the primary grant holder and funding some or all of the animal work, the Principal Investigator may submit an abbreviated LSUHSC-NO IACUC application to provide demographic, title, biosafety, personnel and grant information and submit the performance site IACUC application in lieu of completing the remaining sections of the LSUHSC-NO IACUC application. The PI must provide documented approval from the performance site IACUC. A Memorandum of Understanding (MOU) must also be submitted.
2. If LSUHSC is listed as a subcontract to a primary grant holder at another institution that involves animal research, and the subcontract PI is NOT conducting any animal work at LSUHSC, a Memorandum of Understanding (MOU) must be submitted that attests to the work being conducted at LSUHSC and the performance site's IACUC protocol. No LSUHSC IACUC application is required. Some scenarios this would apply to would be consultation work, data analysis, and animal tissue processing. However, LSUHSC-NO IACUC reserves the right to request additional information including requesting the completion of the LSUHSC-NO IACUC application. DMR will continue to be used in these situations, unless a protocol is submitted at the time the meeting materials are being prepared.
3. The other institution must have a current PHS Assurance only if the animal research is supported by PHS funds.

C. Fellowship Awards

1. If a Fellowship award will be made by NIH or other awarding agency, a new IACUC application must be submitted if the Fellowship grant meets any of the following criteria:

    a. The animal work involved has a different focus from or significantly differs in the methods used from a grant awarded to the post-doctoral fellow's mentor and the mentor's approved IACUC protocol.

    b. The animal work itself is funded by the fellowship grant.

2. An amendment to the mentor's IACUC protocol can be used in the case where the Fellowship award meets all of the following criteria:

    a. The work is part of or very similar to a mentor's grant or approved IACUC protocol

    b. The animal work itself is not funded by the fellowship grant.

    In either case, a copy of the vertebrate animal section of the fellowship grant is required with the IACUC submission.

D. Non-Animal Tissue or Materials

An IACUC application is not required when animal tissue, parts, or materials are collected from non-living animals. Animal tissue use will continue to be described in the IBC protocols. Additionally, the Division of Animal Care will be made aware of these situations and the tissues that are introduced.

4.3 Application Requirements for IACUC Review

In a duly constructed IACUC meeting, the primary reviewer will present a report, which includes a summary of the research, any perceived problems or concerns, any recommendations regarding the problems, and a recommendation on the disposition of the protocol. The chairperson will then open discussion of the protocol to the full committee to decide if the application satisfies all requirements.

A. A complete description of the proposed use of the animals and the rationale for the experiments and the use of animals in those experiments.

B. Identification and justification of the species, the appropriateness of the species, and the numbers used are supported with a current literature search and explanations for addressing reduction, refinement, and replacement.

C. A description of the procedures used so that the reviewers can assure that they are consistent with sound research design and that discomfort and injury to the animals will be limited to that which is unavoidable, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to the animals.

D. Scientific justification for not providing relief measures to procedures that may cause more than momentary or slight pain or distress to the animals.

E. A description of surgical and technical methods and post-procedural care and where applicable, justification for multiple major survival operative procedures.

F. Justification for restricting animals from food/fluids or placing animals in restraints.

G. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

H. The housing and husbandry requirements of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species for animals being maintained or studied.

I. Social housing of social animals is the default method of housing unless otherwise justified and approved by the IACUC, or it meets the criteria under exceptions approved by the IACUC.

J. Criteria and process for timely intervention or removal of animals from a study, or if living conditions of animals will be detrimental to their health and comfort, the animals will be painlessly sacrificed.

K. A description of the euthanasia method, and the method used to confirm death. The method of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

L. Adequacy of training and experience of personnel in the proposed procedures are appropriately qualified and trained in those procedures to ensure a safe working environment for personnel and animals.

M. Institutional approvals as required by the Biosafety , Radiation Safety, Occupational and Environmental Health Safety programs.

4.4 Additional Requirements for Funded Projects

When an IACUC application is associated with an application for funds from a federal agency, such as NIH or any other PHS agency, HHS, NSF, USDA/FDA, DoD, whether competing or non-competing, the IACUC review must include a comparison and verification of the vertebrate animal section (VAS) of the grant proposal and the IACUC application. Where required by other sponsors, verification of the grant proposal with the IACUC application will be

conducted during IACUC review.

For the congruency check, the IACUC will use the following four points of the NIH VAS (https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm).

1. ***Description of Procedures*** *(Vertebrate Animals Section)*
   Provide a concise description of the proposed procedures to be used that involve live vertebrate animals. Identify the species, strains, ages, sex, and total number of animals by species to be used. If dogs or cats are proposed, provide the source of the animals.
2. ***Justifications*** *(Vertebrate Animals Section)*
   Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. ***Minimization of Pain and Distress*** *(Vertebrate Animals Section)*
   Describe the interventions to minimize discomfort, distress, pain, and injury. These include analgesia, anesthesia, sedation, palliative care, and humane endpoints.
4. ***Method of Euthanasia*** *(Cover Page Supplement / PHS Fellowship Supplemental Form)*
   Provide a justification for methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If answer is "No" to the question "Is method consistent with AVMA guidelines?", describe the method and provide scientific justification in the text field provided.

In the IACUC application, the investigator must provide an explanation of any discrepancy between the two documents. Additionally, the investigator must report to the funding agency any reportable subsequent significant amendments regarding the use of animals approved by the IACUC and report the notification date on the IACUC Annual Review Form.

5.0 IACUC PROTOCOL TIMELINE- From Initial Review of a Study to End of the Study

A major function of the IACUC includes reviewing initial and continuing animal research activities conducted at LSUHSC-NO. The IACUC also evaluates all amendments, revisions, and changes to studies. The appropriate IACUC protocol application, amendment or form must be submitted for review by the IACUC. No animal activities may be conducted until IACUC approval is given. When an application is first submitted by an investigator, it is reviewed via full committee review (FCR). Once a protocol is approved, amendments may be submitted to modify the protocol when necessary. In order to keep a protocol active and not risk interruption of the animal work on a study, it is essential that annual reports be submitted in advance of the expiration date. After three years from the protocol's initial approval date, a new protocol must be submitted well in advance of the expiration date, and a complete review will be done. If the PI decides to terminate a study, the IACUC and Animal Care must be notified before the protocol's expiration

date.

5.1 IACUC Protocol Review Methods

A. Full Committee Review (FCR)

1. Conducted by all members present in a properly convened meeting.
2. The IACUC chairperson will designate a primary reviewer on a rotating basis for leading the discussion at the committee meeting.
3. Either the clinical veterinarian or the veterinarian director of Animal Care will comprehensively review each application to assure that appropriate veterinary care is available for all laboratory animals covered in the application. If the reviewing veterinarian cannot be present at the IACUC meeting, the veterinarian will provide written review of the protocol including the consideration of alternatives.
4. The IACUC may use an outside expert consultant in the review process. The consultant acts only as an informative source and cannot vote with the IACUC. The IACUC may request that the principal investigator attend the meeting to justify, explain or clarify the proposed experiments.
5. No IACUC member may participate in the IACUC review or approval of an application in which he or she is involved, except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum. Any members with a conflict of interest must recuse themselves during the committee discussion and voting.

B. Designated Member Review (DMR)

1. Conducted by the IACUC chairperson or a member designated by the chairperson and qualified to conduct the review in the absence of any member requesting FCR after receipt of all materials for review. The chairperson, or designated reviewer, shall make a final review of the merits of the application or amendment and determine whether to approve, require modifications to secure approval. FCR is required if approval cannot be given, and the revised application or amendment must be placed on the agenda for FCR at the next convened meeting. Use of DMR is documented in the minutes of the next convened IACUC meeting.
2. Scenarios in which DMR is used
    a. DMR is used subsequent to FCR when the quorum of members present at a convened meeting decide modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The primary reviewer of the protocol will be the designated reviewer and will review the modifications. The Chair will sign the protocol if approval is given.
    b. Review of protocols with research conducted at another institution.

c. Significant amendments.

5.2 Convening of an IACUC Meeting for Full Committee Review (FCR) of a Protocol

Meetings shall be held on the third Monday of each month unless otherwise directed by the IACUC chairperson. To conduct official business, a convened meeting of a quorum is defined as a majority of IACUC members. Presence by teleconference is permissible when members on teleconference have been provided all materials necessary and can actively participate in discussions and voting. Such members are considered present at the meeting. A vote cannot be taken in the absence of a quorum. Members must be present to vote. A majority of the membership present must vote in the affirmative for a motion to pass. Ruling decision is determined by the majority vote of the eligible voting members present in the quorum. No member may participate in the initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the committee. Members with conflicting interests will leave the meeting room during the deliberations and voting on said project. The chairperson or the Institutional Official may call an emergency meeting with a minimum of twenty-four hours notice to members.

After review and approval by the committee, the minutes of each IACUC meeting serve as documentation of the committee activities, discussions, and decisions. Any minority IACUC views will be included in the minutes. The approved minutes are provided to the IO in a timely fashion to apprise the IO of all committee activities.

At least seven days prior to a regular meeting, the IACUC coordinator or chairperson will email or upload the members of the IACUC an electronic copy of the meeting materials which includes the agenda, previous meeting minutes, research protocols for review, and any other information pertinent to the meeting. The IACUC coordinator or chairperson will post an electronic version of the meeting materials in the IACUC secured folder on the LSUHSC-NO server. The server is available to all IACUC members and key personnel in the Division of Animal Care. Additionally, a paper copy may be provided. In the event of an emergency meeting, an electronic copy of the meeting materials will be sent at the time of notification that an emergency meeting is required.

A. The agenda shall include the following items.
   1. The minutes from the previous convened meeting.
   2. Listing of topics for discussion on any IACUC activity, function and/or concern.
   3. Other items of interest of a continuing education nature.
   4. Listing of protocols approved by Designated Member Review (DMR) after the Principal Investigator made modifications requested by the committee after Full Committee Review (FCR).
   5. Listing of protocols approved by DMR.
   6. Listing of annual reviews approved by DMR.
   7. Listing of amendments for minor changes administratively approved.

8. Listing of amendments for significant changes approved by DMR.
9. Listing of amendments for significant changes where FCR was requested.
10. Listing of protocols for continuing annual reviews.
11. Listing of protocol expiration notifications.
12. Listing of protocols for Full Committee Review (FCR) with primary reviewer designation by the chairperson. This includes both re-presented protocols (previously referred to as deferred) and new protocols.

B. The minutes of all IACUC meetings will be recorded and made available for review at the next IACUC meeting. The minutes will include the following items.

1. Record of attendance at the meeting and a notation of starting and adjourning time.
2. Presentation of previous meeting minutes with notation to approve, modify or note any minority views.
3. Discussions and any actions taken by the committee concerning IACUC policy and procedures, facility or compliance issues, semi-annual and annual reports, any other reporting requirements, and any other items of concern.
4. Record of acceptance of designated approval of protocols approved by DMR after Principal Investigator made modifications requested by the Committee, annual reviews, and amendments and protocols not requiring full committee review.
5. Discussion of amendments for full committee review, re-presented protocols and new protocols including reasons leading to IACUC decision for approval, modifications required to secure approval, or withhold approval.

5.3 IACUC Meeting Determinations

Following the discussion of a Full Committee Review (FCR) of applications and amendments, the IACUC shall vote. A majority vote of the quorum is required. Any minority views shall be recorded.

A. **Approval:** If the committee determines that all criteria, based on the PHS, OLAW and USDA regulations and institutional requirements have been adequately addressed by the investigator, approval is given on the date of the review, and the protocol is active for three years with subsequent annual reviews. If Institutional Biosafety Committee (IBC) approval is pending, approval will become effective by DMR on the date of verification of IBC approval.

B. **Modifications required to secure approval:** The committee determines that approval can be given if the investigator makes specific minor modifications necessary to adequately address all criteria based on the PHS, OLAW and USDA regulations and institutional requirements. There are two review process options if modifications are needed to secure approval. Review via 1) FCR, or review via 2)

DMR.

1) If the committee votes to review via FCR, the IACUC coordinator initiates the process by preparing a letter outlining all the requirements recommended by the committee to secure approval. The investigator shall respond to each item in the letter and incorporate the changes into the electronic version of the application. The investigator shall electronically submit the response letter and the revised application to the IACUC Office. Once received, the application will be sent to the primary reviewer who originally reviewed the protocol, and the application will be put on the agenda for review at the next convened committee meeting.

2) The second review process option after the vote is modifications are needed to secure approval, is review via DMR. On 1/19/2016, the members agreed at a convened meeting of quorum, to use DMR as a possible review process if modifications are needed to secure approval only if its use is approved unanimously by all members at the meeting at which the required modifications are developed. All members must be made aware of this policy, so that if a member is not present at a meeting they are in agreement that the committee may decide by unanimous vote to use DMR as a means to review protocols requiring modifications. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. There is only one designated member performing the review. The IACUC chair designates the DMR. Upon submission of the investigator modified protocol, the chairperson, as the designated reviewer or a member designated by the chairperson to conduct the designated review, shall make a final review of the merits of the modifications and determine whether to send it to FCR, require additional modifications to secure approval, or approve. "Withhold approval" is not a possible outcome of DMR. If the modified protocol cannot be approved, it will be placed on the agenda of the next IACUC meeting for full committee review.

The IACUC coordinator initiates the DMR process by preparing a letter outlining all the requirements recommended by the committee to secure approval. The investigator shall respond to each item in the letter and incorporate the changes into the electronic version of the application. Only the requested modifications shall be accepted. The investigator shall electronically submit the response letter and the revised application to the IACUC Office. If a response is not received within 60 days, the application shall be administratively withdrawn. The IACUC chairperson or a designated member by the chairperson and qualified to conduct the review shall determine if the changes meet all criteria for approval or if additional clarification is necessary. After the investigator's modifications are accepted, approval shall be given for three years with subsequent annual reviews. After verifying receipt of IBC approval, the IACUC coordinator shall prepare the assurance letter and obtain IACUC chairperson and Principal Investigator signatures.

C. **Approval withheld:** The committee did not approve the application. The committee views that the protocol does not protect the welfare of the animals used, or the design of the project is not adequate to provide useable scientific information. The investigator will receive a written letter outlining the requirements needed. The requirements can only be addressed through a new application and FCR.

D. **Tabled:** The committee could not review the application for any number of reasons, including insufficient information, loss of quorum due to conflict of interest, etc. If the primary reviewer determines that there is insufficient information, he/she may recommend tabling the application. The reviewer shall inform the IACUC coordinator of the deficiencies which shall be communicated to the investigator. The study shall be tabled until the investigator has submitted a more complete application.

5.4 Amending an Approved Protocol

Any modification to an approved protocol must be submitted for IACUC review and approval prior to initiating the change.
Modifications are categorized as minor [not significant] or significant. The IACUC chairperson, with committee input as warranted, shall determine the category of any proposed amendment when the amendment does not clearly fall within the following guidelines.
The IACUC coordinator shall forward minor amendments to the IACUC chairperson for consideration of approval, for modifications required to secure approval, or if not approved by the chairperson, minor amendments will then follow the Designated Member Review (DMR) process. DMR will be used for all amendments with significant change(s).

A. Examples of amendments with minor changes:
   1. Substitution of another strain of the same species without a change in the number of animals.
   2. Addition of qualified personnel.
   3. Removal of qualified personnel provided there are remaining qualified personnel to conduct all necessary procedures.
   4. Addition of a Fellowship to the mentor's IACUC protocol where the Fellowship meets all the following criteria:
      a. The work is part of or very similar to a mentor's grant or approved IACUC protocol.
      b. The animal work itself is not funded by the fellowship grant.
   5. Additional title with no change in the experimental design. Since there must be a one to one correlation between the IACUC application and a funded research project, a new title may be amended to an approved IACUC protocol in limited circumstances, such as:
      a. The investigator is publishing a paper under a different title.
      b. The current funding of an approved protocol is expiring and the investigator is submitting a new grant application to secure

another funding source to continue the study as approved by the IACUC. A new literature search is required. Funding cannot be concurrent unless allowed by funding parties and approved by this institution on a case-by-case evaluation.

c. The investigator is submitting a new grant application for a study that was approved by the IACUC, but was not started or was not funded. A new literature search is required if the original search is not within three months of the amendment request. Included with the amendment, where applicable, needs to be a copy of the vertebrate animal section of the new grant proposal for comparison to the approved protocol. Any minor differences must be explained in the amendment. A new IACUC application must be submitted if the scientific design differs from the approved protocol. If the initial grant is funded, the amendment must be withdrawn, and a new IACUC application must be submitted for the new grant title.

The Designated Member Review (DMR) method may be utilized for amendments with significant changes. This process is described below:

- The amendment along with the original protocol and any other supportive documents will be distributed to all IACUC members to allow all members the opportunity to call for full-committee review (FCR).

- The members shall have three business days from notification to request FCR. If any member requests a FCR, the amendment shall be placed on the agenda for the next convened meeting for review, where it will undergo FCR as delineated in III.D.6 above.

- Where FCR is not requested, any member may submit concerns or comments to the IACUC coordinator to give to the designated reviewer for sole consideration in the determination of the amendment.

- Multiple designated reviewers are not used in DMR. If FCR is not requested, the IACUC chairperson, or a member designated by the chairperson and qualified to conduct the review has the authority to approve, require modifications in (to secure approval), or request full committee review of the amendment. "Withhold approval" is not a possible outcome of DMR.

- Amendments determined that modifications are required are returned to the investigator with explanations. The investigator must revise the amendment and then resubmit the amendment to the DMR review process.

- The designated reviewer informs the IACUC office of the decision, and the Chair signs the amendment once approved.

- Amendments approved by DMR, are reported at the next convened meeting and are recorded in the meeting minutes.

B. Examples of amendments with significant changes:

1. Change in principal investigator.
2. Change in purpose or specific aims of study, with or without title change.
3. Increase in the number of animals approved.
4. Change in housing and/or use of animals in a location that wasn't indicated in the IACUC approved protocol.
5. Addition of another species except for USDA covered animals (such as rabbits, gerbils, cats, pigs, non-human primates) requires submission of a new IACUC application.
6. Addition and/or change in sample collection times.
7. Addition and/or change in a drug and/or agent, including dosage.
8. Change from non-survival to survival surgery.
9. Addition of experiments/procedures or a change in previously approved experiments/procedures.
10. Addition and/or change in restrictions or restraints.
11. Changes resulting in greater pain, distress, or degree of invasiveness.
12. Change in euthanasia method.
13. Changes that may impact personnel safety.

5.5 Protocol Approval Periods and Renewals

Most IACUC correspondence and approval notifications are delivered electronically. In situations where electronic media is not available or acceptable, IACUC notifications and other communications will be sent via campus mail or an external postal service.

Animal activity may commence only after Animal Care receives the IACUC approval notification. The Principal Investigator and the appropriate Animal Care personnel (veterinarian, managers and data staff) will simultaneously receive notification of IACUC approval and receive an electronic copy of the approved protocol or amendment.

All IACUC determinations are documented in the IACUC meeting minutes, which are forwarded to the IO. All approved protocols, amendments and forms will be posted in the IACUC secured folder on the LSUHSC-NO sever which serves as the official document for reference to be used by Animal Care personnel and the IACUC. Documents that are not approved will be posted to a secure folder that is only accessible by the IACUC Office staff.

The IACUC protocol approval date corresponds to the date at which all requirements of the IACUC have been met. An approved IACUC protocol can be active for a maximum of three years. At the three year expiration date, a protocol will be closed and a renewal protocol will be needed to continue the study. All ongoing activities are monitored continuously by the staff of the Division

of Animal Care (DAC). An approved amendment follows the subsequent approval periods of the protocol for which it amends. All approved protocols are reviewed within every 12 months of the last approval date.

For annual review of active protocols, the IACUC coordinator shall send an electronic notice to the Principal Investigator at least 30 days prior to the protocol expiration date. The PI must complete the Annual Review Form and return it to the IACUC office at least 2 weeks before the expiration date for consideration under DMR. Electronic submission is required.

Protocols due for annual review will be included in the agenda of the IACUC meeting prior to the protocol's annual review due date. The members shall have access to the protocols for review at the meeting, on the IACUC server or may request the IACUC coordinator or chairperson to email the protocols directly to the members. Unless a member requests a FCR prior to the closing of the meeting, the Annual Review will employ the DMR process. The chairperson, or a member designated by the chairperson, will conduct the review and approve for another year, or send the protocol annual review to FCR. The new approval period will begin on the annual review approval date.

If the PI fails to submit the Annual Review Form prior to the expiration date, the protocol will be administratively closed with confirmation of the closure documented in the IACUC meeting minutes. For any protocol not re-approved, a notice will be sent to the PI and to the Division of Animal Care to cease all animal activities prior to the expiration date. A new application must be submitted if a protocol is closed.

Prior to the three year expiration date, a protocol must be rewritten and submitted to the IACUC for FCR. The PI will receive an electronic Expiration Notification Form at least three months prior to the expiration date of the protocol. At the three year expiration date, the protocol will be closed. If the PI fails to submit a new protocol or the protocol is not approved prior to the expiration date, the PI and the Division of Animal Care will be notified to cease all animal activities upon the expiration date.

Personnel not up to date on training will not prevent a protocol from being renewed and approved, but will preclude the individuals from participating in the study until training is complete.

During any period where IACUC approval is not active for a research or breeding colony protocol, animals must be transferred to an IACUC approved holding protocol with a DAC veterinarian acting as the PI. **Animals being held on a holding protocol may not be used in any research or breeding project.** No manipulations may be performed on animals that have been transferred to a holding protocol except to the extent to preserve the health and welfare of animals where procedures have been initiated on the animal prior to the transfer. The DAC veterinarian shall make the determination at the point in which the animals can be safely removed from the initiated procedure. The holding protocol may also be used for the receipt of animals from a vendor or another institution if a research or breeding colony protocol has not yet been approved by the IACUC.

5.6 Termination of the Study

The PI must notify Animal Care and the IACUC in the event of terminating a study prior to the IACUC expiration date or if transferring a study to another institution. All protocols expire no later than the three-year anniversary of the initial IACUC approval. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved. All animals must be removed from the study by the expiration date. Under no circumstances can work with animals continue beyond the expiration date.

6.0 MONITORING ADHERENCE to PROTOCOLS

6.1 Noncompliance

All reported cases of potential noncompliance submitted by any source will be investigated. Upon notification of a potential issue of compliance, the chairperson will determine if it is a significant deficiency or minor deficiency. If a minor deficiency, the chair, veterinary staff, or IACUC member, will council the PI and draft a corrective action plan. The plan will be reported to the committee and approved via DMR. If acceptable, the chairperson will send an affirmation and acceptance letter of the corrective action plan to the PI. An affirmative response from the PI acknowledging receipt of the letter is required.

If a significant deficiency, the chairperson will prepare a letter of inquiry that will be sent to the PI of the protocol(s) under question. Following the initial inquiry with the PI, other investigators, students, and/or staff, if the chairperson determines a full investigation is required, the chair shall appoint a subcommittee of the IACUC to examine the issue in more detail. The subcommittee will prepare a report to the IACUC for discussion either via email or at a meeting. A corrective action plan will be developed, and will be voted on at a convened meeting of a quorum, if any member makes such a request. If FCR is not requested, then approval of the corrective action plan will occur via DMR with notification to the full committee. In most cases, the designated member reviewers will be the subcommittee. If the corrective action plan includes suspension, then this must be voted on at a convened meeting of a quorum.
The actions in the corrective action plan may include all but not necessarily limited to, additional training, reports required, warning, reprimand, censure, or suspension and prohibition from performing an activity that was previously approved, or future animal use, if the committee determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, and the institution's Assurance.

The chairperson will notify the PI in writing the determination of the investigation and what corrective action will be required. Upon a decision for suspension, the Division of Animal Care and the Institutional Official shall receive a written notice of the suspension. The Institution may take further action as detailed in the Faculty Handbook. If the project has NIH or other federal funding, the IACUC through the IO, will send a report of the findings and corrective actions to OLAW and/or federal agencies. Reporting is applicable to private/corporate funded protocols where stated in the contract. The institution will follow the agency ruling which may include accepting the institution's corrective action plan, making additional corrective actions, repaying grant money, etc.

6.2 Post-approval Monitoring Program (PAM)

The post-approval monitoring program was implemented as a means to determine if PIs are adhering to their IACUC approved protocols. One of the objectives of the program is to identify non-conformance issues and assist the PI with rectifying those issues, as well as provide education and assistance to prevent deviations from protocols in the future. As a result, animal welfare will be monitored, and investigators will be prepared for the semi-annual inspections, USDA inspections, and AAALAC site visits. This program was structured to be collegial in nature, so that the IACUC can provide support to the investigators' research if needed.

During the post-approval monitoring visit, a specific procedure will be selected from the protocol. Choosing a specific procedure is meant to serve as an audit of the protocol. Typically the procedure observed will be invasive or specialized in nature, some examples being surgical and behavioral procedures. The visits will be conducted by a subcommittee.

A. Frequency and scheduling of visits: Approximately 12-15 visits will occur each year. Selection of laboratories for post-approval monitoring will be random, or if potential non-conformance issues are suspected. The PIs will receive a letter informing them that their laboratory was selected. A protocol number and procedure(s) from the protocol will be included in the letter. If the PI is not currently conducting the chosen experiments in the protocol, another protocol and/or procedure can be chosen. Ideally, the appointment will be scheduled two weeks in advance, but may be longer depending on when procedures will be performed in the study. The PI can be present during the visit, but is not required to do so. The visit can be delegated to personnel performing the procedure(s). Included in the letter will be a checklist that will be used during the visit to document what is observed.

B. **Process if there are no conformance issues: If procedure(s) observed are performed according to protocol, an approval letter will be sent to the PI, department chair, executive director of research services, and the institutional official.**

Process if there is a minor non-conformance: the PI will be sent a letter detailing the issue that was observed and how it must be rectified (submit amendment, perform procedure again correctly, etc). If issue is corrected, an approval letter will be sent to the PI, department chair, executive director of research services, and the institutional official.

If it is a major conformance issue (one in which animal welfare is jeopardized), then the corrective action plan will be developed with the PI, the IACUC, and the DOAC if necessary. The IACUC will vote on the corrective action plan and timeline. Then the PI will implement the corrective action plan, and an approval

letter will be sent to the PI, department chair, executive director of research services, and the institutional official.

C. Communication and documentation of visits: At each IACUC meeting, the IACUC will be informed of all the approved and pending visits since the last meeting. These visits will be documented in the meeting minutes.

7.0 IACUC REPORTING

7.1 Semi-Annual Animal Program Review and Facility Inspections

The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals. In the semi-annual evaluation of the animal care and use program, the full committee or designated subcommittees will conduct the program review and inspections of all facilities where animals are used. Subcommittees must consist of at least two IACUC members. No member will be involuntarily excluded from participating in any portion of the review or inspections.

The Committee uses the *Guide* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

The program evaluation will include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); e) Occupational Health and Safety; f) Emergency and Disaster Plans; g) OLAW Assurance as needed (i.e. if member requests due to significant policy changes or updates). If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency.

The chairperson will designate subcommittees to conduct semi-annual inspections on an unannounced or announced date that is within six months of the last inspection. The subcommittees will inspect all animal care facilities, laboratories and any area where animal use is conducted, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals will also be inspected.

If deficiencies are noted during the review or inspections, the subcommittee or chairperson will categorize the deficiency as significant or minor. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. The subcommittee or chairperson will notify the appropriate personnel responsible for correcting the deficiency. The subcommittees or chairperson will prepare a report of the findings for IACUC review at the next regularly scheduled meeting. The report must list any deficiencies found as minor or significant and indicate what corrective action was taken. For deficiencies not corrected at the time of inspection, a reasonable and specific plan and schedule for each deficiency will be developed and revisited to verify that the deficiency was corrected. If it is questionable as to what the corrective action should be, it will be discussed at the regularly scheduled convened meeting, or emergency meeting if necessary, before informing the appropriate personnel.

As stated above, all subcommittee reports are discussed at a convened IACUC meeting. Utilizing these reports and the committee's recommendations on the classification of the findings of the

review, the chairperson, or his or her designee, will draft the Semiannual Report to the IO. The Semiannual Report will include both the program review and inspection of facilities. The report will identify the facilities as accredited by AAALAC International and will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy. The report will identify all IACUC approved departures from the PHS Policy and the Guide, and state the reasons for each departure. In 2017, the committee reviewed the Guide, the institution's performance standards and SOPs, and OLAW's NOT-OD-12-148: Guidance on Departures from the Provisions of the Guide for the Care and Use of Laboratory Animals, for the purpose of distinguishing departures from exceptions. The committee determined that in most instances, Departures from the Guide will identify prolonged use of a physical restraint device on unanaesthetized animals would qualify as a departure, and thus would need to be reported in the semiannual report to the IO. The IACUC interpreted these instances to be a departure, since in most instances animals cannot be acclimated or trained to adapt to the restraint device, because to do so would potentially interfere with the desired behavioral or stress response. This determination of 'use of a physical restraint device' as a departure, does not exclude other activities or instances from being classified as departures if warranted, and thus will be listed on the semiannual report. If there are no departures, the report will so state.

- Any departure not approved by the IACUC as part of a protocol, protocol amendment, or other written document, using either FCR or DMR, is considered a noncompliance, and is reported as such. All noncompliances will also be reported to OLAW. The committee will follow PHS Policy, IV.F.3 and NOT-OD-05-034 to discern reportable circumstances.

The report will distinguish minor deficiencies from significant deficiencies and whether such deficiencies were corrected, and if not corrected will include a reasonable and specific plan and schedule for correcting any outstanding deficiency. Copies of the draft report will be reviewed, revised as appropriate, and approved by the committee. The final report will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the report will reflect such. The final report will be submitted to the Institutional Official within 30 days following the committee's approval.

The IO will address any unresolved facility deficiencies with the Division of Animal Care. The IO, the Director of Animal Care and other parties will work to resolve all deficiencies. If any deficiency remains uncorrected after having notification and an opportunity for correction, the IO will report such deficiency in writing to the IACUC, OLAW and, where applicable, the funding federal agency. Any IO response to the report will be discussed at the next convened IACUC meeting, and any item requiring additional action will be acted upon if necessary. The reports will be maintained for three years by the IACUC Office and made available to regulatory and funding agencies upon request.

7.2 Annual Reporting

The *Annual Report to OLAW* for the calendar year October 1st through September 30th must be submitted before the following December 1st. The report will be prepared by the IACUC chairperson and certified by the IACUC and the IO. Reports filed with OLAW shall include any

minority views filed by members of the IACUC.

A. The annual report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in the Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual program review and facility inspections and submitted the final report to the institution's IO. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

B. Supplemental reports that must be filed by the IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy
2. Any serious deviations from the provisions of the "Guide."
3. Any suspension of an activity by the IACUC.
4. Any event that could affect the accreditation status of this institution.

The *USDA Annual Report of Research Facility (USDA Policy #17; APHIS Form 7023 and 7023A)* must be submitted to the USDA on or before December 1 of each year. The report is based upon the USDA fiscal year from October 1 through September 30 on all species covered by the AWA that were used or are being held for use. The report will be prepared by the personnel in the LSUHSC-No Division of Animal Care. A copy of the report will be submitted to the IO for review and certification before submission to the USDA.

The *AAALAC Annual Report* must be submitted to AAALAC before the 31st of January every year. The report is based upon the January through December calendar year. The report will be prepared by the personnel in the LSUHSC-NO Division of Animal Care. A copy of the report will be submitted to the IO for review and certification before submission to AAALAC.

7.3 Certifications and Accreditations

LSUHSC-NO will maintain certification of compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) through the Office of Laboratory Animal Welfare (OLAW). The Animal Welfare Assurance Renewal application will be prepared by the IACUC chairperson and certified by the IO. The chairperson will be responsible for submission of the application every three to five years as determined by OLAW.

LSUHSC-NO will maintain a Category 1 AAALAC accreditation. AAALAC accreditation must be renewed every three years. The Director of Animal Care in conjunction with the IACUC chairperson will be responsible for providing all documents required for the completion of the

accreditation process. After certification by the IO, the Director of Animal Care will submit the application.

7.4 Record Keeping

The written policies and procedures for the IACUC will be maintained under the title of "LSU Health Sciences Center in New Orleans Institutional Animal Care and Use Program Policies and Procedures Guidebook" and will be made available on the IACUC website.

The office of the IACUC is responsible for maintaining documentation of the IACUC activities and retaining annual and fiscal reports for seven years. IACUC meeting minutes and IACUC protocol documentation shall be maintained for a period of four years following the closure of the study. For studies funded by an agency under the National Institutes of Health (NIH) or any other federal agency, the initial and all subsequent renewal of IACUC protocols related to the federal grants will be kept for four years following the conclusion date of the Final Submission Report (FSR).

The following documentation will be maintained:

1. A copy of the PHS Assurance and any modifications thereto, as approved by the PHS. Correspondences and copies of the Animal Welfare Assurance documentation approved by PHS and certification letters and Annual Reports to OLAW and AAALAC.
2. All IACUC protocols submitted for review, even if the proposal was not approved, granted, or animals were not used.
3. Amendments, progress reports, annual reviews, deficiencies, adverse event reports, post-approval monitoring reports, and any other records that relate directly to ongoing activities reviewed and approved by the IACUC.
4. All protocol correspondence to and from the IACUC, investigator or funding agency.
5. Minutes of the IACUC meetings.
6. Records and reports on the semi-annual inspections and program reviews.
7. Training documentation for IACUC members and staff.
8. Correspondences and copies of other institutions' IACUC approvals, AAALAC accreditations, institutional agreements and any correspondence related to protocols of mutual interests.
    i. All documentation will be stored in electronic format on the LSUHSC-NO server. All IACUC documentation will be electronically backed-up daily according to LSUHSC-NO Information Technology policy. Electronic files are considered official documentation of IACUC records.
    ii. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives in a timely manner.

8.0 PRINCIPAL INVESTIGATOR

8.1 Responsibilities

All investigators, students and staff involved in animal research are required to read the LSUHSC-NO Institutional Animal Care and Use Program Policies and Procedures Guidebook. They also must adhere to all federal, state and institutional policies as presented in this Guidebook. **The Principal Investigator (PI) is responsible for supervising and training all personnel working under his or her protocol.**

A. All participants involved in animal research within the LSUHSC-NO facilities must have some type of LSUHSC-NO appointment. A student worker with a gratis appointment is eligible to participate if all requirements are fulfilled.

B. New personnel must complete the Collaborative Institutional Training Initiative (CITI) course titled *Working with the IACUC- Investigators, Staff, and Students* and any other courses assigned by the DAC veterinarian. All other personnel working with animals must complete the CITI IACUC refresher course every three years. A score of 80% is required for successful completion of CITI courses.

C. All personnel must complete the occupational health and safety assessment prior to working with animals. In some situations, personnel will be required to enroll and participate in the Animal Care Surveillance Program. However, where not mandated, investigators and their staff will be encouraged to enroll and participate in the occupational health and safety program.

D. The PI must identify all personnel participating in the protocol and validate successful completion of the CITI courses and other training assigned by the DAC veterinarian prior to beginning any activity using animals. Zoom training has been added as an alternative to DAC in-person training.

E. The PI must obtain and complete the most current version of the IACUC forms from the website of the Office of Research Services or directly from the IACUC coordinator, specialist, or chairperson. The PI must submit the application electronically.

F. Applications submitted by the last Monday of the month will be reviewed at the next IACUC meeting held on the third Monday of each month. In the event of unusual circumstances, an investigator may appeal to the chairperson for consideration to schedule an emergency meeting of the IACUC to review an application.

G. The PI must complete every item and provide sufficient detail for the IACUC to assess the application requirements. Investigators are encouraged to meet with a veterinarian from the Division of Animal Care to preview the application prior to submitting the application to IACUC review.

H. The PI must obtain and complete the most current version of the Protocol Amendment Form to submit a request for any changes to the protocol prior to implementing the change. If identifying additional personnel, the PI must ensure that they complete all necessary training prior to participation.

I. The PI must submit an Annual Review Form for yearly re-approval to continue working with animals under the approved IACUC protocol. A new application must be submitted to renew the protocol after three years.

J. The PI must obtain and provide documentation of approval from LSUHSC Institutional Biosafety Committee (IBC) and where appropriate, Radiation Safety, Chemical Safety or any other LSUHSC departments.

K. The PI must respond to all IACUC requests in a timely fashion.

L. The PI must maintain all animal research records for a minimum of four years after the close of the IACUC protocol. This includes the IACUC protocol, amendments, re-approvals, and animal records such as surgical and recovery records. If associated with a NIH or any other federal funds, all records must be maintained for five years after the official closing by the NIH agency. This includes the initial IACUC protocol through every subsequent renewal IACUC protocol related to the grant.

8.2 Alternatives to Reduce, Refine and Replace

The PI must justify why animals must be used and indicate the potential benefits or knowledge to be gained. In support of the certification to reduce, refine and replace the use of animals, the Principal Investigator must conduct a literature search for alternatives to the use of animals within 3 months of the IACUC application submission. The PI must demonstrate that each of following points was given consideration in the design of the project.

A. Reduction –The estimates for the number of animals are based on statistical modeling, experimental success rates, inclusion of control groups, or literature review. The experiments do not unnecessarily duplicate previous research.

B. Refinement – The availability and appropriateness of less invasive procedures or alternatives to procedures that may cause pain and distress to the animals were considered. Where pain and distress occurs, techniques are used to alleviate or minimize pain and distress and that the minimal number of animals is used.

C. Replacement – Substitute animal use with alternatives such as cell or tissue cultures, computer models, simulations or lowest species on the phylogenetic scale are used. Rationale for choice of species must be provided.

In addition to consultation with the veterinarians in the Division of Animal Care, the following lists some of the available resources to help develop search parameters for reducing, refining and replacing the use of painful procedures and the use of animals. In developing search criteria, it may be necessary to formulate several key word groupings and to conduct multiple searches to adequately address the 3R's of animal research.

Resources for developing a search for alternatives:

1. USDA Animal Welfare Information Center Alternative Literature Searching https://www.nal.usda.gov/awic/alternatives-literature-searching
2. NIH Alternatives Search Tips Sheets http://www.lsuhsc.edu/administration/academic/ors/docs/AWIC_AlternativesBrochure.pdf

   https://oacu.oir.nih.gov/sites/default/files/uploads/information-for-acuc-members/nihlibrarytip.pdf

   https://mmcri.org/deptPages/iacuc/downloads/USDA_Alternative_Searches_Worksheet.pdf

Suggested databases for search requirements:

1. USDA links to databases by subject areas https://www.nal.usda.gov/awic/databases
2. MEDLINE/PubMed http://www.ncbi.nlm.nih.gov/pubmed
3. AGRICOLA http://agricola.nal.usda.gov/
4. Animal Welfare Institute Enrichment and Refinements Databases http://www.awionline.org/lab_animals/index.htm
5. Alternative to Animal Testing (ALTBIB) https://toxnet.nlm.nih.gov/altbib.html
6. Altweb http://altweb.jhsph.edu/
7. BIOSIS (file 5)
8. CAB (file 50)
9. TOXLINE (file 156)
10. PSYCHINFO (file 11)
11. ZOOLOGICAL RECORD (file 185)
12. SciSearch (file 434)
13. EMBASE (file 73) https://www.embase.com/#search (search fees)

8.3 Investigator Assurances

The investigator will abide by the LSUHSC-NO policy on the use and care of laboratory animals. The investigator acknowledges responsibility for the work described in the IACUC application and assures the following points.

A. PI acknowledges responsibility for the work described in the protocol.

B. The Faculty and Staff on the project are qualified to conduct the study in a humane and scientific manner consistent with PHS document "Guide for the Care and Use of Laboratory Animals" and the provisions of the Animal Welfare Act and are knowledgeable of the procedures for reporting animal welfare concerns.

C. The individuals listed in the study are authorized to conduct the listed procedures involving animals under this proposal, have attended the institutionally required investigator training course, and received training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary).

D. All individuals working on this proposal who are at risk were informed of the Institution's Occupational Health and Safety Program.

E. Full consideration was given to reduce, refine and replace the use of live animals and that these experiments do not unnecessarily duplicate previous work using animals.

F. After reviewing the pertinent scientific literature and the sources and/or databases, found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

G. Prior approval from the IACUC will be obtained before initiating any minor or significant changes in this study.

H. Will notify the IACUC regarding any unexpected study results that impact the animals; and that any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.

I. PI certifies that he/she is familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

8.4 Conflict of Interest

Investigators and staff must comply with LSUHSC-NO policy and procedures regarding management of financial conflicts of interest that could bias the outcome of sponsored projects involving research, education, and Health Sciences Center service. Under LSUHSC-NO Chancellor's Memorandum CM35 - Significant Financial Interests, all participants in a research project must disclose any significant financial interest that may present an actual or potential conflict of interest in relationship with a research project. The Principal Investigator is responsible for submitting the COI Team Member Form for every research project.

9.0 TRAINING PROGRAMS AND OTHER REQUIREMENTS

9.1 Training Required to Participate in Animal Research

Individuals must be authorized to conduct or participate in animal research activities via approved IACUC and IBC protocols and must complete all appropriate training prior to beginning any research activity. Failure to complete training by any project team member will delay approval of IACUC and IBC applications and amendments. Individuals are responsible for maintaining their training records, and must list the correct dates of completion of the applicable courses on the application or change in personnel form. If training is incomplete, then that should be indicated so that the proper modules and courses can be assigned in an expedited manner.

The **Training Required for Research Matrix** lists the training courses, source and frequency of training required to participate in research and can be viewed on webpage https://www.lsuhsc.edu/administration/academic/ors/docs/ResearchComplianceTrainingGuide2019Jul.pdf

9.2 CITI Training

Collaborative Institutional Training Initiative (CITI https://about.citiprogram.org/en/homepage/) is an independently-contracted service provider which provides on-line training. A score of 80% is required for successful completion of CITI courses. Investigators and staff participating in the use of animals must complete the initial course titled *Working with the IACUC for Investigators, Staff and Students* and the additional courses appropriate to the species that will be used (refer to the Training Required Matrix above). These initial courses are taken only once; however, retraining is required every 3 years and CITI course *Working with Animals in Biomedical Research - Refresher Course* will fulfill the retraining requirement. Documentation of attendance to a qualified animal research conference may be substituted for the CITI refresher course.

9.3 DOAC Training Program

The Division of Animal Care (DOAC) provides specific education, training and safety programs for personnel involved in the care and use of live animals.

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.

The LSUHSC-NO Animal Care Laboratory Animal Training Program covers all aspects of the requirements of the Animal Welfare Act 9CFR, Part 2, Subpart C, section 2.32(c). Every investigator, technician and animal caretaker must complete the training program prior to working with animals. Successful completion of a training course is documented by the participator's name, position, the subjects covered, date and instructor.

The program uses a combination of in-house classes, Zoom video conference training, individualized training sessions, videos, on-line courses and literature, including Standard Operating Procedures, to provide the necessary information and techniques to ensure performance of all animal procedures occur with the minimum level of pain and stress to the animals. During the training program, emphasis is placed on the proper use of anesthesia, analgesia, and euthanasia. Specific training courses include recovery, surgery, bleeding techniques, restraint, and gavage and injection route of administration.

For investigators, the training program also covers the need to and how to conduct adequate search for alternatives to the use of animals in research, and if animals must be used, how to minimize the numbers of animals without compromising the quality of research and how to replace or refine procedures that may cause pain or stress to the animals. The investigator is advised that he or she is required to list in the IACUC protocol application form all personnel performing animal procedures and that it is the investigator's responsibility to ensure that all listed have been trained to perform the procedures included in the project and have completed the Animal Care Laboratory Animal Training Program.

The DAC shall provide reports on completion of training to the IACUC at each of its semi-annual reviews of the IACUC program.

Documentation of all training, including documentation of the distribution of materials listed above, will be maintained by the Institution for at least three years and available to OLAW upon request.

9.4 Animal Care Occupational Health and Safety Program

The Animal Care's occupational health and safety program for personnel working in laboratory animal facilities or having frequent contact with animals is managed under the Animal Exposure Surveillance Program. This program includes an occupational health and safety assessment prior to having exposure to animals and where determined necessary, a medical screening examination as well as annual testing of participants. The director of the Animal Exposure Surveillance Program submits an activity report to the IACUC at each of its semi-annual reviews of the IACUC program.

The Animal Laboratory Education and Training Program thoroughly reviews the potential occupational exposures and occupationally related medical problems associated with contact with animals. In addition to verbal instruction, every employee is provided literature of the work health history and explanation of the Animal Exposure Surveillance Program. They also receive information about personal hygiene, allergies, toxoplasmosis, Q fever, rabies, herpes simplex virus, and primate related issues.

Investigators, students and staff working with primates are tested for tuberculosis every six months. Individuals who have previously been found to be positive on the skin test are given a chest x-ray. To decrease the chances of employees being exposed to zoonosis, non-human primates are quarantined for three months upon arrival, and T-B tested five times during that period. After being released from quarantine, they are T-B tested every six months, as long as they are housed in our facilities. A surveillance program is in place to monitor the health status of

other species. If any zoonosis is detected, the area goes into quarantine until its status is returned to normal.

Injuries which occur in the animal facility are handled and addressed in the manner dictated by LSUHSC-NO policy. Employees injured on the job are processed by workmen's compensation claims and are examined at an occupational health facility which is contracted with LSUHSC- NO. Injury resulting from direct animal contact is best handled by the physicians who are familiar with potential complications which might arise as a result of animal contact. Therefore, in the event an animal contact injury occurs, employees are evaluated through the Animal Exposure Surveillance Program. Treatment decisions are based on the probability of disease transmission and whether or not the animal involved is in good health. The use of specific treatment protocols that were developed by the DAC depends on the extent of injury and the nature of the animal incident. Medical tests, vaccinations, and treatment will be performed as deemed appropriate by the responsible licensed medical professional.

An incident report of the injury must be filed by the employee and his/her supervisor. After the employee is treated and the appropriate feedback is received by the animal care facility, the incident will be reviewed and appropriate measures will be taken to prevent any other incidents.

9.5 LSUHSC-NO Environmental Health and Safety Department

The Office of Environmental Health and Safety promotes a safe and healthy campus environment by providing the following programs and services that minimize safety, health, and environmental risks to the University community. It assures compliance with all occupational and environmental rules and regulations. Experiments involving the use of hazardous agents must follow LSUHSC-NO safety procedures and protocols. The use of these agents is monitored by three committees: the Radiation Safety Committee, the Chemical Safety Committee, and the Institutional Biosafety Committee (which includes general safety, chemical and rDNA issues). These committees are comprised of qualified research individuals and safety personnel.

All employees working on experiments involving hazardous agents are properly informed of the details of each experiment prior to beginning procedures. When animals are to be housed in the animal facilities following exposure to hazardous agents, special precautions must be taken. This information must be posted on the front door of the animal rooms. Workers involved in handling hazardous agents are provided with disposable coveralls to be worn over their regular uniforms, disposable gloves, face masks, goggles, shoe covers, surgical scrub bonnets, and face shields. Although all applications may be submitted concurrently, IACUC approval is contingent upon approval of the required training and safety applications. All investigators should consider this a process whereby the institution can determine and document that all investigators and others involved in the research have completed necessary training and that all procedures and performance site issues related to occupational, environmental, biosafety and radiation safety have been met. Note that many of these requirements are established by various federal and/or state agencies and departments.

A. An initial laboratory safety class is required for anyone who is involved in lab work,

operations, or management which covers general laboratory, chemical, biological, fire and operational safety as well as emergency and waste procedures.

B. Annual bloodborne pathogen training is required for all employees who can anticipate having contact with blood and other potentially infectious body fluids.

C. The Chemical Safety Committee includes hazardous waste disposal, laboratory and workplace inspections, and training.

D. The Radiation Safety Committee oversees the use of ionizing radiation and approves personnel who need to procure radiation sources for research and/or teaching purposes. All faculty, staff and students who will be handling radionucliotides must take the LSUHSC Radiation Safety Course.

9.6 Institutional Biosafety Committee (IBC)

Institutional Biosafety Committee (IBC) acts as the framework for risk management associated with research-related, biosafety issues. This includes reviewing and reporting activities that involve biological agents or chemicals that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Also included are items that are considered “Dual Use” items, i.e., used for commerce/research and could be used as a potential bio- terrorist weapon or “select agents". Depending on the circumstances there may be limitations on the use and licensing requirements of such items.

Required IBC training must be completed and the appropriate institutional safety applications, e.g. Institutional Biosafety Committee (IBC), must be submitted for each research project conducted at LSUHSC-NO. Every IACUC protocol approval is contingent upon the investigator obtaining approval from the Institutional Biosafety Committee. Experiments involving the use of hazardous agents must follow LSUHSC-NO safety procedures and protocols. Using the guidelines set forth from the IBC review, the Principal Investigator, the Director of Animal Care, the Manager of the Animal Care facility, technical help, and the Animal Caretaker, meet to discuss the risks and list the necessary precautions and procedures that are warranted.

When an investigator submits an IACUC protocol, a current IBC protocol must be listed. This IBC protocol must be congruent with the IACUC protocol. If there is not congruency, a new IBC application or amendment to the current protocol must be submitted.

10.0 OTHER ANIMAL WELFARE PROGRAM AND INSTITUTIONAL POLICES

10.1 Transportation of Animals

Precautions must be taken for the protection of humans and animals in the transportation of animals from the Animal Care facility in the Clinical Science Resource Building (CSRB) to laboratories. Investigators who need to transport animals, tissues, bedding and other waste materials to and from the animal care facility must follow the guidelines established by the Division of Animal Care. Animals and materials must be properly contained and covered with every effort utilized to prevent or minimize the transport of animals through public areas.

Animals cannot be transported through the atrium of the Medical Education Building (MEB) at any time. Investigators needing to use animals in the MEB must follow the guidelines set forth by the Animal Care Advisory Committee (ACAC). The transport route involves use of the restricted maintenance hallway on the second floor of the MEB. After applying for transport access, investigators are provided clearance to this area by using their LSUHSC ID cards. This route for animal transport is available 24 hours a day, seven days a week with the exception of 11:00 AM to 1:00 PM from Monday through Friday. Animals can be taken from animal care in the CSRB through the second floor crosswalk, to the 2nd floor stairwell of the MEB, with card access go through the 2nd floor maintenance area of the MEB and use elevator #8 to access the laboratories. The purpose of this route is for the transport of animals only. Use of this route for other purposes is not permitted. As a secured area, access is restricted by ID card and by the presence of video cameras to monitor access into the maintenance area.

On-foot transportation from LCRC to CSRB, or vice versa, is not allowed.

Transportation of animals onto or off of LSUHSC property must be done via a LSUHSC approved vehicle. A personal vehicle may also be used, but it must be inspected and approved by the IACUC. Each time transportation occurs, the transportation request must be reviewed and the vehicle must be inspected. Any transportation vehicle must be inspected during the semi-annual inspection. No bus, taxi, Uber, Lyft, or other public transportation is allowed. The temperature of the vehicle must be kept within 70-72 degrees F at all times during transportation. Animals may not be left unattended at any time. No smoking, vaping, or music while transporting animals. Seats must be covered with a sanitized plastic bag or tarp. Animals are not allowed to be transported in the bed of truck or trailer hitch. Covered cage must be placed on plastic covering and secured to seat. Alternatively, a Rubbermaid type secondary container can be used and secured to the seat. The IACUC Animal Transportation Addendum must be filled out-
https://forms.office.com/Pages/DesignPage.aspx?fragment=FormId%3DiTYGNNSCiU6jKBq3nMWNnZ7BqeNZ-Y1MiukZBg51r7pUNkNRM0dYRjg5M0haR09WMDRCMUI1Uk9NSi4u%26Token%3Dc50079d22350499fbee2cbd00e95e309

10.2 Pets and other Animals on Campus

Due to the possibility of pathogens and other contaminants being introduced into animal care facilities and/or exposure of research animals to such agents, it is the policy of LSUHSC-NO that

non-research animals may not be brought onto campus for any reason. Such exposure could compromise the welfare of research animals as protected by the Animal Welfare Act and the *Guide for the Care and Use of Laboratory Animals*. In addition, bringing such animals onto campus could create health and safety concerns for health science center personnel and legal liability for the institution. Animals purchased or bred, whether used in research or not, cannot be taken from LSUHSC-NO for domestic or personal purposes.

10.3 Testing Cell Lines and Biologicals Prior to Introduction into Animals

A potential source of virus outbreak in the animal facility is contaminated biological materials that are injected into animals. To protect the health status of the animals at LSUHSC, all cell lines, stem cells, and any biological products originating outside of LSUHSC-NO animal facilities and all rodent serum products must be screened for contamination with rodent pathogens as directed through consultation with one of the DOAC veterinarians. This includes products from the ATTC (American Type Tissue Collection). Documentation of screening or a health certificate is required prior to shipment of cell lines and biological products to LSUHSC. Exceptions to testing are listed in DOAC SOP 208.

10.4 Social Housing Exceptions

In general, social animals must be housed in stable pairs or groups of compatible individuals. Social housing of social animals is the default method of housing unless otherwise justified and approved by the IACUC prior to using single housing. Exception to social housing may be based on experimental design, social incompatibility resulting from inappropriate behavior, standard husbandry practices, veterinary concerns regarding animal well-being, or scientific necessity approved by the IACUC.
If singly housing animals is deemed necessary, LSUHSC DOAC's standard animal husbandry and management practices include single housing of social animals in situations where attempts to socially house the animals could jeopardize animal welfare.

A. Single housing should be limited to the minimum period necessary.

B. Animals should be rehoused with other appropriate conspecifics if possible.

C. During single housing, where possible, visual, auditory, olfactory and, depending on the species, protected tactile contact with compatible conspecifics should be provided.

D. In the absence of other animals, additional enrichment must be offered, such as positive interaction with humans, and/or periodic release into larger enclosures.

E. Supplemental enrichment items, and/or the addition of a companion animal in the room or housing area.

The IACUC approves the following scenarios in which single housing is acceptable where single housing was not previously approved in the protocol and is temporary. There is no need for LSUHSC veterinary approval (or documentation within the medical record).

A. Quarantine prior to entering or reentering a facility or herd.

B. Individual housing due to attrition of cage/pen mates or uneven number of animals.

C. Animals housed singly for short term recovery post-operatively; single housing must be for the minimum amount of time post-operatively necessary for recovery and/or healing as determined by the PI in consultation with the Animal Care veterinarians.

D. Intact males and females of the same species should not be group housed with members of the opposite sex unless breeding is approved by the IACUC, and then only when breeding is needed as part of the research activities. Female mice may be singly housed after litters are weaned and subsequent breeding schemes are being coordinated.

E. Intact male breeders of any species separated for breeding should not be reintroduced into a group of other intact male animals.

F. Individual housing in preparation for pending parturition.

G. Pregnant females separated to prevent overcrowding following birth of offspring.

H. Separation of littermates at weaning when the number of offspring does not allow for all animals in a litter to be placed with a compatible cage mate (for example, single male weanlings).

I. Separation of aggressive or incompatible conspecifics (for example adult males of certain species such as mice, rabbits, dogs and primates where aggression is a documented issue)

J. Individual housing when an animal is considered a danger to other animals, to itself or personnel.

K. Adult rabbits unless previously socially housed and compatible.

L. Clinical reasons where DOAC veterinary staff may require individual housing of animals due to medical concerns. In such cases, the responsible veterinarian will record the period of single housing and the frequency of reevaluation in the animals' medical record, will monitor the animal as noted and re-house the animal when the clinical concern is resolved. These cases will be reported to the IACUC at the discretion of the Attending Veterinarian.

An IACUC amendment would be required where multiple incidents of moving animals into single housing supports justification for a change to singly house all social animals under the IACUC protocol.