Annual Report to OLAW

Institution: University of South Florida
Assurance Number: D16-00589(A4100-001)
Reporting Period: 01/01/19– 12/31/19

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes [*Select A or B*]

[ ] A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. [*Skip to Item II.*]

[X] B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. (FAQ 6)

Select all that apply:

[ ] This institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).

[ ] AAALAC Accredited – Category 1

[ ] Non-Accredited – Category 2

[X] This institution's program for animal care and use has changed (PHS Policy IV.A.1.a-i.). [*Attach a full description of the changes.*]

[ ] The individual designated by this institution as the Institutional Official has changed. [*Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.*]

[X] The membership of this institution's IACUC has changed. [*Provide current roster of members in Item VI.*]

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. [*Do not provide semiannual reports unless they include a minority view.*]

A. Program Evaluations

[*Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.*]

Date 1:4/30/2019	Date 2:10/29/2019

B. Facility Inspections

[*Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.*]

Date 1:4/1/2019 through 4/30/2019	Date 2: 10/1/2019 through 10/29/2019

III. Minority Views [*Select A or B*]

[X] A. There were **no minority** views during this reporting cycle.

[ ] B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	**Institutional Official**
Name: Jay B. Dean, Ph.D.	Name: Paul R. Sanberg, Ph.D., D.Sc.
Signature: DocuSigned by: (b) (6) 8A86CE565503433...	Signature: DocuSigned by: (b) (6) 9948D7922D7A41A...
Date: 4/6/2020	Date: 4/6/2020

V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Name of Institution:	
Address: [*street, city, state, zip code*]	
E-mail:	
Phone:	Fax:

VI. Change in IACUC Membership [*Current roster*]

Institution: University of South Florida

IACUC Contact Information

Address: [*street, city, state, zip code*]

3702 Spectrum Blvd. (b) (4)
Tampa, FL, 33612-9444

E-mail: iacuc@usf.edu

Phone: (b) (6) | Fax: (b) (6)

IACUC Chairperson

Name: Jay B. Dean

Title: Chairperson of IACUC, Professor in Dept. of Pharmacology and Physiology | Degree/Credentials: Ph.D.

PHS Policy Membership Requirements***: Scientist

IACUC Roster [*Provide below or attach*]

Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Jay Dean	Ph.D.	Professor	Scientist; Chairperson
(b) (6)			Nonscientist; Unaffiliated
			Scientist; Moffitt Affiliate; Vice-Chairperson
			Scientist; Veterans Hospital Affiliate
			Scientist
			Scientist
			Scientist
			Veterinarian
			Scientist; Moffitt Affiliate
			Veterinarian
			Scientist; pool alternate; Veterans Hospital Affiliate
			Scientist; pool alternate; Veterans Hospital Affiliate
			Nonscientist; Nonaffiliated-alternate
			Scientist; pool alternate; Moffitt Affiliate
			Scientist; Moffitt Affiliate;
			Scientist; pool alternate;

(b) (6)			Scientist; pool alternate;
			Scientist; pool alternate;
			Scientist; pool alternate; Moffitt Affiliate
			Scientist, pool alternate
			Scientist, pool alternate
			Scientist; pool alternate
Robert Engelman	D.V.M., Ph.D.	Director	Veterinarian; pool alternate
(b) (6)			Veterinarian; pool alternate
			Scientist; pool alternate; Veterans Hospital Affiliate
			Scientist; pool alternate;

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

*** PHS Policy Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[*Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.*]

ATTACHMENT OLAW ANNUAL REPORT, 2019

University of South Florida
Assurance #D16-00589(A4100-001)
Accredited Unit #000434
Reporting Period: 01/01/19 – 12/31/19

The University of South Florida IACUC and the IO report that the Institution's program for animal care and use has changed with respect to the indicated sections of the PHS Policy on the Humane Care and Use of Animals as follows:

1. The membership of the institutions IACUC has changed and the current roster is included in the OLAW annual report form in Item VI (relevant to PHS Policy IV.A.1.c. and IV.A.3.b).

2. The institution's program has changed with respect to its written IACUC principles, forms, and procedures. Changes were implemented or acknowledged by a quorum of members at convened meetings. Revisions to the following IACUC Principles were approved by a quorum of the IACUC at February 22, March 22, May 17, June 28, November 15 2019, and March 27, 2020 meetings, as itemized below:

FEBRUARY 22, 2019, IACUC MEETING

III.5. All live vertebrate animal use, including field studies, conducted by University faculty, students, or staff, or supported by University funds, must first be described in a draft IACUC application using the ARC system and be pre-reviewed by University veterinarians prior to its submission to the IACUC for full committee review (FCR) or designated member review (DMR), as appropriate. All vertebrate animal use must be proposed to, and approved by the IACUC as an IACUC protocol prior to the initiation of that activity, regardless of where it will be performed. Activities involving wild animals in natural settings (field studies) that will not alter or influence the activity of the study animals or other species in the study area (i.e., unobtrusive observational studies), will not impact the animal's environment, and will not impact the health or safety of involved personnel need not be proposed to the IACUC. An IACUC protocol application or aspect of an application that describes procedures not previously encountered or that have the potential to cause pain or distress that cannot be reliably predicted or controlled, may be proposed as a limited pilot study, designed to assess both the procedure's effects on the animals and the skills of the research team conducted under IACUC oversight. In such cases, the IACUC will require the protocol to be limited to and conducted as a pilot study, which stipulates the number of animals to be used, and the recordkeeping, oversight, and IACUC reporting intervals and content requirements to be used regarding outcomes. It is the Principal Investigators responsibility for submitting an outcome report of the pilot study to the IACUC in the timeframe requested by the IACUC. The outcome report will be used to by the IACUC as follows: to evaluate whether a subsequent larger study is justified; whether to release pilot study status and permit protocol modifications allowing a subsequent larger study; and used to define clinical endpoints.

MARCH 22, 2019, IACUC MEETING

III.13. Protocol types "wildlife", "murine colony only", "antiserum production only", and "tissue use only" are subject to DMR as follows. Within 3 days of receipt of the new application, any member of the full IACUC can ask for clarifications or revisions of the IACUC application involving "wildlife", "murine colony only", "antiserum production only", or "tissue use only", or can call for a review of the application at the next regular IACUC meeting. If FCR is called, the clarified or revised IACUC application is reviewed by the full IACUC. If there are no clarifications, revisions or full IACUC review requests within three days of receipt of the application, the application is reviewed by a designated IACUC member. The designated member reviewer assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or returning the protocol for FCR. Members for DMR are appointed by the IACUC Chair. Annually or whenever the IACUC membership changes the IACUC Chair provides the Research Integrity and Compliance administrative staff with a spreadsheet/grid with DMR assignments. The IACUC Chair reviews research protocol categories/areas of expertise (e.g., murine colony only, tissue use only, procedural changes, etc.), determines which

IACUC member(s) can be tasked for a specific DMR role, depending on the nature of the application or proposed modification, and matches the IACUC member for DMR to their area of expertise. At any time during this process, any IACUC member may request to view/review the modified application, or may request FCR of the application. When considered complete and appropriate, the designated member reviewer approves the application, and this approval is communicated to the full IACUC membership at its next regular monthly meeting. Any IACUC application that is added as an agenda item to the next regular IACUC meeting, or not approved by the designated member reviewer, is then reviewed by the full IACUC at the next regular monthly meeting. Written IACUC approval is required prior to implementing any animal use.

III.14. The protocol type "research or teaching" is added as an agenda item to the next regular IACUC meeting. Each new research, or teaching, or other protocol type added as an agenda item to the IACUC meeting is presented by a primary reviewing IACUC member using entries made directly on the IACUC application. After verbally presenting their findings regarding the application to a quorum of the IACUC members, the primary reviewing IACUC member proposes a motion to either approve the application, require modifications to secure approval of the application, or disapprove the application. IACUC members listed as participating personnel on the IACUC application must leave the room during the presentation and discussion of the protocol and are not permitted to participate or vote. No IACUC member participates in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC. IACUC members who have a conflicting interest in a proposed protocol do not contribute to the constitution of a quorum. After discussion and a motion is made, the motion is seconded, and the full IACUC committee votes. If the approved motion is "Requires Modification to Secure Approval," it is understood that all members of the IACUC, in attendance or not, forgo a full review of the to-be revised application in favor of the designated primary reviewing IACUC member's review. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use this designated member review subsequent to full committee review when modification is needed to secure approval. This understanding is part of each IACUC member's initial orientation to regulatory processes, processes that are agreed upon in advance in writing using a form entitled "Orientation and Certification of New IACUC Members". This form documents the use of designated member review subsequent to full committee review of a protocol application, which all IACUC members agree to by unanimous vote. New ACORP applications and ACORP applications found to "Require Modification to Secure Approval" are reviewed by a minimum of two designated reviewing members affiliated with the VA. Once members have chosen this designated-member review, then the primary reviewer(s) assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or returning the protocol for full review. At any time during this process, any member may request to view/review the modified application, or may request full committee review of the application.

MAY 17, 2019 & MARCH 27, 2020 IACUC MEETINGS

III.17. Changes that are handled administratively as an amendment include a change in the certified research personnel other than PI, title, funding source other than federal sources, or strain of the same species if justified in writing. Amendments proposed to an IACUC protocol are submitted by direct modification of the approved protocol. Requests to add new research personnel are reviewed first by Research Integrity & Compliance to validate that all documents required of IACUC certification have been completed and submitted via the ARC system.

III.19. When using DMR procedures, the designated reviewer(s) cannot withhold approval of a protocol. The outcomes of DMR are approval, requires modification(s) to secure approval, or refer to full committee for review. Changes that are considered significant requiring FCR or DMR include those that change (a) from non-survival to survival surgery, (b) resulting in greater pain, distress, or degree of invasiveness, (c) new housing or use location outside of Comparative Medicine managed facilities, (d) species, (e) study objectives, (f) Principal Investigator, or (g) impacting personnel safety. When the change request is for a new species, Research Integrity & Compliance first validates that that the PI and staff ARC profiles identify the new species of interest, and if the request is for unvaccinated or uncharacterized carnivores, pregnant sheep, goats, cattle, or nonhuman primates, that a new updated Health and Risk Assessment for Employee Safety in the Care and Use of Animals form has been completed and uploaded to ARC by the PI and staff. Changes considered significant requiring FCR or

DMR are reviewed by the full IACUC membership. Within 3 days of receipt, any member of the full IACUC can ask for clarifications or revisions of the Protocol Change, or can call for FCR at the next regular IACUC meeting. If there are no clarifications/revisions or FCR requests within three days of receipt of the protocol change, it is reviewed by a designated IACUC member. If clarifications/revisions are requested, the PI will be given the opportunity to respond and incorporate these changes into the approved protocol. When revisions are incorporated, the revised Protocol Change is reviewed by a designated IACUC member assigned by the IACUC chair. When considered complete and appropriate, the designated member reviewer approves the change, and this approval is communicated to the full IACUC membership at its next regular monthly meeting. Any Protocol Change that is added as an agenda item to the next regular IACUC meeting, or not approved by the designated member reviewer, is then reviewed by the full IACUC at the next regular monthly meeting. Written IACUC approval is required prior to implementing any changes.

VII.3. Individuals determined to be at risk as determined by completion of the Health and Risk Assessment for Employee Safety in the Care and Use of Animals form are encouraged to complete a Health History Assessment form and consult with a health provider. When special considerations are declared, including the proposed use of infectious agents requiring biosafety level III containment, or the use of unvaccinated or uncharacterized carnivores, pregnant sheep, goats, cattle, or nonhuman primates, which require additional services, Research Integrity & Compliance ensures that at-risk personnel make arrangements for health services, and receives written confirmation that health services have been initiated, documentation of which is uploaded to the researcher's profile in the ARC system.

VIII.4. All research personnel must complete the AALAS Learning Library course entitled "Laws, Regulations, Policies, and the Guide – USF Orientation Lessons" and provide the certificate of completion, which documents that they have received training in animal care and use legislation, IACUC function, ethics of animal use and the concepts of the Three Rs, methods for reporting concerns about animal use, occupational health and safety issues pertaining to animal use, animal handling, aseptic surgical technique, anesthesia and analgesia, and euthanasia.

VIII.6. All new personnel using live vertebrate animals must complete a Health and Risk Assessment for Employee Safety in the Care and Use of Animals form. Annually, all research personnel must review their Health and Risk Assessment for Employee Safety in the Care and Use of Animals form, and when declaring any changes, must upload to ARC the updated, completed form.

VIII.10. Principal Investigators and all personnel proposing to use immune deficient mice must upload to their ARC profile a certificate of completion for the AALAS LL course entitled "Handling and Use of Immune Deficient Mice". All personnel intending to directly handle and use immune deficient mice must also upload a certificate of completion of CM in person training in such procedures, prior to protocol approval. Personnel proposing physical methods of euthanasia without the benefit of anesthesia (e.g., decapitation, cervical dislocation) must upload to their ARC profile a certificate of training and proficiency is such procedures, prior to IACUC protocol approval. Personnel proposing physical methods of euthanasia without the benefit of anesthesia (e.g., decapitation, cervical dislocation) must upload to their ARC profile a certificate of training and proficiency is such procedures, prior to IACUC protocol approval. Comparative Medicine offers formal hands-on wet-laboratory training. Curricula may vary depending on need as requested by research faculty or staff, or as required by the IACUC, and may include basic animal needs, proper animal handling, routes and methods of substance administration, proper pre-procedural and post-procedural care, aseptic surgical technique, methods of anesthesia and analgesia, use of equipment, and methods of euthanasia. Attendance and curricula are documented.

XII.19 Physical restraint is defined as the use of manual or mechanical means to limit some or all of an animal's movement for the purpose of examination, sample collection, drug administration, therapy, or experimental manipulation. In some cases, personnel safety may also necessitate the physical restraint of an animal. Prolonged restraint is defined as physical restraint of a conscious animal lasting >30 minutes. Prolonged restraint, including chairing of non-human primates, should be avoided unless it is justified in writing, essential for achieving research objectives, and approved by the IACUC. Chairing of non-human primates is considered prolonged restraint regardless of duration. When proposing prolonged restraint, the IACUC application must include (1) a scientific justification for the use of

prolonged restraint, (2) a description of the restraint device, (3) a description of acclimation procedures to condition the animal to prolonged restraint, (4) the maximum amount of time the animal may be restrained, (5) a description of how the animal will be observed and monitored during restraint, (6) when the duration of prolonged restraint is ≥6 hours, a description of when food and water will be given, how body weight will be monitored, and how hydration status will be monitored. Physical restraint that is <30 minutes, and does not cause distress or discomfort to the animal is not considered prolonged, and as such, a detailed description is not required in the IACUC application.

XVI. Multiple Survival Surgical Procedures

XVI.1. Major surgery penetrates and exposes a body cavity (e.g., laparotomy, thoracotomy, craniotomy), produces impairment of physical or physiologic function (e.g., joint replacement, limb amputation) or involves extensive tissue dissection or transection.

XVI.2. Multiple survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the applicant and approved by the IACUC.

XVI.3. Multiple survival surgical procedures may be justified if they are related components of a research project, if they conserve scarce animal resources, or if they are needed for clinical reasons. Cost savings is not an adequate reason for performing multiple major survival surgical procedures.

XVI.4. If multiple survival surgical procedures are approved by the IACUC, particular attention must be provided by the research staff to animal health and well-being through frequent and continuing evaluations, and the IACUC must evaluate outcomes of multiple surgical procedures.

JUNE 28, 2019, IACUC MEETING

III.21. IACUC applications describing mentorship of precollege students are reviewed by the IACUC if the PI attaches all applicable school, county, and/or state forms, including parental permission, the precollege student is certified for animal use within the PI's laboratory, and the PI assures that they or their designated staff who are named on the application will continually directly supervise the precollege student while an animal care staff member is available in the facility during the conduct of the proposed research involving animals. As USF Policy 6-038 prohibits minors from working or volunteering in an animal housing or use area, requests to certify precollege students as qualified for unescorted access to an animal facility are not granted.

IV.5. The applicant Principal or Secondary Investigator must have a faculty appointment with the University or an appropriate appointment with the James A. Haley Veteran's Administration Medical Center, H. Lee Moffitt Cancer Center and Research Institute, or New College of Florida. Extramural research interests involving animals may be led by an extramural IACUC certified scientist, assuming the extramural entity has a written understanding on file with a program member institution, all costs of infrastructural services are fully reimbursed, and in the event resources become limited, faculty and intramural scientist interests are shown priority.

NOVEMBER 15, 2019 & MARCH 27, 2020 IACUC MEETINGS

III.12. New IACUC applications are reviewed either by full IACUC committee review (FCR) or using a designated member review (DMR) process. Each IACUC application is designated a protocol type by the applicant PI as either "research or teaching", "wildlife", "murine colony only", "antiserum production only", or "tissue use only". The protocol type "research or teaching" describing Research Pain Category B and C procedures and ACORP applications are added as an agenda item to the next regular IACUC meeting for FCR. Protocol types "research or teaching" describing Research Pain Category A procedures, "wildlife", "murine colony only", "antiserum production only", and "tissue use only" are subject to DMR.

III.13. When using DMR procedures, the designated reviewer(s) cannot withhold approval of a protocol. The outcomes of DMR are approval, requires modification(s) to secure approval, or refer to full committee for review. Protocols subject to DMR, are reviewed as follows. Within 3 days of receipt

of the new application, any member of the full IACUC can ask for clarifications or revisions of the IACUC application, or "tissue use only", or can call for a review of the application at the next regular IACUC meeting. If FCR is called, the clarified or revised IACUC application is reviewed by the full IACUC. If there are no clarifications, revisions or full IACUC review requests within three days of receipt of the application, the application is reviewed by a designated IACUC member. The designated member reviewer assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or returning the protocol for FCR. Members for DMR are appointed by the IACUC Chair. Annually or whenever the IACUC membership changes the IACUC Chair provides the Research Integrity and Compliance administrative staff with a spreadsheet/grid with DMR assignments. The IACUC Chair reviews research protocol categories/areas of expertise (e.g., murine colony only, tissue use only, procedural changes, etc.), determines which IACUC member(s) can be tasked for a specific DMR role, depending on the nature of the application or proposed modification, and matches the IACUC member for DMR to their area of expertise. At any time during this process, any IACUC member may request to view/review the modified application, or may request FCR of the application. When considered complete and appropriate, the designated member reviewer approves the application, and this approval is communicated to the full IACUC membership at its next regular monthly meeting. Any IACUC application that is added as an agenda item to the next regular IACUC meeting, or not approved by the designated member reviewer, is then reviewed by the full IACUC at the next regular monthly meeting. Written IACUC approval is required prior to implementing any animal use.

III.14. The protocol type "research or teaching" describing Research Pain Category B and/or C procedures, and ACORP applications are added as an agenda item to the next regular IACUC meeting. Each protocol added as an agenda item to the IACUC meeting is presented by a primary reviewing IACUC member using entries made directly on the IACUC application. After verbally presenting their findings regarding the application to a quorum of the IACUC members, the primary reviewing IACUC member proposes a motion to either approve the application, require modifications to secure approval of the application, or disapprove the application. IACUC members listed as participating personnel on the IACUC application must leave the room during the presentation and discussion of the protocol and are not permitted to participate or vote. No IACUC member participates in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC. IACUC members who have a conflicting interest in a proposed protocol do not contribute to the constitution of a quorum. After discussion and a motion is made, the motion is seconded, and the full IACUC committee votes. If the approved motion is "Requires Modification to Secure Approval," it is understood that all members of the IACUC, in attendance or not, forgo a full review of the to-be revised application in favor of the designated primary reviewing IACUC member's review. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use this designated member review subsequent to full committee review when modification is needed to secure approval. This understanding is part of each IACUC member's initial orientation to regulatory processes, processes that are agreed upon in advance in writing using a form entitled "Orientation and Certification of New IACUC Members". This form documents the use of designated member review subsequent to full committee review of a protocol application, which all IACUC members agree to by unanimous vote. New ACORP applications and ACORP applications found to "Require Modification to Secure Approval" are reviewed by a minimum of two designated reviewing members affiliated with the VA. Once members have chosen this designated-member review, then the primary reviewer(s) assumes the responsibility for the full committee in granting unanimous approval, requiring modification, or returning the protocol for full review. At any time during this process, any member may request to view/review the modified application, or may request full committee review of the application.

III.29. If test substance(s) that are potentially hazardous are to be administered to animals, prior authorization of use of the test substance(s) by the appropriate Safety Committee is required before approval by the IACUC. Approval of the IACUC application involving hazardous materials not previously proposed by the PI and approved by the IACUC, can be contingent on a pre-performance meeting involving the PI and relevant staff that represents the applicant's laboratory, Comparative Medicine, the IACUC, and the appropriate Safety Committee(s). This pre-performance meeting may be helpful to ensure that all involved personnel are aware of the precautions, containment practices, facilities, protective devices, disposal and decontamination procedures, and other necessary safety procedures

that must be followed to protect personnel, and prevent accidental animal exposure to the hazardous material. The IACUC may also require a pre-performance meeting whenever an applicant PI proposes infrequently used species or techniques, or proposes surgical or teaching procedures involving anesthetized non-rodent mammals. This pre-performance meeting may take place before or after IACUC approval of the protocol at the discretion of the IACUC, but must occur before initiation of the IACUC approved activity, and ensures that appropriate personnel, equipment, supplies, recordkeeping, and practices of animal care and use have been identified and will be employed.

III.30. The IACUC, assisted by the staff of Research Integrity & Compliance and Comparative Medicine, conduct observational post approval monitoring (PAM) and periodic audits of active animal use protocols, and inspect laboratories outside of the animal facilities where animals are used (e.g., observational PAM of FKML). These audits, and inspections, and observational PAM serve as an additional review of the effectiveness of the animal care and use program, and are initiated during each semi-annual inspection of facilities and program by the IACUC, or whenever necessary. These audits, inspections, and observational PAM ensure that sufficient animal care and clinical oversight is provided and recorded, that animal pain, distress, or discomfort are anticipated, avoided, or alleviated, that work areas are uncluttered and adequately decontaminated, that current supplies and procedures are used, that appropriately sanitized/sterilized instruments are used, and that the risks of all hazards are minimized. In determining which protocols to audit and laboratories to inspect, the IACUC is especially interested in ensuring the good practices of protocols involving satellite animal housing, Pain Category C procedures, survival surgery, the administration or use of hazardous materials, or the use of controlled substances. In addition, in accordance with the VA Handbook, during each semi-annual Program Review, the IACUC must ensure that IACUC records representing at least 5 percent of the total active VA projects, or a minimum of five protocols, are randomly reviewed to determine if appropriate documentation of initial review, approval letter(s), annual and triennial approvals, modifications, and investigator correspondence are present, and present their semi-annual summaries to the IACUC.

VII.1. Medically trained occupational health professionals are involved with the IACUC in the planning and monitoring of, and assess participation in the Occupational Health and Safety Program. Health Administrations and Environmental Health & Safety offices offer to all personnel who will be working with animals, information regarding health monitoring, potential zoonosis, and health assessments, immunizations, and safety procedures relating to their animal contact and/or exposures. Field studies are also reviewed by these offices to ensure that the proposed field study does not compromise the health and safety of persons in the field.

XII.10. When proposing Research Pain Category C activities involving animals where painful or stressful outcomes are anticipated or possible, the PI must define in writing the clinical criteria which will be used to ensure timely intervention and treatment, or removal of the animals from the study, either in advance of, or immediately after recognition of the discomfort, or the specific clinical end point at which euthanasia of the animals will be accomplished. The earliest possible clinical endpoint that will contribute to the resolution of the hypothesis must be separately identified and utilized for each vertebrate species requested in the application. If avoidance or alleviation of animal pain or discomfort adversely affects the protocol, the PI must provide a detailed justification of why treatments cannot be initiated. When identifying the earliest clinical endpoint in applications to the IACUC, the PI should consider proposing both early notification criteria (e.g., tumor diameter) which when met causes staff to alert the PI to consider whether study objectives have been met, and also later exclusion criteria (e.g., larger tumor diameter, and/or complications referable to the tumor) which when met requires the euthanasia of the animal. When identifying the earliest clinical endpoint, the PI should refer to section C.2.c. of the ARENA/OLAW Guidebook entitled "Humane Endpoints" viewable at **http://grants1.nih.gov/grants/olaw/GuideBook.pdf**.

XII.12. The written justification for the use of animals involved in Research Pain Category C procedures must separately identify and utilize for each vertebrate species requested in the application the earliest possible clinical end point that will contribute to the resolution of the hypothesis. If death is determined to be the earliest possible endpoint that will contribute to the specific aims of the research, then a written justification of why an earlier clinical endpoint is inadequate for resolving the proposed hypothesis must be included in the IACUC application. When determining the earliest possible clinical endpoint for a proposed research activity, the applicant PI should refer to the guidelines reviewed in

"Humane Endpoints for Animals Used in Biomedical Research and Testing", vol. 41(2), 2000, published by the Institute for Laboratory Animal Research, National Research Council and viewable at **http://grants.nih.gov/grants/olaw/GuideBook.pdf**.

March 27, 2020, IACUC MEETING

VII.2. New research and animal care personnel must submit a completed *Health and Risk Assessment for Employee Safety in the Care and Use of Animals* form to the ARC system. A medical evaluation and health history are required by occupational health professionals for those individuals with relevant animal contact, the collection of which complies with all federal, state and local HIPAA regulations for privacy. Every six years, all IACUC-certified personnel must provide a revised Health and Risk Assessment for Employee Safety in the Care and Use of Animals form. Personnel whose duties require access to an animal facility but whose duties do not include working with animals must submit a completed *Personnel Entering Animal Facilities Health and Risk Assessment* to the IACUC.

VII.3. Individuals determined to be at risk as determined by completion of the *Health and Risk Assessment for Employee Safety in the Care and Use of Animals* form are encouraged to complete a *Health History Assessment* form and consult with a health care provider. A medical evaluation and health history are required by occupational health professionals for those individuals with relevant animal contact, the collection of which complies with all federal, state and local HIPAA regulations for privacy. When special considerations are declared, including the proposed use of infectious agents requiring biosafety level III containment, or the use of unvaccinated or uncharacterized carnivores, pregnant sheep, goats, cattle, or nonhuman primates, which require additional health services, Research Integrity & Compliance ensures that at-risk personnel make arrangements for health services, and receives written confirmation that health services have been initiated, documentation of which is uploaded to the researcher's profile in the ARC system.