THE UNIVERSITY OF MISSISSIPPI
D16-00232
(Previously A3356-01)
Animal Welfare Assurance

I, Dr. Joseph R. Gladden, as named Institutional Official (IO) for animal care and use at The University of Mississippi (UM), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

A. This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by PHS, NSF, and NASA. This Assurance covers only those facilities and components listed below.

B. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All components of the University's Oxford Campus (Schools, Departments, etc.) that are physically located in Lafayette County, Mississippi, including Faser Hall, Shoemaker Hall, the Thad Cochran Research Center, National Center for Natural Products Research that are located on the Oxford Campus and the UM Field Station at 15 County Road 2078, Abbeville, MS 38601. This station is located approximately 11 miles from the University's main campus. All of these components are within the purview of the IO and the Institutional Animal Care and Use Committee (IACUC). There are no other satellite facilities and/or other covered components.

C. The following are other institution(s), or branches and components of another institution: Not applicable—None.

II. Institutional Commitment

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

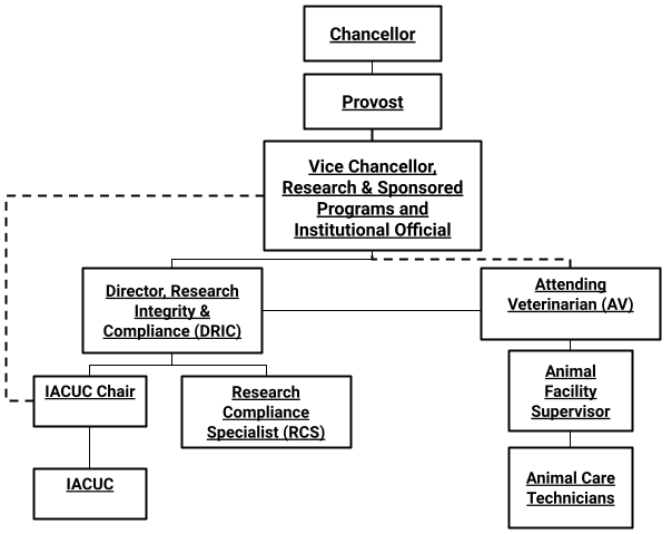
D. This Institution has established and will maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals (Guide).

E. This Institution agrees to ensure that all performance sites engaged in activities involving

live vertebrate animals under consortium (sub-award) or subcontract agreements have an Animal Welfare Assurance and that the activities have IACUC approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:



1. Overall program authority and responsibility to implement this policy and the recommendations of the Guide are vested in the UM Vice Chancellor for Research and Sponsored Programs, Dr. Joseph R. Gladden. The Vice Chancellor for Research and Sponsored Programs is the IO.
2. The IACUC and IACUC Chair have open and direct lines of communication to the IO.
3. The Attending Veterinarian (AV), Dr. Harry C. Fyke, has the authority and responsibility to implement the PHS policy and the recommendations of the Guide, and has open and direct lines of communication with the IO.
4. The AV reports to the Director of Research Integrity and Compliance (DRIC) who is responsible for ensuring compliance with all regulations, laws, and policies.
5. The Vice Chancellor for Research and Sponsored Programs reports to the Provost, who reports to the Chief Executive Officer (CEO) of The University of Mississippi, Chancellor Glenn F. Boyce. The Chancellor has delegated, in writing, the authority to appoint IACUC members to the Vice Chancellor for Research and Sponsored Programs.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1. Name: Harry C. Fyke, D.V.M., Attending Veterinarian

2. Qualifications:

   a. Degrees: B.S. 1992, Microbiology, Mississippi State University, D.V.M., 1996, Veterinary Medicine, Mississippi State University

   b. Training and/or experience in laboratory animal medicine: Dr. Fyke has 25 years of experience with small animals and exotic species in a clinical setting, plus 19 years of experience with laboratory animals. He is a member of the Scientists Center for Animal Welfare, American Society of Laboratory Animal Practitioners, and Institute for Laboratory Animal Research. Dr. Fyke regularly receives continuing education through participation in national meetings and webinars involving laboratory animal medicine, animal welfare, and regulatory issues. He also consults, when necessary, with two American College of Laboratory Animal Medicine-certified veterinarians, Dr. Lucy H. Senter, at Mississippi State University and Dr. Andrew Grady at The University of Mississippi Medical Center, and with Dr. Timothy Cummings, a diplomate of the American College of Poultry Veterinarians, and Dr. S.W. Jack an expert in veterinary pathology, both at Mississippi State University.

3. Authority: Dr. Harry C. Fyke has direct program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide. Dr. Fyke is responsible for providing veterinary support and consultation to animal users on matters concerning health and surgical procedures; choosing appropriate animal models or alternatives to animal models; providing basic health care to animals; providing training to investigators and animal technicians on animal welfare laws and the appropriate care, use, and management of vertebrate animals. He has unfettered access to all animals.

4. Time Contributed to Program: The AV is a three-quarter-time position, approximately 30 hours per week, which at present is adequate for the animal population. 100% of the AV's time at UM is devoted to the animal research program.

5. Provisions for Back-up Veterinary Care: For times when Dr. Fyke is unavailable, Dr. Ware Sullivan has a contractual agreement to be on call for consultation and emergency care. He graduated with his D.V.M. from Mississippi State University in 1997 and holds a MS veterinary license #1372.

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The Vice Chancellor for Research and Sponsored Programs, as delegated by the Chancellor (CEO), appoints the members of the IACUC. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached (Part VIII) is a list of the chairperson and members of the IACUC and their, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1. **Review at least once every six months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC**

procedures for conducting semiannual program reviews are as follows:

a. The UM Animal Care and Use Program semiannual program reviews are conducted at least once every six months—usually in May and November.

b. The IACUC conducts the program review at a convened meeting during which all members present participate, and the Institution's Assurance is included and available for review.

c. The OLAW Sample Semiannual Program Review Checklist has been adapted for use to conduct the review and includes the following items:

- Institutional and Individual Responsibilities;
- IACUC Membership and Functions;
- IACUC Member Experience and Training;
- IACUC Records and Reporting Requirements;
- Husbandry and Veterinary Care (all aspects);
- Personnel Qualifications (Experience and Training);
- Emergency and Disaster planning;
- Occupational Health and Safety; and
- Security (personnel and facility).

d. If program deficiencies are noted during the review, they will be categorized as significant or minor and the IACUC will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

e. No member will be involuntarily excluded from participating in any portion of the reviews.

2. **Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:**

a. The UM Animal Care and Use Program semiannual facility inspections are conducted at least once every six months—usually in April and October.

b. The IACUC uses a rotating schedule for members to participate in the semiannual facility inspections. All members are invited to participate in the facility inspections. The IACUC Office coordinates the inspection schedule and team assignments.

c. The Facility Inspection Team conducting the inspections consists of at least two IACUC members.

d. Team members are provided materials to prepare them for the inspection,

including: OLAW sample semiannual facility inspection information; previous facility inspection report and summary with follow-up findings; blank inspection review form; tips for maintaining animal facility areas; vivarium dos and don'ts; and a list of rooms by building and Principal Investigator (PI) with active protocols.

e. Inspection Teams visit all of the institution's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, animal surgical areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment, including vehicles other than from commercial animal vendors/suppliers used for transporting animals, is also inspected.

f. The Inspection Team 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.

g. To facilitate the evaluation, the Inspection Team will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

h. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Inspection Team will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

i. No member will be involuntarily excluded from participating in any portion of the inspections.

3. **Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the IO. The IACUC procedures for developing reports and submitting them to the IO are as follows:**

   a. Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee (typically a Research Compliance Specialist), who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.

   b. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.

   c. The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy and state the reasons for each departure. If there are no departures, the report will so state.

   d. Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either Full Committee Review (FCR) or Designated Member Review (DMR) as delineated below in Section III.D.6.

   e. Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

f. If deficiencies are noted during the evaluations, the reports will distinguish significant deficiencies from minor deficiencies and will contain a reasonable and specific plan and schedule for correcting each deficiency.

g. If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.

h. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the IACUC.

i. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.

j. Following completion of each evaluation, the completed report will be submitted or presented to the IO in a timely manner, usually within 30 days.

k. Deficiencies will be tracked by the Division of Research Compliance and Integrity and the AV to ensure they are appropriately resolved.

4. **Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:**

   a. Any individual may report concerns anonymously, in person, in writing, via telephone, or electronically to the IO, IACUC Chairperson, AV, or any member of the IACUC.

   b. Notices are located in the animal facilities and on the IACUC website under the ‘Reporting Concerns’ tab 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.

   c. All reported concerns will be brought to the attention of the IACUC.

   d. If necessary the IACUC Chairperson will convene a meeting to discuss, investigate, and address any reported concern.

   e. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The IACUC will report such actions to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.

5. **Make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the IO are as follows:**

   a. The IACUC bases recommendations to the IO about the UM animal program, facilities, or personnel training on issues identified by investigators, research personnel or members of the IACUC.

   b. Issues are reviewed by the IACUC Executive Committee (IEC), which is

comprised of the IACUC Chair, AV, DRIC and RCS, or other subcommittee. The IEC or subcommittee reconciles all issues, makes recommendations, and sends these to the full IACUC for review and approval.

c. The IACUC Chairperson sends a letter to the IO describing the issue/s and the recommendation/s of the full IACUC.

6. **Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:**

   a. **Submission, Pre-review, & Distribution**

      - Protocol applications are submitted via email attachment to the IACUC Office. The IACUC Office screens all applications for completeness and clarity. Protocol applications are then submitted via email attachment to all IACUC members for review and comments.

   b. **IACUC Reviews (General Information)**

      - In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review by full-committee review (FCR) or by designated-member review (DMR) of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

        i. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design;

        ii. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator;

        iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure;

        iv. The living conditions of animals will be appropriate for their species and contribute to their health and comfort;

        v. The housing, feeding, and nonmedical care 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 being maintained or studied;

        vi. Medical care for animals will be available and provided as necessary by a

qualified veterinarian;

vii. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures; and

viii. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator and approved by the IACUC.

- No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC.
- Any use of telecommunications for meetings, if needed, will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- Prior to the review, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals, and any member of the IACUC may request FCR of those protocols.
- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC.

c. **Full-Committee Review**

- IACUC meetings are held monthly as needed and are conducted in person.
- A quorum of members is required for meetings. There are no additional requirements. However, the AV's attendance is requested and generally occurs.
- Any member may make a motion and any member may second a motion in a meeting. Following a motion, a second, and any discussion, voting proceeds with members raising their hands to indicate they agree with the motion as stated, disagree, or abstain from the vote.
- FCR of a protocol can result in a) approval, b) requiring modifications to secure approval, c) disapproval, or d) tabling a protocol until the next meeting.
- Review of Required Modifications Subsequent to FCR. The review of required modifications subsequent to FCR will be done in accordance with PHS Notice Number: NOT-OD-09-035, January 2009. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are

reviewed as follows:

i. FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance;

Or

ii. DMR if approved unanimously by all members at the meeting at which the required modifications are developed and delineated AND if the entire current Committee has previously approved and documented a policy of DMR for review of required modifications (to secure approval) subsequent to FCR. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- Minor modifications of an administrative nature, i.e., typographical or grammatical errors, etc. may be confirmed by IACUC administrative/support personnel.

d. **Designated-Member Review**

- In instances where the IACUC uses the DMR method, protocols will first be distributed to all IACUC members to allow all members the opportunity to call for FCR.
- Records of approval of protocols via DMR are maintained and recorded in the activity report and distributed to members of the IACUC at the next convened meeting.
- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- If FCR is not requested by at least one member of the IACUC, the chairperson will designate at least two IACUC members qualified to conduct the review to serve the DMR function and have the authority to approve, require modifications in (to secure approval) or request FCR of those protocols.
- While other IACUC members may provide the designated reviewers with comments and/or suggestions for the reviewers' consideration, concurrence to use the DMR method may not be conditioned.
- Correspondence between designated reviewers and PIs is coordinated by the RCS/designee. After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval.
- The decisions of multiple designated reviewers must be unanimous; if not, the protocol will be referred for FCR.
- DMR of a protocol can result in approval, requirement of modifications to secure approval, or sending the protocol to FCR.

e. **Special or Expedited Reviews**

- There are no alternate processes or procedures for special or expedited reviews.

7. **Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:**

a. Significant changes described below must be approved by DMR or FCR (see Part III.D.6. above).

- in the objectives of a study;
- from non-survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- in the species;
- in Principal Investigator; and
- that impact personnel safety.

b. Significant changes described below may be handled administratively in consultation with a University of Mississippi veterinarian who is authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare.

- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and
- in the duration, frequency, or number of procedures performed on an animal.

c. Review and approval of change in in approximate number of animals use may also be handled administratively, but without requiring additional veterinary consultation, as described in IACUC approved written policies that are compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will address the rational for the original number of animals used, approved study objectives, the rational for the additional animals, and possible negative impacts on animal welfare.

d. All such aforementioned written policies related to veterinary verification and consultation and administrative review will be adopted [reviewed and approved] by

formal action of the IACUC.

e. All such aforementioned policies may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.

f. If the IACUC wishes to continue the procedures/policies beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC.

g. All approved changes will be documented in the associated protocol file.

8. **Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:**

   a. Notification that modifications are required to secure IACUC approval is communicated to the PI via e-mail, and the specific modifications required for approval are delineated in that notification.

   b. IACUC decisions to approve or withhold approval of protocols are communicated in a letter that is sent to the PI electronically.

   c. If approval is withheld, the IACUC will include in its written notification to the PI a statement of the reasons for its decision and give the PI an opportunity to respond in person or in writing.

   d. A report of all protocol activity, including IACUC decisions regarding protocol review, is provided to the full IACUC at their monthly meetings.

   e. The IO is informed of IACUC activities via the monthly IACUC meeting minutes and via recurring weekly meetings with the DRIC, who is also an IACUC member.

9. **Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:**

   a. **Post-approval Monitoring**

      - All ongoing activities are monitored continuously by the animal care and use staff.

      - The UM IACUC Post-Approval Monitoring Program ensures that research and teaching activities involving live vertebrate animals are conducted in accordance with regulations and are consistent with the IACUC-approved protocol and amendments.

      - Post approval monitoring may occur in the form of a comprehensive site visit,

routine animal care staff inspections, and with the annual update form submitted by PIs. Protocols are subject to post-approval monitoring site visits according to selection criteria below.

- The post-approval monitoring procedures include the following steps:

  i. Monitor(s) – Monitor(s) will be IACUC members or persons designated by the IACUC.

  ii. Protocol Selection – Protocols will be selected for monitoring based on PI history and/or protocol type. For example:

  - PIs with past compliance issues.
  - Multiple Survival Surgery (MSS) protocols.
  - Pain category D protocols.
  - Species requiring satellite housing, i.e., field station.
  - Recommendations from Animal Care Staff (ACS).

- Pre-Review – To ensure monitors have a thorough understanding of the study before the review meeting, they will pre-review the protocol and amendments using the Post-Approval Monitoring Checklist, formulate additional questions, and highlight areas of interest.
- Notification of PI – IACUC staff may notify the PI approximately 1 month in advance that one or more of their protocols will be reviewed. IACUC staff will call the PI or PI's designee to answer any questions and schedule the review. Other protocol research personnel and student assistants should make every attempt to participate in the review along with the PI.
- Protocol Review – The protocol review will be conducted in the PI's office, laboratory or accessible conference room using the Post-Approval Monitoring Checklist and protocol records.
- Report of Findings - If necessary, corrective action and timelines will be discussed with the PI at the time of the review. A report including findings, recommendations for improvement, action to be taken, and/or follow-up procedures (as necessary) will be submitted to the IACUC for review during a convened IACUC meeting. The PI will receive a copy of the final report, which will be filed in the corresponding protocol folder(s).

b. **Continuing / Periodic Protocol Review**

- Protocols for USDA Covered Species are reviewed by a member or members of the IACUC at least annually.
- As part of annual review of protocols for USDA Covered Species, PIs submit a Protocol Annual Update Form. This form follows up on the same areas covered in the Protocol Application Form (e.g., numbers of animals obtained, pain category, unanticipated problems, humane endpoints reached, alternatives, 3

Rs, and planned changes to the protocol).

- Protocols for non-USDA Covered Species are administratively monitored at least annually.
- As part of annual update of protocols for non-USDA Covered Species, PIs submit an abbreviated Protocol Annual Update Form. This form follows up on the numbers of animals used and any unanticipated problems.
- Annual protocol reviews for USDA Covered Species are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.
- Protocols for both USDA-covered species and non-USDA covered species are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.
- If ongoing activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.

10. **Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:**

    a. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.

    b. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

    c. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Assurance, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, in writing, to OLAW. Preliminary reports may be made verbally.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

    1. **Administration/management**.

        a. Overall management of the Occupational Health and Safety Program (OHSP) for Personnel involved in the care and/or use of laboratory animals resides with the Director, Research Integrity & Compliance (DRIC).

        b. Key roles in the Program are covered by the Laboratory Services Department, the

AV, and the Employee Health Physician – who serves as the Occupational Health Professional involved in planning and monitoring the Program.

2. **Scope.**
    a. The OHSP covers all personnel who are involved in animal care and/or use.
    b. Research personnel are enrolled in the OHSP by being listed on a Protocol Application (or in a Personnel Amendment to the Application).
    c. Animal care staff are enrolled upon hire.
3. **Health Histories / Evaluations and Risk Assessments.**
    a. Health histories, completed by all research and animal care personnel, are used to identify current health status. They are used in conjunction with an OHSP Risk Inventory that identifies potential hazards that individuals will be exposed to.
    b. The Occupational Health Professional conducts a medical evaluation of risks by reviewing both of these forms.
    c. The collection, review, and confidentiality protection of the health information meets all applicable laws and regulations, including HIPAA.
    d. All animal care workers are given a physical by the employee health physician when hired.
    e. The IACUC Office receives the notification from the employee health physician indicating that an individual is cleared to work with animals.
4. **Hazard Identification and Risk Assessment.**
    a. The OHSP is based on hazard identification and risk assessment.
    b. Hazard identification: Hazards are identified in three ways:
        - in the original protocol by the PI;
        - on an OHSP Risk Inventory that is filled out by each individual listed on a protocol; and
        - by review by the AV – who modifies the OHSP Risk Inventory to include any additional hazards and risks.
    c. The process for risk assessment lies with the Occupational Health Professional who analyzes potential hazards and risks on the OHSP Risk Inventory in conjunction with the confidential health history to form recommendations for minimizing risks to individuals' health.
    d. A new health history must be completed whenever the individual's health status or risks change, and a reminder of this is listed on each protocol annual update.
5. **Procedures in Place to Alleviate Hazards and Minimize Risks.**
    a. The primary engineering control is the use of negative air flow pressure in all

animal colony and procedure rooms

b. Most animals are housed in filter-top cages.

c. Biological safety hoods are in the BSL2 biological hazard suite and in several procedure rooms.

d. A down-draft bedding disposal station is employed when dumping bedding.

e. Institutional policies mandate health and safety training to make individuals aware of risks and how to avoid or minimize risks.

f. The UM Laboratory Services Department schedules and maintains safety training in biological, pathogen, and chemical, radiological materials and ionizing radiation producing devices on the Oxford Campus. These training requirements apply to faculty, staff, graduate and undergraduate students when they are working in these areas in an animal study protocol, as well as visiting investigators working with these materials under the supervision of trained University personnel on the campus.

g. All persons are required to read and sign a document on laboratory animal allergies.

h. Each PI is responsible for ensuring all personnel listed on or added to an IACUC-approved study obtain safety-related training before beginning work with research animals.

i. Personnel Training [regarding zoonoses, chemical safety, physical hazards, allergies, handling of waste materials, precautions taken during pregnancy, illness or immune suppression] – Species specific training is required for each individual listed on a protocol. All personnel are required to complete pertinent training courses in chemical, biological, pathogen, and radiation safety conducted by the Laboratory Services Department.

j. PPE such as gloves, masks, safety eyewear are provided by the PI based on recommendations from the Occupational Health Professional. Facility personnel are provided with masks, gloves and other PPE and instructed on appropriate use. Animal care personnel wear proper PPE when dumping bedding material.

k. Lab coats and facility-dedicated footwear or shoe covers are required for all persons entering the animal facility. Hand-washing facilities are located throughout the animal facilities and signs emphasizing the importance of this procedure are posted in many locations. Showers are available. Eating and drinking are not allowed in animal activity areas.

6. **Immunizations.**

a. Under the institution’s Occupational Health Program, tetanus vaccinations are strongly recommended for all personnel who have not been vaccinated in the previous 10 years.

b. Tetanus vaccinations are paid for by UM and administered by the Student Health

Center.

7. **Precautions taken during pregnancy, illness or decreased immunocompetence.**

   During training, all personnel involved in animal care are advised that if they or any of their staff become pregnant, ill, or have decreased immunocompetence, they should consult with their primary care provider and avoid contact with potential hazards until they obtain this medical advice.

8. **Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.**

   a. Personnel involved in building maintenance or security who must enter areas where animals are housed or where personnel use or store biohazardous materials or biological waste must:

      - read and sign off on an Asthma and Allergy in Animal Handlers information page, and
      - complete a biological safety training course and pass a written test on biological safety awareness.

   b. No housekeeping personnel are permitted in any animal areas or research laboratories.

   c. PPE is available to visitors, including vendors and maintenance personnel, and they are provided with a cursory briefing and, if warranted, escorted through the facilities.

9. **Availability and procedures for treatment of bites, scratches, illness or injury.**

   a. In the event of bites, scratches, illness, or injury, personnel are made aware of and use first aid kits, emergency showers, and eye wash stations as needed.

   b. If injuries are minor and occur during the working day, personnel are examined at the Employee Health Center.

   c. If injuries are minor and occur when the health center is closed, personnel may go to the minor emergency clinic on campus or to another provider of their choice.

   d. Serious injuries trigger 911 calls and/or transport to the local hospital.

10. **Procedures/program for reporting and tracking injuries and illnesses.**

    a. Employees and student workers injured on the job notify their direct supervisor or department head when an injury occurs.

    b. The department has 48 hours from date of injury to complete the Workers' Compensation Injury Report Packet and submit to the Department of Human Resources.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals by species, in each facility is provided in Part X., Facility and Species Inventory.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

1. **IACUC Members**

   a. Each IACUC member will be provided with a copy of or information on and electronic access to, each of the following:

      - The PHS Policy on the Humane Care and Use of Laboratory Animals;
      - The NRC Guide for the Care and Use of Laboratory Animals;
      - The ARENA/OLAW IACUC Guidebook;
      - The AVMA's Guidelines for the Euthanasia of Animals; and
      - UM's OLAW current PHS Assurance.

   b. All members of the IACUC will complete the Essentials for IACUC Members Course through the CITI online training program.

   c. IACUC members are required to complete the "Semiannual Program Review and Facility Inspection unit within the Animal Research Oversight Course (AROC) through PRIM&R. Prior to each semiannual inspection and program review, IACUC members receive refresher materials and previous reports to assist with conduct of these activities.

   d. Seminars, Workshops and Conferences – Members are informed about and provided the opportunity to participate in seminars, workshops, conferences or other training and education sessions throughout the year, including those sponsored by Vicon Publishing Inc.'s Audio/Web, AALAS, National Council of University Research Administrators, OLAW, USDA, Public Responsibility in Medicine and Research, AAALAC, etc.

2. **Animal Care and Use Personnel**

   a. This Assurance is posted on our website under guidance so that all personnel involved in animal care and use have access to its contents.

   b. All personnel performing procedures using animals must be identified in the corresponding protocol(s).

   c. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be available for IACUC review.

   d. Any person needing additional protocol-specific training will be identified during the review process and such required training will be required for approval of the protocol.

   e. Web-based training modules and examinations are a primary training vehicle for principal investigators, research and teaching staff, and students involved in research or teaching utilizing animals on campus. These modules are used to

ensure a basic standard of training and familiarization with applicable animal care and use principles and laws. Principal investigators using species other than those covered by the training modules must describe their applicable experience and/or training on the animal use protocol and are responsible for training all staff and students participating in the project.

- The module *Working with the IACUC* is a required training tool based on familiarization with the principles and practices in the Animal Welfare Act and the Guide. All personnel must complete this basic training module. This module includes training in the following areas:

  i. The intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations and PHS Policy;

  ii. Minimizing animal numbers;

  iii. Limiting animal pain and distress;

  iv. Alternatives to the use of live animals in research to prevent unintended and unnecessary duplication of research involving animals;

  v. Personnel Safety;

  vi. Procedures such as surgery and blood collection;

  vii. Special considerations related to animal welfare; and

  viii. Reporting concerns.

- Completion of other web-based training modules is required as appropriate for the study under consideration. These modules include: Minimizing Pain and Distress; Aseptic Surgery; Working with Animals in Biomedical Research - Refresher Course; and species-specific modules for animals under study.

- Successful completion of a web-based examination for each training module is required to certify appropriate training.

f. All persons involved in animal care and use will be encouraged to attend an orientation seminar given by the IACUC Chair, AV, or other qualified individual(s), which covers the ethics, laws, and regulations covering laboratory animal care and use with an emphasis on the contents of the Guide and the 3Rs. The training includes the importance of employing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).

g. Training in experimental methods, i.e., specific animal manipulations and techniques, will be conducted based on the types of research being conducted at the institution. PIs will sometimes ask the AV to train them and their research personnel on a procedure specific to their animal study. The AV keeps track of all training activities and provides that information to the IACUC office. This training is included in the monthly Training and Education Report to the IACUC.

h. Documentation of Training - Research personnel, IACUC members and administrative staff receive notice of instructions to access the training courses by the IACUC Office. The RCS/designee track progress in completing mandatory training.

i. Educational Materials Distribution – In addition to the above, the Animal Resources Office and the IACUC Office staff maintain online mailing lists of all IACUC members, principal investigators, department heads, technicians, and project personnel working with animals. Educational materials are distributed and the online mailing list groups are notified periodically of web-based educational materials. Particular attention is given to alternatives and refinement resources (i.e. computer-based training modules, simulations, new online databases, and so forth).

IV. Institutional Program Evaluation and Accreditation

A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS PolicyIV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the IO. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

B. This Institution is Category 1 — accredited by the AAALAC. As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

A. This Institution will maintain for at least three years:

1. A copy of this Assurance and any modifications made to it, as approved by the PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Joseph R. Gladden.
5. Records of accrediting body determinations.

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the

duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. The Institutional reporting period is October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW by December 1 of each year. 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).
2. Any change in the description of the Institution's program for animal care and use as described in this Assurance.
3. Any change in the IACUC membership.
4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Joseph R. Gladden.
5. Any minority views filed by members of the IACUC.

B. 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.

C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Dr. Joseph R. Gladden	
Title: Vice Chancellor for Research and Sponsored Programs	
Name of Institution: The University of Mississippi	
Address: (street, city, state, country, postal code) 100 Barr Hall, P.O. Box 1848 University, MS 38677	
Phone: 662-915-7482	Fax: 662-915-7577
E-mail: jgladden@olemiss.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: Jul 30, 2021

B. PHS Approving Official (to be completed by OLAW)	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: July 2021			
Name of Institution: The University of Mississippi			
Assurance Number: D16-00232			
IACUC Chairperson			
Name*: Mandy King			
Title*: Director, Research Integrity and Compliance		Degree/Credentials*: M.S., CPIA	
Address*: (street, city, state, zip code) The University of Mississippi 215 Barr Hall University, MS 38677			
E-mail*: mlking9@olemiss.edu			
Phone*: 662-915-5458		Fax*: 662-915-7577	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Harry C. Fyke	D.V.M.	Attending Veterinarian	Veterinarian
Member 3	Ph.D., Zoology	Associate Professor of Biology	Scientist
Member 4		Assistant Director of Maintenance Services	Non-voting
Member 5	Ph.D., Medical Neuroscience	Assistant Professor of Pharmacology and Research Assistant Professor in the Research Institute of Pharmaceutical Sciences	Scientist
Member 6	Ph.D., Pharmacy	Associate Professor of Pharmaceutics and Drug Delivery and Research Associate Professor in the Research Institute of Pharmaceutical Sciences	Scientist
Member 7		Vacant, replacement search underway	
Member 8		Vacant, replacement search underway	
Member 9	M.L.S., Library Science	County Librarian-Retired	Nonscientist and Non-affiliated member

Member 10	B.S., General Studies	Research Compliance Specialist II	Non-scientist
Member 11	B.A., Chemistry	Research and Environmental Compliance	Scientist

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission 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	A 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	A practicing scientist experienced in research involving animals.
Nonscientist	A member whose primary concerns are in a nonscientific area In evaluating the qualifications of an individual to serve as a nonscientific member, the CEO should consider appointing those with a naïve attitude with regard to science and scientific activities. A person without scientific training meets the Policy's intent, such as an ethicist, lawyer, or member of the clergy, as the Policy gives as examples. Some other examples include librarians, those working in business or finance, or instructors in English, history, or other liberal arts disciplines. When the rationale for categorizing an individual as a nonscientist is not apparent based on their occupation or training, the institution should maintain written documentation of the reason for the categorization
Nonaffiliated	The nonaffiliated member must represent the general community interests in the proper care and use of animals. The nonaffiliated member must not be (1) a laboratory animal user or former user, (2) affiliated with the institution, or (3) an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling. In evaluating the qualifications of an individual to serve as a nonaffiliated member, the CEO should confirm the appointee has no discernible ties or ongoing affiliation with the institution. Regarding service of former employees or students as nonaffiliated members, the appointing official must be assured that the person is not in any way obligated to the institution. Real or perceived conflicts of interest must be avoided to ensure the IACUC's and the institution's integrity. Appointment of an individual who is unambiguously unaffiliated is the most effective way to fulfill the intent of the Policy

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.

IX. Other Key Contacts (optional)

Contact #1	
Name: Mandy King	
Title: Director, Research Integrity and Compliance	
Phone: 662-915-5458	E-mail: mlking9@olemiss.edu
Contact #2	
Name: Miranda Core	
Title: Research Compliance Specialist II	
Phone: 662-915-5006	E-mail: iacuc@olemiss.edu

X. Facility and Species Inventory

Date: July 2021			
Name of Institution: The University of Mississippi			
Assurance Number: D16-00232			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
Vivarium	10,000	Rats	42
		Mice	1959
		Rabbits	7
Faser Aquatic Facility	3350	Zebrafish	4000
Biology/ Shoemaker	250	Zebra Finch	200
UM Field Station	500	Wild caught birds (blue birds, house finches, tufted titmouse, American robin, Carolina chickadee, American goldfinch, Pine siskin)	40

Unless otherwise indicated, mice and rats means mice of the genus *Mus* and rats of the genus *Rattu*s that are purposely bred for research.