

Animal Welfare Assurance for Domestic Institutions

I, Frank Einhellig, PhD, as named Institutional Official (IO) for animal care and use at Missouri State University, 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

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 the PHS. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

Missouri State University – Springfield, MO (main campus)
Missouri State University – Mountain Grove campus
Missouri State University – West Plains campus
Missouri State University – Darr Agricultural Center
Missouri State University – Bull Shoals Field Station
Missouri State University – Shealy Farm
Missouri State University – Journagan Ranch
Missouri State University – Baker's Acres
Missouri State University – Jordan Valley Innovation Center

- B. The following are other institution(s), or branches and components of another institution:

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 (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (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 the PHS Policy are as follows:

See Attachment A – Program Administration flow chart

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

- 1) Name: Michael Stafford, DVM

Qualifications

- Degrees:
 - BS, Biochemistry, University of Missouri (1984)
 - DVM, University of Missouri (1989)
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Attending Veterinarian for Missouri State University for ten years. Veterinarian for American National Fish and Wildlife Museum, Dickerson Park Zoo, and Cardin Circus. Contract services to the University of Missouri College of Agriculture, Missouri Department of Conservation, Springfield Greene County Health Department, and Bass Pro Shops. Background includes specific experience with small rodents, hoofstock, reptiles, amphibians, birds, fish, aquatic mammals, and primates at the above institutions.

Authority: Dr. Stafford has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

5-20 hours per week with 100% effort dedicated to the animal care and use program.

- 2) Name: Lacy (Hobbs) Sukovaty

Qualifications

- Degrees:
 - B.S. Animal Science, Missouri State University (2004)
 - DVM, University of Missouri (2008)
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Private, mixed animal practitioner for 11 years. Background includes specific experience with hoofstock, small rodents, lagomorphs, dogs, cats, and birds, including poultry.

Responsibilities:

Dr. Sukovaty is currently serving as an alternative veterinarian who will attend IACUC meetings and fill in during the absence of the Attending Veterinarian.

Time contributed to program:

0-5% time contributed to the animal care and use program, dependent upon availability of the Attending Veterinarian, Michael Stafford.

- 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 IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

See Part VIII: Membership of the IACUC

- D. The IACUC will:

- 1) Review at least once every 6 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:
 - Review of institutional policies, standard operating procedures, and responsibilities
 - Review of semiannual facility inspections
 - Review of veterinary care
 - Review of institutional training and occupational health and safety programs

The IACUC will utilize the *Sample Semiannual Review Checklist* resource recommended by the Office of Laboratory Animal Welfare (OLAW) in conjunction with the *Guide* as a basis for program evaluation. They also use the OLAW Sample Semiannual Report to the IO to ensure that the reports are complete and meet the informational requirements of the PHS Policy and the AWARs and Guide.

Any IACUC-approved departures from the Guide or the PHS Policy or the Animal Welfare Act and Regulations (AWARs) will be included in the report along with the reasons for each requested and approved departure. Departures submitted by investigators to the IACUC are reviewed and approved by the IACUC.

Any deficiencies identified during the semiannual program review or facility inspections are identified as minor or significant. Additionally, for each deficiency, the report contains the plan for correction and correction schedule. The plan for correction identifies the parties responsible for ensuring the specific deficiency is corrected. In addition, the Office of Research Administration (ORA) monitors the status of corrections, assists the responsible parties when applicable, and reports the status of corrections to the IACUC and IO.

Written reports of the semiannual program review and facility inspection will be signed by a majority of the IACUC and submitted to the IO.

- 2) Inspect at least once every 6 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:

Inspections of the animal facilities and animals conducted by the IACUC are to adhere to all USDA and PHS guidelines. The inspections are conducted by at least two IACUC members and a veterinarian (the IACUC veterinarian can fulfill both the IACUC member role and veterinarian role). However, all IACUC members are welcomed and encouraged to participate in the inspection. In addition, a representative from the ORA is encouraged to attend. The IACUC utilizes the *Sample Semiannual Facility Inspection Checklist* resource recommended by the Office of Laboratory Animal Welfare in conjunction with the *Guide* as a basis for inspection of the animal facilities.

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

- Semiannual Reports of Program Review & Facility Inspection

Through semiannual reports to the IO and open channels of communication, the IACUC informs the IO of the status of the program and alerts the IO to potential non-compliance. Reports are drafted by the Office of Research Administration (ORA), with the assistance of the IACUC Chair. The IACUC utilizes the *Sample Semiannual Review Checklist* resource recommended by the Office of Laboratory Animal Welfare (OLAW) in conjunction with the *Guide* as a basis for program evaluation. They also use the OLAW Sample Semiannual Report to the IO to ensure that the reports are complete and meet the informational requirements of the PHS Policy and the AWARs and Guide. IACUC members will be given the semi-annual report and allowed time to edit and approve the report. After approval and signage from the majority of IACUC members, the semi-annual report will be submitted to the IO for review.

- Departures from the PHS Policy & the Guide
Any IACUC-approved departures from the Guide or the PHS Policy or the Animal Welfare Act and Regulations (AWARs) will be included in the report along with the reasons for each requested and approved departure. Departures submitted by investigators to the IACUC are reviewed and approved by the IACUC.
- Deficiency Identification & Correction
Any deficiencies identified during the semiannual program review or facility inspections are identified as minor or significant. Additionally, for each deficiency, the report contains the plan for correction and correction schedule. The plan for correction identifies the parties responsible for ensuring the specific deficiency is corrected. In addition, the ORA monitors the status of corrections, assists the responsible parties when applicable, and reports the status of corrections to the IACUC and IO.

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

The IACUC takes seriously concerns regarding the care and use of animals at the institution whether staff, employees, members of the IACUC, or individuals in the community raise these concerns.

When an employee or student identifies a concern about a suspected compliance issue, he/she is encouraged to make a report to his/her immediate supervisor, or an appropriate University official. If, however, a student or employee is uncomfortable discussing concerns with a University official, the University has made available a third-party anonymous hotline service, provided by EthicsPoint. An individual may submit a report through this hotline service: Via telephone, call 1-888-233-8988 (toll free) or Via internet, <http://www.missouristate.edu/internalaudit/Ethics%20Hotline.htm>.

Missouri State University has an established Whistleblower Policy in place. In addition, the University utilizes "Ethicspoint," an online reporting system for individuals to anonymously report compliance violations. Every lab and animal facility posts a sign informing individuals about how to report a concern. The sign states the following:

NOTIFICATION OF ANIMAL ABUSE

Persons suspecting that activities being conducted in the University or by University personnel are not in compliance with the USDA Animal Welfare Act and the PHS Policy on Humane Care and Use of Laboratory Animals and are to report their concerns to the Institutional Animal Care and Use Committee. In accordance with applicable laws and implementing regulations, whistleblower protection will be afforded to these persons reporting suspicion of violations.

*Written reports should be submitted to Carrington 405
or emailed to: IACUC@missouristate.edu.*

The IACUC will investigate the validity of all complaints. This will include inspection of the applicable animal facilities and research or educational sites, discussions with the supervisor and other involved personnel, and further discussion with the person submitting the allegation. The Attending Veterinarian will advise a supervisor to make corrections in a timely manner where the facilities or practices are determined to be significantly deficient, defined as *a threat to animal health or safety*.

All reported concerns and investigations will be reviewed by the IACUC and any necessary actions will be voted on by a quorum of IACUC members. Outcomes of the vote with recommendations for discipline or correction will be forwarded to the IO. A formal report will be drafted by the IACUC and submitted to the IO.

Written notification of the findings of the complaint will be filed with the supervisor of the research or educational activity, that person's supervisor, the Dean of the Academic College, the IO, and the ORA. Where required under applicable federal laws and implementing regulations, the IO will report violations to the agency sponsoring such activities.

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

The IO relies on the IACUC to oversee the program, to develop plans to correct program deficiencies, to address concerns that may arise regarding the institution's use of animals, and to make recommendations with regard to the program. All recommendations regarding aspects of Missouri State University's animal program will be drafted by the Office of Research Administration, with the assistance of the IACUC Chair. Once drafted, the document(s) will be distributed to the IACUC members for review and approval. After the majority of members have approved the document(s), it will be delivered to the IO. Once approved, the necessary changes and updates will be included in the Animal Care and Use Manual/Veterinary Care Program.

- 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:

Receipt & Pre-Review

Procedures for submitting protocols should follow the current Missouri State University Animal Care and Use Manual.

Protocols (including attachments and supplemental forms) must be submitted to the ORA through the MSU online submission system, LabTracks or via email to ORA. The link to LabTracks as well as supplemental forms can be found on the ORA website. The most current version of the supplemental forms should be used.

Submissions must be sent 2 weeks prior to the IACUC meeting for proper pre-review. Meeting dates and deadlines can be found on the ORA website. Only submissions received 2 weeks prior to the IACUC meeting will be guaranteed review at the IACUC meeting. To assure timely approval, it is also recommended that researchers obtain any necessary veterinarian consultation or statistician review prior to the 2 week deadline.

Once submissions are received, the ORA will notify the IACUC Chair and Veterinarian for pre-review. In consultation, the Chair, Veterinarian, and ORA personnel will determine if the submission requires significant revision or can be considered further. Once approved for further consideration, the ORA will distribute the submission to all members of the IACUC.

Types of Review

- **Full Committee Review (FCR)**
Full Committee Review occurs during a convened meeting of a quorum of the IACUC members, and with a formal vote. Full IACUC review results in approval, a requirement for modifications (to secure approval), or withholding of approval. A majority vote of the members present at a convened meeting is required to approve, require modifications in (to secure approval), or withhold approval. When using the FCR method, polling each member individually in lieu of a convened quorum is not allowed.
- **Designated Member Review (DMR)**
Designated Member Review is utilized only after all members have been provided the opportunity to call for a FCR by notifying the Chair or ORA. Members are given at least 3 business days to call for a FCR. If any member requests a FCR, then the FCR method will be used. If not, the IACUC Chair may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer. DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. Designated Review may not result in withholding of approval. If more than one designated reviewer is appointed to a protocol, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers, then the other reviewers must be aware of and agree with modifications.

The MSU IACUC may conduct reviews by DMR subsequent to FCR. 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 DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- **Expedited Protocol Review**
All protocols are reviewed through the processes listed in III.D.6. – Full committee or designated member review. Where special, time sensitive circumstances arise, i.e., seasonal availability of animals, grant funding deadlines, etc., the two week pre-review submission deadline may be waived. However, protocols must still be reviewed by FCR or DMR.
- **Veterinary Verification and Consultation (VVC)**
Certain categories of significant changes described, below, may be handled administratively according to IACUC-reviewed and approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting Designated Member Review, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. These include changes in:
 - anesthesia, analgesia, sedation, or experimental substances;
 - euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
 - duration, frequency, type, or number of procedures performed on an animal.
 - an increase in previously approved animal numbers

Results of Review

- **Approval**
The IACUC is authorized to approve protocols using FCR or DMR. Once a protocol has been approved, the ORA will send out an approval letter, generated by LabTracks, to the submitting PI and listed e-mail contacts.
- **Modifications Required**

The IACUC may require modifications (to secure approval) during the initial review process. The IACUC Chair or ORA will communicate to the submitting PI through LabTracks and/or e-mail if modifications to secure approval are necessary. All revisions should be resubmitted through LabTracks. Once the final protocol has been approved by FCR or DMR, the ORA will send out an approval letter, generated by LabTracks, to the submitting PI and listed e-mail contacts.

- **Tabled**
If significant questions regarding animal use or protocol procedures arise during project review and cannot be resolved by the IACUC reviewers or during the course of discussion at a meeting, the IACUC may choose to table the protocol until the next convened meeting, pending additional information from the principal investigator, or from an outside consultant or reviewer. Tabled protocols and their responses and/or modifications must be re-reviewed at a fully convened meeting.
- **No IACUC Approval Required**
Certain animal related activities may not require IACUC approval and oversight, such as when animal tissues or fluids used in a study are obtained from historical samples instead of from a live animal. However, it is IACUC's responsibility to determine the need for IACUC oversight, not the researcher. Therefore, all activities involving animals, animal specimens, etc., must be reviewed and approved by the IACUC prior to starting any such activities. In addition, while IACUC approval may not be required, certain training requirements and enrollment in the OHSP may still be required.
- **Withholding of Approval**
If the IACUC decides to withhold approval of an activity, the PI will receive written notification of the reasons for its decision and gives the PI an opportunity to respond in writing or the PI is asked to attend a convened meeting of the IACUC.

The specific method of review for a given protocol is documented along with the outcome of the review in the IACUC meeting minutes.

Conflict of Interest (COI)

No IACUC member shall participate in the IACUC review or approval of an application or proposal in which the member of has a real or apparent conflict of interest except to provide information requested by the IACUC. The IACUC member with the real or apparent COI must recuse themselves from voting and may not contribute to the quorum requirements for the specific application.

- 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:

Changes in ongoing, previously approved research or teaching activities involving animals may not be initiated without obtaining IACUC approval. The PI is responsible for submitting a request for prior approval of a modification prior to implementation. Amendments should be submitted using the current Missouri State University procedures for submitting protocols. The review procedures used for significant changes are the same as those stated in number six of this Assurance. Examples of changes considered to be significant include changes:

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

Amendments that are not considered to be significant may be administratively approved by the IACUC Chair or the ORA. Changes that are considered to be not significant include:

- Date extension, not to exceed three years from original approval date.
 - Date extension must be reviewed by FCR or DMR if the original protocol had been designated for a certain approval period due to IACUC discussed stipulations (e.g., a pilot study having an original IACUC approval time period of 6 months due to the need for additional oversight).
- Changes in personnel other than the principal investigator
 - Personnel must be properly trained and qualified, enrolled in applicable occupational health and safety programs, and meet any other criteria as required by the IACUC

- 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:

The specific method of review for a given protocol is documented along with the outcome of the review in the IACUC meeting minutes. A copy of each meeting minutes are provided to the IO.

Approval

The IACUC is authorized to approve protocols using FCR or DMR. Once a protocol has been approved, the ORA will send out an approval letter, generated by LabTracks, to the submitting PI and listed e-mail contacts.

Modifications Required

The IACUC may require modifications (to secure approval) during the initial review process. The IACUC Chair or ORA will communicate to the submitting PI through LabTracks and/or e-mail if modifications to secure approval are necessary. All revisions should be resubmitted through LabTracks. Once the final protocol has been approved by FCR or DMR, the ORA will send out an approval letter, generated by LabTracks, to the submitting PI and listed e-mail contacts.

Withholding of Approval

If the IACUC decides to withhold approval of an activity, the PI will receive written notification of the reasons for its decision and gives the PI an opportunity to respond in writing or the PI is asked to attend a convened meeting of the IACUC.

- 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 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC will conduct continuing reviews of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. In accordance with USDA regulations, approved protocols covered by USDA regulations are reviewed annually. In year one and year two it is required that renewal applications be submitted to the IACUC for FCR or DMR as described in III.D.6. In year three, a de novo application is required and is handled in the same manner as a new protocol application as described in III.D.6.

Annual Reviews

The IACUC protocol approval date is used to determine the month in which the protocol is due for review. The PI is sent a reminder along with an annual review form via email

approximately 30 days before the application needs to be reviewed. Upon receipt of the annual review to the ORA, a designee of the IACUC Chair reviews and makes recommendations for approval before the expiration date. Investigators may be asked to clarify or update certain information about the protocol.

If the investigator fails to submit an annual review, or fails to respond to requests for additional information, the protocol approval will terminate on the expiration date. If a protocol expires, research may no longer be conducted under that protocol. Maintaining, acquiring or using animals under an expired protocol approval places the University out of compliance with federal regulations and guidelines.

Post Approval Monitoring (PAM)

The purpose of a post-approval monitoring (PAM) program is to work with investigators to facilitate their animal research and to be proactive in identifying potential problems in compliance with active IACUC approved protocols, with an emphasis on education and training.

Post approval monitoring of IACUC-approved protocols is achieved through several different mechanisms including: the Attending Veterinarian's observation of research and teaching procedures, IACUC semi-annual inspections, annual reviews as stated in the above section, and inspections completed by the ORA personnel. In addition, the ORA also conducts periodic meetings with investigators to review and discuss ongoing research activities to maintain regulatory compliance throughout the life of active protocols.

Specific benefits of this PAM program:

- A mechanism for documenting compliance with applicable animal care and use policies, guidelines, and laws
- An opportunity for dialogue, education, and exchange of information between individuals conducting research and teaching involving animals and the IACUC/ORA
- Assistance to investigators preparing for visits by outside evaluators

- 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:

Suspension of Activities

In order to deal promptly with conditions that may jeopardize the health or well-being of animals, the Attending Veterinarian and/or IACUC Chair is authorized to halt procedures that he/she believes do not comply with institutional policies until the IACUC can be convened and consider the matter formally.

The IACUC may suspend a protocol 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. The IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action to any federal agency based on requirements. A decision by the IACUC to suspend an activity may be appealed. Research may not continue on a protocol that has been suspended by the IACUC, even if during the appeal process. In the event of an appeal, the IACUC Chair will report the IACUC vote to the IO and the ORA, who will consult with the IACUC regarding the suspension. The IO will take appropriate corrective action based on the appeal decision and a full report of that post-appeal action with an explanation will be made to the Office of Laboratory Animal Welfare (OLAW) as required. However, only when the IACUC is satisfied that problems leading to a suspension have been corrected will that suspension be lifted. A suspension is lifted after a majority vote of the quorum present at an IACUC meeting.

Remediation

The supervisor of the cited activity will submit a report to the IACUC for review. On-site inspections also may be conducted by the IACUC. If corrective measures are found to restore compliance, written notification will be submitted to all involved parties.

- 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:

Purpose

The OHSP is intended to provide University personnel with a safe work place and provide information that will enable compliance with the SOP. The ORA administers the OHSP with the assistance of Magers Health and Wellness Center.

Required Enrollment

All persons (covered person), including faculty, staff, students, and volunteers, who will be working with or have a reasonable expectation of exposure to animal tissues, fluids, secretions and/or excretions (collectively referred to as "exposure to animals") while involved in research and/or education projects at on or off-campus locations are required to enroll in the OHSP. In addition, non-employees (e.g., visiting researchers and educators) are required to enroll in the MSU OHSP or provide certification that they are participants in a similar program at their home institution.

Purpose

The OHSP is intended to provide University personnel with a safe work place and provide information that will enable compliance with the SOP. The ORA administers the OHSP with the assistance of Magers Health and Wellness Center.

Required Enrollment

All persons (covered person), including faculty, staff, students, and volunteers, who will be working with or have a reasonable expectation of exposure to animal tissues, fluids, secretions and/or excretions (collectively referred to as "exposure to animals") while involved in research and/or education projects at on or off-campus locations are required to enroll in the OHSP. In addition, non-employees (e.g., visiting researchers and educators) are required to enroll in the MSU OHSP or provide certification that they are participants in a similar program at their home institution.

Enrollment Process

1. Initial Enrollment

a. *Risk Assessment Form*

A Risk Assessment Form will be completed by the supervisor of covered person and covered person. The form will be signed by the covered person, PI or manager/supervisor and submitted to the ORA. The ORA will then enroll the covered person into the program. Based on the level of exposure, health and vaccination history of the covered person, the ORA may require the covered person to schedule a Medical Risk Assessment through Magers Health and Wellness Center. Persons can request a waiver of participation in the completion of the Medical Risk Assessment. Such a request must be approved by his/her supervisor, the medical professional at Magers Health and Wellness Center and the ORA. Approval of waiving participation will be based on the relative risk of potential exposure to zoonotic diseases (transferable between animals and humans) and other hazards associated with the intended involvement with animals, and the apparent health of the participant. A waiver will not be permitted for completion of applicable training programs and the use of personal protective equipment (PPE).

b. *Medical Risk Assessment*

Depending on the level of exposure recorded and health of the participant, the ORA may require the person to schedule a Medical Risk Assessment through Magers Health and Wellness Center. The risk assessment will involve review of the covered person's medical history (e.g. allergies to animals), duties that may result in exposure to animals or other hazards, and the need for vaccinations required as protection against specific hazards. The health professional will also provide the person with information on the potential hazards related to their

involvement with animals and extra precautions necessary to be taken during periods of illness or pregnancy. All screening charges and any prophylactic vaccinations (with consent of person) will be paid for by the ORA. Tetanus vaccination and/or prophylaxis is offered to the employees at the recommendation of the health professional. A record that the assessment took place will be forwarded to the ORA. These records may contain protected health information (PHI) and be maintained in accordance with the Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA).

c. Additional Information

The ORA will provide a listing of sources and information related to all the identified hazards associated with current animal/facility activities to Magers Health and Wellness Center, supervisors, and covered persons. The supervisor is responsible for instructing the worker of the required training programs, procedures, and PPE intended to minimize the assessed risks, as well as assure the prescribed health and safety precautions will be implemented. Records of hands-on training must be documented and kept on file by the supervisor in order to be reviewed by the IACUC and/or ORA at any time requested.

2. Annual Renewal of Enrollment

Each year the person covered is required to renew enrollment in the OHSP by filling out a new Risk Assessment for Animal Contact Form (provided by the ORA). If the person's duties or health status have changed since their last enrollment, depending on the new associated risk(s), the ORA may require the person to schedule a Medical Risk Assessment through Magers Health and Wellness Center.

A. Other Components of the OHSP

1. Surveillance Measures

- a. The ORA, Magers Health and Wellness, and the IACUC may recommend surveillance measures that are to be undertaken for activities that use species known to have zoonotic diseases. It will be the responsibility of the Supervisor to implement these measures. Inspections by the IACUC and the ORA, as described elsewhere, will include review of these surveillance measures.
- b. There are a number of personal hygiene issues which apply to all workers who are exposed to animals. These include:
 - There should be no eating, drinking, smoking or applying of cosmetics in areas where animals are housed or used.
 - Appropriate personal protective equipment must be worn when working with animals but should be removed before leaving the facility.
 - Careful hand washing should be done after handling of animals.
 - Certain infections are transmitted from animals to humans primarily by contaminating hands with animal feces or urine and then putting contaminated objects into the mouth. Examples of organisms utilizing this mode of transmission are *Salmonella spp.* and *Cryptosporidium*. Every precaution should be taken to avoid this mode of transmission by alertness and careful personal hygiene. Additional health problems are encountered when these organisms are carried home and children/infants are exposed.
 - Appropriate personal protective equipment, in addition to the standard components outlined above, will be documented and described in individual laboratory standard operating procedures. These SOPs will be reviewed by the IACUC and ORA.

2. Injury or Illness

a. Injury or Illness Coverage

Injuries or illnesses resulting from involvement with research and educational activities approved in accordance with the University Policy are covered as listed:

- Faculty, staff, and student employees will be covered by Workers' Compensation.

- Students not employed by the University will be covered by their personal health insurance.
- Visiting researchers and educators participating in projects as part of their employment by external organizations will be covered by their employer's insurance or their personal health insurance.

b. Injury or Illness Reporting

Individuals should contact Magers Health and Wellness Center at any time for medical review and consultation if the individual becomes injured, feels that an allergy may be developing, or have other health concerns related to animal research exposure. In the event Magers Health and Wellness Center is unavailable (e.g., after hours, field study emergency, etc.), the nearest medical facility with services applicable to take care of the injury should be utilized. In the event that an individual suffers an injury (such as an animal bite) or is exposed to a hazardous biological or chemical agent during the course of a project, medical treatment or assistance will always be the first priority. However, the supervisor and ORA must be notified as soon as possible.

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

See 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:

General Training Program

- Online training will be provided that includes an overview of the federal laws and implementing regulations, and the University Policy and SOP. This training also includes information regarding the humane practices of animal care and use, research and testing methods that minimize or eliminate the use of animals or limit animal pain or distress, and utilization of electronic and published information sources that could prevent the unintended duplication of animal experimentation or improve the methods of animal experimentation.
- Completion of this training program will be required of all persons involved in the care and use of animals.
- Online refresher training is required every three years to ensure that covered persons understand applicable laws, regulations, and policies.

Survival Surgery Training

- Online training for survival surgery of rodents and pain category E procedures of mice and rats is required. The online training focuses on reducing pain and distress in mice and rats.
- Survival surgery training for other organisms other than mice and rats will be determined on a case by case basis and reviewed by the IACUC.
- Completion of training is required for all persons who are to be involved with animals that will undergo surgical procedures and survive for educational and research activities.
- A certificate of completion will be submitted with applications of research activities covered by the policy.

Laboratory Procedures

Principal investigators conducting educational and research activities involving animals are responsible for providing their staff and students with laboratory-specific training on particular hazards associated with their activities, as well as procedures and equipment to be used to reduce risks (e.g. personal protective equipment). Staff and students may be exposed to hazards, including zoonotic diseases (transferable between animals and humans), bites and scratches, etc. These persons also may be exposed to hazardous biological and chemical

substances that are used as part of these activities. No faculty, student or staff member is allowed to work unsupervised in a position in which they are exposed to risks as described above, handle or are exposed to hazardous materials or wastes, or are involved in spill response until they have received the required laboratory specific training. All lab specific training must be documented by each principal investigator.

Training of IACUC and Other Responsible Officials

To assure that the University Policy is in compliance with this policy, and that the SOP is effective and efficient, members of the IACUC and the responsible units will participate in training programs offered by the federal agencies, and other national organizations recognized for their leadership in matters related to animal care and use.

- Initial Training – All members of the IACUC will undergo training prior to being involved in decision making by the committee. This training will include completion of online training specific to IACUC members. The following materials will also be provided:
 - Animal Welfare Act
 - USDA Regulations – 9 CFR Chapter 1
 - PHS Policy on Humane Care & Use of Laboratory Animals
 - US Government Principles for the Care & Use of Animals Used in Testing, Research, & Education
 - University's Animal Care & Use Policy
 - University's Standard Operating Procedures for Implementation of the University's Policy (Missouri State University Animal Care & Use Manual)
 - University's approved Animal Welfare Assurance
 - *Guide for the Care & Use of Laboratory Animals*
 - *Occupational Health & Safety in the Care & Use of Research Animals*
 - *Guidelines for the Care & Use of Mammals in Neuroscience & Behavioral Research*
- Follow-Up Training - Members of the IACUC will participate as possible in relevant training programs offered by PRIMR/ARENA or other organizations. The University attendees will provide a review of the materials covered in these training programs for members of the IACUC, as well as other University officials having responsibilities under the Animal Care and Use Policy.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.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 Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category 2 — not accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 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. Frank Einhellig.
 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 3 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 the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 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. Frank Einhellig.
 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: Frank Einhellig, PhD	
Title: Provost	
Name of Institution: Missouri State University	
Address: <i>(street, city, state, country, postal code)</i> 901 South National Avenue Springfield, MO 65897-0027	
Phone: (417) 836-5119	Fax: (417) 836-8432
E-mail: frankeinhellig@missouristate.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:

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
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) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: 07/15/2019			
Name of Institution: Missouri State University			
Assurance Number: A3057-01			
IACUC Chairperson			
Name*: Brian Greene			
Title*: Professor, Biology			Degree/Credentials*: PhD
Address*: (street, city, state, zip code)			
901 South National Avenue Springfield, MO 65897-0027			
E-mail*: briangreene@missouristate.edu			
Phone*: (417) 836-6379			Fax*: (417) 836-4204
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Michael Stafford	DVM	Attending Veterinarian	V
Lacy Hobbs	DVM	Alternate Veterinarian	V, S (alternate)
Wayne Mitchell	PhD	Professor, Psychology	S
Gary Webb	PhD	Professor/Dept. Head, Animal Science	S
Johnna Pedersen	MNAS	Senior Research Scientist/Biosafety Officer	S
Chris Craig	EdD, EdS, MEd	Deputy Provost	NS
Harold Bengsch	MS	Greene County Commissioner	NA
Jianjie Wang	PhD	Associate Professor	S

* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	Practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	Member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	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.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name:	Rachel McGinnis
Title:	Director, Research Administration
Phone:	(417) 836-3194
E-mail:	rachelmcginnis@missouristate.edu
Contact #2	
Name:	James Baker, PhD
Title:	Vice President, Research and Economic Development
Phone:	(417) 836-8501
E-mail:	jbaker@missouristate.edu

X. Facility and Species Inventory

[illegible]

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

