

Animal Welfare Assurance for Domestic Institutions

I, Michael F. Malone as named Institutional Official for animal care and use at University of Massachusetts Amherst 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 PHS, DHHS, and/or NSF. 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:

The University of Massachusetts Amherst including all Institutional/Amherst campus departments and off-campus facilities that use live vertebrate animals in teaching, training, and research activities.

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

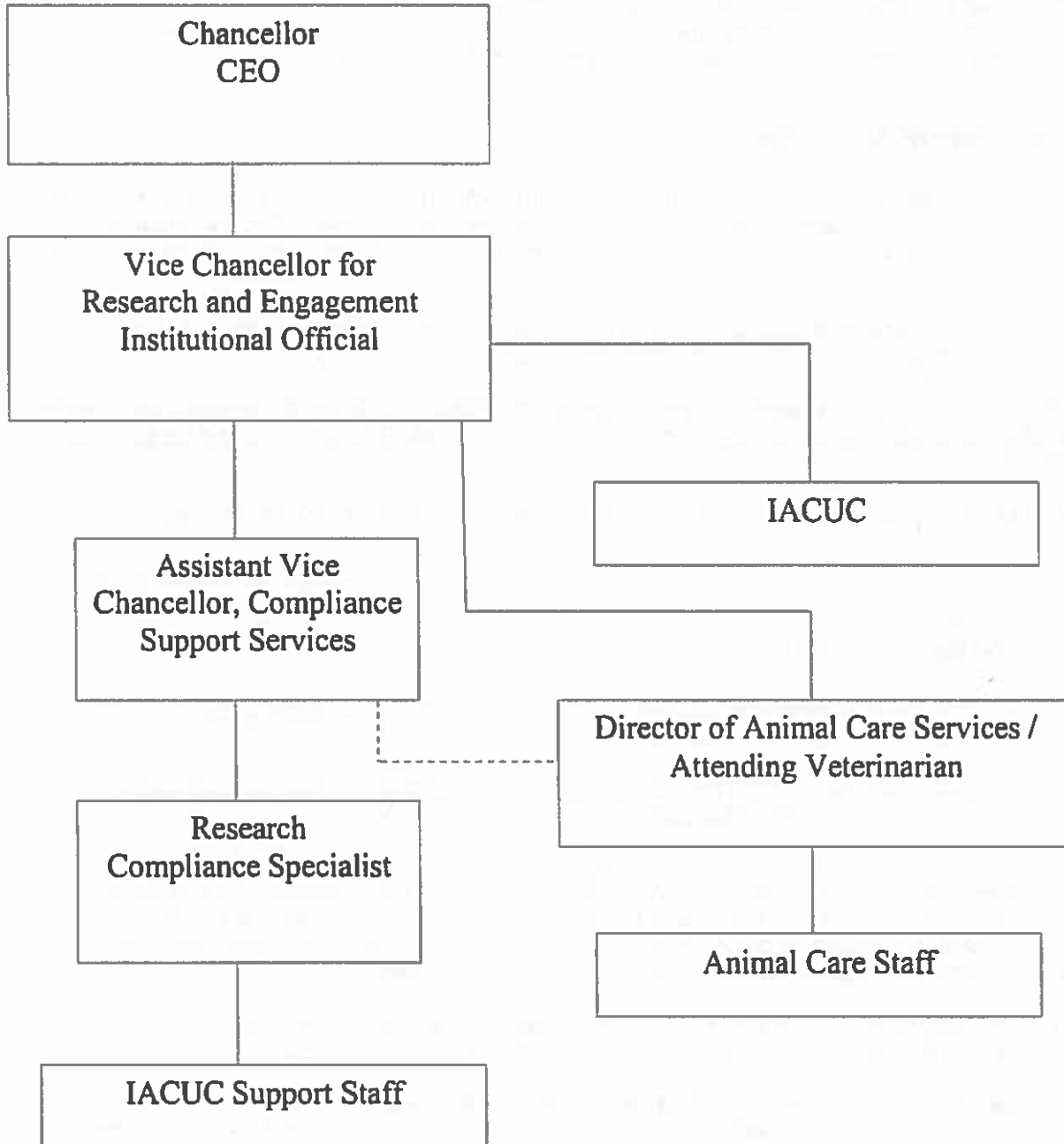
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II. Institutional Commitment

- 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:



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

1) Name: Dr. Jimmie Paul Spurlock

Qualifications

- **Degrees:**
Doctor of Veterinary Medicine and Master of Public Health
- **Training or experience in laboratory animal medicine or in the use of the species at the institution:**
Dr. Spurlock is a graduate of the Louisiana State School of Veterinary Medicine. He has 25 years of experience in Laboratory Animal Medicine.

Authority: Dr. Spurlock has direct program authority and responsibility for the Institution's animal care and use program and responsibility for the implementation of the PHS Policy and the recommendations of the *Guide*. Dr. Spurlock has access to all animals.

Time contributed to program:

Dr. Spurlock is a full-time employee; he contributes 100% of his time to the Animal Care and Use Program.

2) Name: Dr. Joanne Huyler

Qualifications

- **Degrees:**
Doctor of Veterinary Medicine
- **Training or experience in laboratory animal medicine or in the use of the species at the institution:**
Dr. Huyler is a graduate of the Washington State University School of Veterinary Medicine and completed an AVMA Preceptorship in Laboratory Animal Medicine in 1994. She has 24 years of experience in Laboratory Animal Medicine and serves as a consulting veterinarian for multiple academic institutions.

Responsibilities:

As the institution's consulting veterinarian, Dr. Huyler has secondary program authority and responsibility for the implementation of the PHS Policy and the recommendations of the *Guide*.

Time contributed to program:

Dr. Huyler is a half-time employee and works 19 hours per week for the institution. She contributes 100% of those hours to the animal care and use program.

3) Name: Peg Piwonka

Qualifications

- **Degrees:**
Doctor of Veterinary Medicine, Masters in Epidemiology and certification in Veterinary acupuncture
- **Training or experience in laboratory animal medicine or in the use of the species at the institution:**
Dr. Piwonka has training in exotic animal medicine. She is a graduate of Cornell University College of Veterinary Medicine.

Responsibilities:

Dr. Piwonka provides clinical veterinary care. She serves as back-up veterinarian for the institution and is on call for veterinary emergencies.

Time contributed to program:

Dr. Piwonka is a local veterinarian with a private practice. She contributes 2% of her time to caring for animals at the institution.

4) Name: Dr. Carlos Gradil

Qualifications

- Degrees
 - Doctor of Veterinary Medicine, Ph.D., DACT
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - Dr. Gradil is a large animal veterinarian. He is a graduate of the University of Lisbon, Portugal College of Veterinary Medicine. He holds a Massachusetts license to practice veterinary medicine.

Responsibilities:

Dr. Gradil provides clinical veterinary care. He is a full-time member of the Department of Veterinary & Animal Sciences as Extension Associate Professor. Dr. Gradil has veterinary responsibility for horses housed at the UMass farms. Dr. Gradil is also the director of animal health and provides veterinary services for other UMass farm animals as needed.

Time contributed to program:

Dr. Gradil contributes 10% of his time to caring for research horses and other large animal health care at the institution's farms.

5) Name: Katherine Beltaire

Qualifications

- Degrees
 - Doctor of Veterinary Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - Dr. Beltaire is a large animal veterinarian. She is a graduate of the Tufts University School of Veterinary Medicine.

Responsibilities:

Dr. Beltaire provides clinical veterinary care. She is a full-time member of the Department of Veterinary & Animal Sciences as a faculty lecturer. Dr. Beltaire provides primary care for the UMass food animals.

Time contributed to program:

Dr. Beltaire is available to assist as backup veterinarian specializing in large animal species, but does not provide a set level of effort to the animal care and use program.

6) Name: Sharon McCutchen

Qualifications

- Degrees
 - Doctor of Veterinary Medicine

- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. McCutchen is a graduate of the University of Minnesota School of Veterinary Medicine. She has 20 years of experience in small animal medicine with a special interest in exotics.

Responsibilities: As a part-time clinical veterinarian, Dr. McCutchen provides clinical care as needed and serves as a back-up veterinarian to the program.

Time contributed to program:

Dr. McCutchen is a part-time clinical veterinarian and works approximately 4 hours per week for the institution. She contributes 100% of those hours to the clinical care of the animals at the institution.

- 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 in section VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

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:

A preliminary program review is conducted by an IACUC sub-committee consisting of all interested IACUC members. The sub-committee generally includes, at minimum, the IACUC Chair, IACUC Associate Chair, Attending Veterinarian/Director of Animal Care, Biosafety Officer, Consulting Veterinarian, and the Research Compliance Specialist. A sub-committee meeting is scheduled after semi-annual inspections are completed so that inspection results can be discussed in the context of the Program Review. Each participating member is provided with OLAW's Sample Review Checklists as a guide to ensure all program areas requiring review are covered, and other reference materials. Members refer to the *Guide* as basis for their evaluations. IACUC concerns and recommendations documented in past Reports are reviewed to determine how they were addressed, and whether IO or IACUC follow-up is needed. After the subcommittee has convened, notes from the meeting are drafted and sent to the full committee for review. The committee is informed that the formal program review will be conducted at the next full committee meeting. All members are invited to attend. The formal program review includes discussion of the committee's findings and recommendations and addresses issues including, but not limited to: Occupational Health & safety, Veterinary Care, PHS Policy/Animal Welfare Assurance, The Guide, Emergency Response Plan and the training program.

- 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:

An inspection schedule is drawn up to ensure all the facilities (on-campus animal facilities and satellites) are inspected within a four-week period. A satellite is any location where an animal is housed for more than 12 hours. Semi-annual inspection teams consist of at least two voting IACUC members. All members have the opportunity to participate in the inspections. Often more than two voting members participate. The IACUC does not

physically inspect remote locations where animals might be housed related to field studies, or sub-contracting institutions where animals are housed. However, the IACUC does ask that photographs are provided for review by the IACUC when appropriate. In addition, the IACUC is aware of the locations for field studies as well as the procedures that will be involved and ensures that the appropriate permits are in place as a part of the protocol review process. Inspectors are instructed to distinguish between significant and minor deficiencies. OLAW standard forms are used for recording inspection findings. A record is made for every animal room, service area and animal study/procedure areas whether or not a deficiency is found. Deficiencies are flagged as "minor" or "significant". The IACUC Coordinator completes an inspection worksheet for each facility, noting the correction plan, completion dates set for correction, and the correction date. She follows up to ensure that deficiencies are corrected on or before the completion date. This institution uses the *Guide* and OLAW's sample checklists and summary format as basic guidelines.

- 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:

Once the facilities inspections results and Program Review have been discussed by the IACUC a report from the IACUC to the IO is written using the OLAW Semiannual Report to the Institutional Official as a template. The report describes the date and outcome of the Semi-Annual Program Review and facilities inspections and provides correction plans with deadlines for correcting deficiencies. The report is forwarded to IACUC members for review and discussion at the next IACUC meeting. The final Report is generally signed by members present at an IACUC meeting. A majority of IACUC members sign the completed report. Minority views concerning the Report are included in the Report. Departures from the PHS Policy and the "Guide" identified through the inspections are included in the IACUC Semi-annual Report to the IO as well as IACUC approved departures along with reasons for each.

How the IACUC addresses the correction of deficiencies depends on the nature of the deficiency. Immediately after a significant deficiency has been identified by an inspection team the responsible party is notified of the deficiency with a plan for correction, and a deadline for correcting the deficiency. Significant deficiencies that could impact animal welfare must be addressed promptly and, if necessary, handled like the report of a complaint (see below) if they are not addressed promptly. Programmatic concerns are generally documented in the Report to the IO together with the IACUC's recommendations for addressing those concerns. The IACUC and IO work together to address programmatic deficiencies.

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

New animal users are informed of procedures for reporting concerns involving animal care and use and informed of "Whistle Blower" statutes. IACUC procedures for handling reports of concerns are posted on the IACUC web site. Often, an individual will choose not to make a formal complaint but will copy communications concerning problems to the Research Compliance Specialist who follows up with the individuals involved and, if she is either unable to resolve the problem promptly or the situation involves a serious animal welfare issue, she brings it to the IACUC Chair and Attending Veterinarian/Director of Animal Care.

In summary the process by which the IACUC follows up when it receives a report of a concern is the following:

- IACUC Chair or a Chair-appointed IACUC investigator looks into the complaint. An investigator reports back to the IACUC Chair within 24 hours.
 - When the IACUC Chair finds there is a basis for the complaint he immediately contacts the responsible person with a plan to correct the deficiency quickly.
 - Following the IACUC Chair's investigation of the complaint, if he does not consider there are any significant compliance issues that need addressing immediately, he reports the complaint at the next IACUC meeting for input from the full committee.
 - If the IACUC Chair finds the situation poses an immediate threat to the health or safety of the animals and the responsible person is not cooperative, he convenes a special IACUC meeting with quorum to discuss the problem and vote on actions to be taken to remedy the complaint. In the event the IACUC finds serious animal welfare issues that must be addressed immediately, the IACUC may vote to suspend the activity involving animals pending resolution of the problem (see item #10).
 - The IACUC will report serious animal welfare issues to the Institutional Official (IO); the IO may opt to take additional action beyond the scope of the IACUC's action.
 - OLAW, USDA, and Federal and/or private funding agencies are notified, as required by federal law or agreements with private funding agencies, of significant deficiencies and/or suspension, with a timetable for correction.
- 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:

Recommendations to the IO that are the outcome of the semi-annual inspections and program review are communicated to the IO via the Semi-annual Report. The procedure for making recommendations to the Institutional Official at other times is similar and via written recommendations from the IACUC to the IO. Justification and background information to support the recommendations are included in the letter.

- 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:

The IACUC meets monthly throughout the year to review protocols and discuss other business.

Protocol submission. Animal use protocols are submitted to the IACUC Office electronically. A tracking number is assigned. A protocol is generally pre-reviewed for completeness by IACUC staff before submission to the IACUC. Protocols must be received at least eight days prior to an IACUC meeting to be guaranteed inclusion on the agenda. Seven business days before an IACUC meeting copies of the protocols to be reviewed at the meeting are made available to each member via the electronic protocol management system or mail.

Protocol review. Reviews of protocols involving pain category D or E procedures are generally conducted at a convened IACUC meeting. All IACUC members receive notice of the meeting, and all members have access to the protocols to be reviewed. Review

discussion is recorded in written minutes maintained in accordance with the PHS Policy, IV.E.1.b.

As noted in the PHS Policy IV.2., IACUC members who are involved in the research project or have any other potential conflict of interest do not participate in the review of a protocol and leave the meeting for the discussion and voting. These individuals may not be part of the quorum voting on the submission. The conflict of interest is noted in the minutes of the meeting.

Full reviews. At least two IACUC reviewers, one of whom is also Presenter, are assigned to review the protocol. Full reviews are conducted at a convened IACUC meeting with a quorum present. The reviewers and the veterinarian present their reviews of the protocol to the members. Following discussion, a motion is voted on to either: "approve", "require modifications to secure approval", or "withhold approval". A voice vote is taken and the decision represents the majority vote. The outcome of the vote, dissenting votes, and abstentions are recorded in the minutes. Minority views are recorded.

Designated Review Subsequent to Full Committee Review. The committee previously agreed in writing that the quorum of members present at a convened IACUC meeting may decide by unanimous vote to use the designated review process subsequent to full committee review when modifications are required to secure approval. However, any member of the IACUC may call for full review at any time. After a unanimous vote by the committee to use the designated review process, the IACUC Chair appoints one or more voting members to serve as designated reviewers. The DRs submit questions and comments to the IACUC Coordinator for compilation and checking. Questions are then forwarded to the investigator to guide the revision of the protocol. The investigator addresses the DRs' comments by revising the protocol and the revised protocol is returned to the DRs for review to ensure their questions have been answered. Decisions made by DRs must be unanimous. DRs may "approve", "require modifications to secure approval", or "refer the protocol to the full committee for review." All DRs review identical versions of the protocol and submit responses to the IACUC Coordinator. In the event that one of the DRs requests modifications, all other reviewers are made aware and must review the newly revised protocol and submit a response to the IACUC Coordinator. This holds true even in the case when a DR has recommended approval in a previous review cycle. Designated review may not result in withholding of approval. If DRs are unable to be unanimous in a protocol decision, the protocol is returned to the full committee.

Designated reviews. The IACUC may use the Designated Review (DR) process to review protocols and amendments to protocols. Generally protocols that are reviewed by DR are those involving non-invasive procedures in pain/distress categories B and C, or protocols where the only change to a previously-approved protocol is change in PI. Designated review is conducted as follows: the protocol is made available electronically to all IACUC members to review and record a vote for designated or full review. A single member calling for full review sends the protocol to full review. Members have four days to record their vote. After four days if no vote for full review is received the review continues electronically using designated reviewers. The IACUC Chair has instructed IACUC staff to always assign the Consulting Veterinarian and the IACUC Chair as DRs unless they have a conflict of interest in which case the Associate Chair replaces the Chair and the Attending Veterinarian replaces the Consulting Veterinarian. The IACUC Chair may assign additional IACUC members as DRs. The review process proceeds as described above for "Designated Review Subsequent to Full Committee Review" with the same possible outcomes.

Expedited reviews. The IACUC does not recognize “expedited review” as a review category. However, on occasion an investigator has a compelling reason to request the IACUC expedite the review of a protocol. In that case, the IACUC Coordinator may submit the protocol to the IACUC with the request they consider conducting the review by DR and shorten the voting for DR decision time to a period that is less than four days. She will simultaneously suggest the default reviewers for a DR (IACUC Chair and Consulting Veterinarian) submit pre-reviews prior to the review decision being finalized. IACUC members may respond to a request for a shortened DR decision period by either voting for full review or DR, or requesting the full four day period to reach a review level decision. No response from a member within the decision period suggested is tacit agreement for DR. If a request for full review is received the review is put on the agenda for the next convened IACUC meeting and the PI notified of the decision.

- 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:

An amendment to the protocol must be submitted for IACUC review when a significant change to the approved animal use is planned. Significant changes that must be approved by the IACUC before any of the new animal use include, but are not limited to:

- Changes in objectives
- Changing from survival to non-survival surgery and vice versa.
- Changes in anesthesia, doses or the method of administering anesthetics.
- Changes in the use of analgesics.
- Changes in the use of sedatives and tranquilizers.
- Changes in methods of euthanasia.
- Changes in the species used.
- Changes in procedures and/or the duration of a procedure and/or the frequency of a procedure. Changes in the invasiveness of a procedure.
- Changes in housing and husbandry.
- Changes in animal numbers such that the total number of animals to be used is expected to exceed the approved total by more than 10%.

The PI edits the protocol and submits the amended version for IACUC review. The electronic protocol form flags changes and new material, and notifies IACUC members automatically via email that an amended protocol has been received for review.

The decision-making process to determine whether an amendment to a protocol is handled via full or designated review is the same as for a new protocol submission, and the review process for an amendment recording significant changes is handled in the same way as described in Section III.D.6 above.

A change in personnel, other than the PI, can be handled administratively. When change in personnel is the only change, IACUC Office processes this change in the electronic protocol management system by using administrative review. The protocol is assigned the Research Compliance Specialist or the IACUC Coordinator. The addition is approved once the

IACUC Office staff has verified that the new person is adequately trained and qualified and is participating in the animal users Occupational Health Program.

Minor changes to a protocol are submitted and reviewed in the same way as changes in personnel. Examples of minor changes are:

- Less than a 10% increase in the number of animals to be used for a previously approved procedure
- Change in source or strain of animals to be used
- Change in transportation or shipping arrangements
- Changes in room location within the animal facility

The electronic protocol management system maintains the history of the protocol including reviewers' comments, PI responses, records of amendment and annual reviews, and all versions of the protocol. The most recent version of a protocol is always the active version.

- 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:

Notice of approval: The electronic protocol management system, eprotocol, notifies an investigator via email when a protocol, amendment to a protocol, or annual review has been approved and the approval letter is published as a .pdf file in the PI's eprotocol record. The PI and IACUC Office staff have access to the letter on file and may print a hard copy of the approval letter as needed, e.g., by the UMass Amherst Office of Grants and Contracts (OGCA) if the project is funded through extramural funding. The IACUC Chair does not normally sign the approval letter as the electronic system records his and the attending veterinarian's votes to approve the protocol.

The letter includes the principal investigator's full name, the title of the protocol, the date of approval, the period of approval (three years' maximum for a protocol). The expiration date is always shown as one year from the date of the current approval because continuation of the approval at the end of the first two years is subject to annual review by the IACUC.

Notice of a tabled review: When the IACUC votes to table the review of a protocol the eprotocol system generates a brief automatic notice of the decision to the PI. The IACUC Chair follows up with a letter detailing the reasons for the decision to table the review and the IACUC's recommendations to the PI for revising and resubmitting the protocol.

Notice a protocol is not approved: When the IACUC votes to not approve a protocol the PI receives an automatic notice of the decision via email from the eprotocol system. The IACUC Chair follows up with a letter detailing the reasons for the decision not to approve the protocol.

Notification of the Institutional Official of protocol review decisions: Monthly the IACUC office forwards IACUC minutes plus the IACUC office's monthly reports that include documentation of protocol approvals to the IO.

- 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:

All researchers submit an Annual Renewal before the first and second anniversaries of the protocol's original approval date documenting the number of animals used, and providing an updated personnel list. Protocol renewals are sent out electronically to all IACUC members and members are given the opportunity to review and record a vote for designated or full review. Designated or full review of protocol renewals are conducted as described in Section III.D.6 above. The annual report form reminds PIs that they need IACUC approval before making changes to the protocol. The IACUC Office staff checks animal use reported against totals approved in the protocol, and verifies that all personnel listed on the protocol have current IACUC animal user training certification and are participating in the Occupational Health Program for animal users. Post-approval monitoring related to procedures is done by the Research Compliance Specialist, Animal Care Managers and Attending Veterinarian who check medical and surgical records regularly to ensure surgery and use of pharmaceuticals is as described in the protocol. A description of the post-approval monitoring system is available on the university website located at: <http://www.umass.edu/research/policy/post-approval-monitoring>

On the third anniversary of a protocol's approval the protocol approval expires. If the PI wishes to continue a project described in the expiring protocol he/she submits a new protocol. The IACUC review process for a 'renewal protocol' is the same as for a new protocol. If the third anniversary of the approval passes without the IACUC having approved a new protocol no further use of the animals as described in the expired protocol is allowed. Animals covered by an expired protocol are transferred to the Director of Animal Care's holding protocol pending approval of a new protocol.

- 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 decision to suspend an approved activity using animals requires a majority vote at a convened IACUC meeting. If necessary, an emergency meeting of the IACUC is convened. Criteria and timelines for resolution of the matter are recorded in the minutes along with the outcome of the vote to suspend and any minority views. A written statement of the IACUC's decision is sent to the PI by the IACUC Chair (or his/her designee) and the IO. The IO reviews the reasons for the suspension and the actions the IACUC requires of the PI to have the suspension lifted. He provides a preliminary written report to OLAW. The IO may impose additional conditions for lifting the suspension. If animal use is suspended by the IACUC because of a significant animal welfare concern, following correction of the deficiency, and before the suspension is lifted, the PI must provide a plan in writing to the IACUC for preventing the deficiency from recurring. Once the suspension has been lifted the IO sends a final report to OLAW describing the reason(s) for the suspension and measures that were taken to address the problem.

The IACUC is authorized to deny investigators with a history or pattern of non-compliance, or who are recalcitrant in following the *Guide*, the Animal Welfare Act and/or the direction of the IACUC and/or the attending veterinarian, the right to have animals for research or teaching purposes. This step is executed by the IO after consultation with the IACUC Chair, the appropriate University Dean, and the PI's Department Head.

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:
The occupational health and safety program for animal users at this institution is a collaborative program involving:

1. *The Office of the Vice Chancellor for Research and Engagement.* This office manages IACUC review, training new personnel regarding the occupational health program (OHP), collecting OHP forms from new animal users, and interfacing with OH personnel at University Health Services (UHS) to ensure their recommended precautions are followed.
2. *Laboratory Safety personnel in Environmental Health & Safety.* EH&S staff provide training in safe laboratory practices, waste management, and safe use of hazardous materials, and inspect equipment, laboratories and facilities to ensure the work environment is safe and use and disposal of hazardous agents is appropriate. They also provide respirator fit testing.
3. *Health care providers at University Health Services.* UHS occupational health personnel review the proposed use of animals in the context of an individual's personal health history, ensure any necessary health-related precautions are taken prior to working with animals, and provide follow-up services as needed once the animal use starts. This is accomplished by individuals completing a health history form, checking off the species they are working with and the type of work they will be doing and submitting vaccination records. Individuals complete this information on paper and place in a sealed envelope to go to UHS, or submit the information through an online portal. All information is handled as confidential HIPAA data and only reviewed by medical professionals who are trained in handling PHI (personal health information). Any vaccinations, including tetanus are offered if they are needed.

Covered personnel are all full-time, part-time, and temporary employees, students and contractors of the University of Massachusetts Amherst who have contact, in terms of physical proximity or handling animals in the course of their employment for research, teaching or testing purposes.

Hazard identification and risk assessment. The PI lists hazardous agents to be used in the study in the animal use protocol. The Biosafety Officer, or his/her designee, reviews each protocol for the Risk Level to personnel. A health history is reviewed by Occupational Health Services (OHS) personnel in University Health Services in the context of the proposed animal use for each person listed on the protocol. The IACUC may refuse approval to work with animals for individuals whose risk of injury or disease related to the proposed animal use is unacceptably high, or individuals who refuse to take precautions recommended by UHS (vaccinations, use of PPE etc.).

Personnel training regarding zoonoses, chemical safety, physical hazards, allergies, handling of waste materials, precautions taken during pregnancy, illness or immune suppression.

- 1) *The basic training provided by IACUC staff.* This training is required for all new animal users and includes discussion of occupational health issues including risks from zoonotic diseases, allergies, physical hazards, and how pregnancy and other health conditions may increase risk.

Safety personnel in the Department of Environmental Health and Safety (EH&S) provide training on Chemical Safety, Waste Handling, and other topics through:

2) *Laboratory Health and Safety Seminar.* The two-hour seminar is given by EH&S safety staff and covers Laboratory Safety and Hazardous Waste Management. Employees who work in laboratories and animal care must take a refresher online laboratory safety training at least annually to maintain their training certification.

Laboratory Safety Training covers:

- The UMass Laboratory Health and Safety Plan.
- The Massachusetts Right to Know Law,
- How to read SDS forms.
- Basic toxicology including routes of entry and occupational exposure limits.
- Physical and health hazards of hazardous chemicals.
- Information on safety equipment and personal protective equipment.
- Proper use of fume hoods.
- Laboratory inspections.
- Emergency awareness.

Hazardous Waste Training includes:

- Federal and state Requirements for point of generation collection.
- Management and disposal of hazardous waste.

2) *Radiation Safety Training.* This is provided by EH&S Radiation Safety staff and is required for all personnel using radiologicals. It includes:

- Classroom training covering general radiation safety, RAM use, x-ray analytical equipment use, and laser use.
- Hands-on training in the laboratory under the direction of an experienced RAM user.
- Follow-up observation by radiation safety staff to ensure users have a complete understanding of safe use of RAM.

A description of the Laboratory Safety policies, procedures and guidelines are contained in the Laboratory Health and Safety Manual at <http://www.ehs.umass.edu>. This document includes policies, procedures and guidelines for personal hygiene, handling hazardous agents, and personnel protection.

Personal hygiene

All employees and students working in animal facilities are instructed to:

- Keep hands away from mouth, nose and eyes.
- Not eat, smoke, drink, prepare food, change contact lenses or apply cosmetics in the facility.
- Use appropriate PPE (including protective gloves, and scrubs or a lab coat).
- Wash hands after animal contact and before leaving the facility.
- Remove gloves and wash hands after handling animals, carcasses, or tissues derived from them before leaving the facility.
- Decontaminate work surfaces after spills and when procedures are completed.

Facilities, procedures, and monitoring.

Ensuring the safety of personnel in animal facilities is shared between the Departments of Animal Care and Environmental Health & Safety (EH&S). Washing facilities and eyewash stations appropriate to the animal use are provided in animal facilities. An ergonomics expert in EH&S provides advice on ergonomically sound operations to reduce the risk of physical injury. Safety equipment like biosafety cabinets and hoods are routinely tested and calibrated by EH&S personnel. A variety of animal housing and equipment is available in animal facilities as appropriate for the needs of the study and protecting personnel, including dump stations for cage changes, ventilated racks, microisolator cages, and biosafety cabinets. ABSL3 laboratory space was added in the summer of 2013 when CDC approved registration of BSL3 within renovated vivarium space. In 2018, new non-animal BSL3 facilities will come on line. In 2018, an additional ABSL3 facility will be added.

Animal experimentation involving hazards.

Safety personnel in EH&S complement the IACUC's new users' training with training in recommended procedures (see p. 11). For safe use of biohazardous agents they refer to the different biosafety levels as described in *Biosafety in Microbiological and Biomedical Laboratories 5th Edition* to determine the equipment and precautions needed to protect personnel. Personnel working with, or potentially exposed to, biological hazards in the context of their animal use, including zoonotic agents, take a classroom training with the Biosafety Program Manager in addition to the laboratory safety trainings listed above. The biohazards class is followed by project-specific hands-on training in the laboratory/facility provided by EH&S biosafety personnel. IACUC approval for the person to start the project is withheld until the Safety Officer in EH&S is satisfied the person is competent in the safety procedures, including, as needed:

- Safe practices at the appropriate biosafety level (BL2, BL2+, and BL3 as defined in *Biosafety in Microbiological and Biomedical Laboratories 5th Edition*).
- Working in a biosafety cabinet.
- Use of PPE appropriate for the project and the person's health status, and how to wear it (including respirator fitting and test as necessary).
- Project-specific procedures for disinfecting and cleaning up spills, and reporting spills and exposures.
- All personnel are instructed to report changes in their health status (e.g. pregnancy, illness or immune suppression). Review of changes, with OHP personnel in UHS, will determine whether the person needs to take additional precautions against exposure to hazards or to stop working with animals.

Personal protective equipment (PPE).

Basic PPE (shoe covers, gloves, disposable lab coats, masks) must be worn in all animal facilities and disposable PPE is available at the entrance to an animal facility with a container for discarded PPE. Face shields and arm protecting gloves are also provided to personnel exposed to non-human primates.

Medical evaluation and preventive medicine for personnel.

Participation in the institution's Occupational Health and Safety Program (OHSP) is required for all animal users and animal care staff. A new animal user completes a form documenting the

species he/she will be working with and completes a health history questionnaire. Both forms are reviewed by OHS personnel in University Health Services who contact the new user if there are special precautions the person needs to take prior to starting work with animals. Precautions include: tetanus shots for all animal users and other vaccinations as needed. If the OHS nurse identifies other precautions the person needs to take she contacts them directly. Special precautions for personnel working with nonhuman primates (NHPs) include TB screening annually, education regarding Herpes B virus, and training and special procedures for bites and scratches.

Reporting and treating injuries

Injuries are seen promptly by a health care professional at University Health Services (UHS). After being seen at UHS the injured employee completes and returns an accident report form to the Animal Care Office.

In the event of injury (e.g. bite, scratch that breaks the skin, needle puncture) from a non-human primate the following procedures are followed:

- Seek assistance. Make sure that any person assisting wears gloves to prevent transmission of infection.
- Clean the injured area thoroughly with a 10% bleach solution (9 parts of water with 1 part of household bleach). Scrub the affected area vigorously with betadine, soak the wound for at least 15 minutes then rinse with fresh water.
- Notify the PI and the Animal Care Office about the injury and identify the NHP that inflicted a bite or scratch.
- Get the injury checked promptly at UHS or a local hospital. UHS emergency care staff start antiviral treatment.
- Complete an accident report form and return it to the Animal Care Office.

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.

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

Laboratory Safety and biohazards training for researchers is described in section E. Animal technicians receive the same training and, in addition, hands-on and facility-specific training for new animal care staff provided by the Animal Care Managers. Training for animal care staff is ongoing via monthly seminars given by the Attending Veterinarian/Director of Animal Care.

Before starting to work with live animals, staff, students and investigators at the institution are all required to attend a classroom training provided by the Research Compliance Specialist or IACUC Coordinator. The training session may also include sections taught by Animal Care Service Staff. In addition they must take online training components via the CITI training website. The online training requirement includes the "Working with the IACUC" course as well as applicable species-specific courses. In addition, any individuals who will be performing

surgery must take the "Aseptic Surgery" course. Training certification must be renewed every three years for the "Working with the IACUC" course. New animal user training includes discussion of the 3Rs and the need to justify animal numbers. The IACUC reviewers work with the PI if it is evident that he/she has not understood how to estimate and justify numbers needed. The new users' training also includes "searching for alternatives" to minimize pain and distress and USDA's brochure "Alternatives and the Animal Welfare Act" is included in the package of materials provided to new PIs through the IACUC Office.

Topics covered include:

Working with the IACUC

The Veterinary Consultation

Alternatives

Avoiding Unnecessary Duplication

USDA Pain/Distress Categories

Refinement, Replacement, Reduction (including examples)

Surgery

Collecting Blood Samples

Housing Social Animals

Euthanasia

Making changes to protocols

The Occupational Health and Safety Program

Reporting Misuse, Mistreatment, or Non-compliance

In addition, animal users receive project-specific training from a member of the laboratory staff with appropriate experience and, as needed, the Attending Veterinarian for projects involving anesthesia, surgery and/or the need for pain relief. How project-specific training will be provided is described in the protocol and approved by the IACUC. Project-specific training includes all procedures including surgery, post-surgery care, and record-keeping for surgery and post-op monitoring, and maintaining medical records for the animal(s). The attending veterinarian monitors the performance of surgery and other invasive procedures and provides ongoing training as needed.

IACUC Members and Coordinators

Training for new IACUC members is provided through the CITI online IACUC Member training. The online training for IACUC members must be refreshed every three years. Topics covered include:

Responsibilities of the IACUC and IACUC Members

The Members of the IACUC

The IACUC, the CEO, and the IO

Authority of the IACUC

The Types of Protocol Reviews and Review Procedures

Documenting IACUC Actions

Semi-Annual Evaluations - Facility Inspections and Program Review

Correcting Deficiencies

Investigating Allegations of Improper Animal Care or Use.

In addition, new IACUC members are provided with a resource packet which includes among other resources: a copy of the Guide for the Care and Use of Laboratory Animals, a copy of the Animal Welfare Act and Animal Welfare Regulations, and OLAW's Public Health Service Policy on Humane Care and Use of Laboratory Animals. A new IACUC member is not assigned a review until they have attended at least two meetings.

IACUC coordinators and other IACUC support staff take the training required for animal care staff, researchers and IACUC members. Additional training required will depend on the person's level of prior experience in IACUC administration. An IACUC Coordinator hired with minimal experience in IACUC administration attends the first available IACUC 101 in addition to receiving hands-on training provided by the Research Compliance Specialist.

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.

- (1) 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, Michael F. Malone, Vice Chancellor for Research and Engagement.
 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, Vice Chancellor for Research and Engagement, Michael F. Malone.
 - 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: Michael F. Malone

Title: Vice Chancellor for Research and Engagement

Name of Institution: University of Massachusetts Amherst

Address:

362 Whitmore Administration Building
181 President's Drive
Amherst MA 01003

Phone: 413-545-5270

Fax: 413-577-0007

E-mail: vcrc@umass.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: 10/17/2018

B. PHS Approving Official (to be completed by OLAW)

Venita B. Thornton, DVM, MPH
Senior Assurance Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500 - MSC 6910
Bethesda, Maryland 20892
Email: thorntov@od.nih.gov
Phone: (301) 451-4208
Fax: (301) 480-3421

Venita B. Thornton -S Digitally signed by Venita B. Thornton -S
Date: 2018.10.25 10:41:45 -04'00'

Signature: _____ Date: **October 25, 2018**

Assurance Number: **D16-00337 (A3551-01)**

Effective Date: **October 25, 2018** Expiration Date: **October 31, 2022**

VIII. Membership of the IACUC

Date: May 8, 2018			
Name of Institution: University of Massachusetts Amherst			
Assurance Number: D16-00337			
IACUC Chairperson			
Name*: Jesse Mager			
Title*: Associate Professor		Degree/Credentials*: Ph.D.	
Address*: 427M Integrated Sciences Building 661 North Pleasant St. University of Massachusetts Amherst Amherst, MA 01003			
E-mail*: jmager@vascd.umass.edu			
Phone*: 413-545-7368		Fax*: 413-545-6326	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
1-BN	B.S., RLATG	Research Compliance Specialist	Scientist
2-SL	Ph.D.	Professor	Scientist
3-KN2	LICSW	Social Worker	Nonaffiliated
4-KI	D.V.M.	Clinical Veterinarian	Veterinarian
5-NL	Ph.D., D.V.M.	Adjunct Faculty	Non-voting
6-BM	Ph.D.	Associate Professor	Scientist
8-SO	B.S.	Capital Project Manager	Nonscientist
9-HA	Ph.D.	Assistant Professor	Scientist
10-J. Paul Spurlock	D.V.M.	Attending Veterinarian/Director, Animal Care	Veterinarian
11-LE	Ph.D.	Research Assistant Professor	Scientist
12-BS	Ph.D.	Senior Lecturer	Scientist
13-QT	Ph.D.	Research Associate Professor	Scientist
14-NZ	M.S.	IACUC Coordinator	Non-voting

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

Scientist practicing scientist experienced in research involving animals.

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

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

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

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: Jen Donals	
Title: Assistant Vice Chancellor Compliance Support Services	
Phone: 413-545-5896	E-mail: jdonals@research.umass.edu
Contact #2	
Name: Allison Miller	
Title: Research Compliance Specialist	
Phone: 413-545-5204	E-mail: amiller@research.umass.edu