

Animal Welfare Assurance for Domestic Institutions

I, **Dr. Robert Lindquist**, as named Institutional Official for animal care and use at the **University of Alabama in Huntsville**, 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 Public Health Service (PHS), National Science Foundation (NSF), and/or the National Aeronautics and Space Administration (NASA). (For consistency and efficiency, the UAH IACUC also applies the same procedures and policies and standards to projects funded by other means and/or other agencies). 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:

University of Alabama in Huntsville

College of Science
College of Engineering
College of Liberal Arts
College of Nursing

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

Not Applicable

II. Institutional Commitment

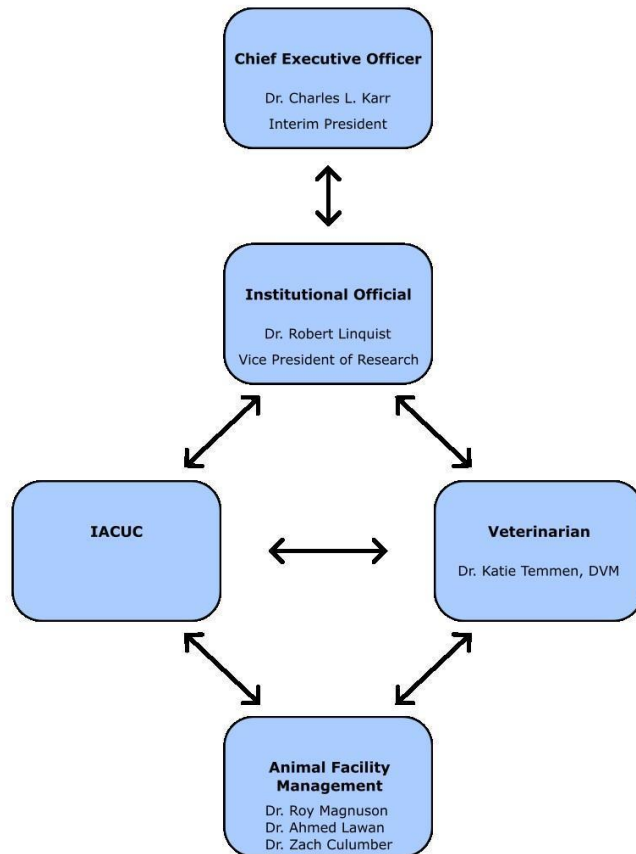
- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, 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:

The Institutional Official (IO) at UAH (Vice President of Research, Dr. Robert Lindquist) reports directly to the chief executive officer (Interim President Dr. Charles L. Karr). The chair of the IACUC (Dr. Roy Magnuson) reports directly to the Institutional Official on all matters pertaining to the animal care and use program and works with the Office of the Vice President for Research and Economic Development (OVPRED) for ensuring the proper execution of the responsibilities of the Committee. The chair of the IACUC sends semiannual reports to the Institutional Official. Any member of the IACUC can also submit a minority report for the institutional official. The veterinarian (Dr. Katie Burris Temmen, DVM, of Bentley Animal Hospital) is a member of the IACUC, and also communicates directly with the Institutional Official. The animal facility is directly supervised by the chair (Roy Magnuson) and the Vice-Chair of the IACUC (Dr. Ahmed Lawan). The fish rooms are supervised by an additional member of the IACUC (Dr. Zach Culumber).

Chart Showing Lines of Communication for Animal Care and Use at UAH



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. Katie Burris Temmen, DVM**

Qualifications

- Degrees:
 - DVM, 2016, Auburn University College of Veterinary Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - In addition to receiving formal education in veterinary medicine at Auburn University, Dr. Temmen became experienced with laboratory animal veterinary medicine via an externship in the animal research services department at the University of Alabama in

Birmingham under the tutelage of Dr. Samuel Cartner, DVM. Dr. Temmen currently serves as Associate Veterinarian at Bentley Animal Hospital in Huntsville, Alabama.

Authority: **Dr. Katie Burris Temmen, DVM** has **direct** program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Dr. Katie Burris Temmen, DVM, contributes an average of two hours per month to UAH, 100% of which is contributed to the Animal Care and Use Program. She is a Veterinarian at Bentley Animal Hospital, which has a contract to provide veterinary services to UAH. Additionally, when Dr. Temmen is not physically on-site, she is regularly available by phone or email to offer remote consultations to UAH faculty and members of the UAH IACUC.

2) Name: **Dr. Eric Hulsey, DVM** (Backup veterinarian)

Qualifications

- Degrees:
 - DVM, 1991, Auburn University College of Veterinary Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Hulsey received his degree from Auburn University in 1991. Dr. Hulsey has taken coursework in laboratory animal medicine and surgery and has been practicing small animal medicine and surgery for 16 years. He is Past-President of the Veterinary Medicine Association of Madison County and has served on the Board of Directors of the Animal Emergency Clinic of North Alabama. He has previously served on the UAH IACUC and is familiar with our program. He is the owner of Bentley Animal Hospital in Huntsville, Alabama, which has a contract to provide veterinary services to UAH.
- Responsibilities:

Dr. Hulsey serves as the backup veterinarian for UAH, offering consultation and emergency services to investigators, IACUC members, and the IO at UAH as necessary if Dr. Temmen is unavailable.

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 programs 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.

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. All IACUC members are invited to participate in the review and no IACUC member can be excluded from participation. The IACUC procedures for conducting semiannual program reviews are as follows:

The Semiannual program review is conducted as part of a comprehensive semiannual meeting. The typical conduct of the semiannual meeting, and of the semiannual review, is described below:

1. Scheduling of an IACUC meeting. A Tentative meeting time and date is proposed by the Chair and if a supermajority of the committee RSVP affirmatively then the time and date are confirmed, Alternatively, the process is repeated, until a suitable time and date are confirmed.

2. Preparation for an IACUC meeting. Before the meeting, the following items are circulated by the chair by email:

- a. Contact information for the Committee members and the IO.
- b. Links to the Guide and helpful Excerpts from the Guide.
- c. Pdfs of Proposals to be reviewed. Proposals are generally given a serial code and a short title, to minimize confusion.
- d. An Agenda for the meeting

3. The IACUC Meeting. The IACUC meeting contains the following elements:

a. Discussion of Membership. A welcome to any new committee members, a thanks to any departing members, and nominations for any future positions. This is usually moderated by the Chair.

b. Review of the Program. Areas of the animal program the IACUC evaluates in the semiannual reviews may include, but are not limited to:

- 1) The purpose, role and scope and duties of the committee
- 2) The membership and operation of the committee
- 3) The state of the Animal Facilities and the need for any modifications.
- 4) Personnel, Training and Records
- 5) How well our program conforms to the guide, to this assurance, to PHS policy and to other applicable animal welfare regulations.
- 6) Any and all aspects regarding welfare of animals under the authority of the IACUC.
- 7) Positive and negative aspects of the programs, and areas for improvement.
- 8) Any deficiencies in the program
- 9) Classification of any deficiencies as minor or as significant/major (a significant deficiency is defined as one which is or may be a threat to animal health or safety).
- 10) Actions and schedules for correcting any identified deficiencies.

c. Review of the Proposals. Please see section 6, below, for details.

d. Other items of business. This is an explicit opportunity for any member of the committee to raise any issue of possible interest to the committee.

e. Inspection of the Facilities. Please see section 2, below, for details.

f. Preparation of the Semiannual report. Please see section 3, below, for details.

- 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. All IACUC members are invited to participate in the inspection of the facilities and no IACUC member can be excluded from participation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Inspection of the Facilities. Generally the full committee participates in inspection of the facilities, and any problems or deficiencies are noted in the minutes. (During the pandemic, inspections have been sometimes delegated to the chair or other suitable IACUC member). A formal checklist is not used, but the inspection generally covers all of the following items:

- Do all animals appear to be healthy and in good shape?
- Is food and water and bedding adequate in all cages?
- Is the water clear?
- Is aeration working properly (in fish tanks).
- Are all animal cages and racks adequately labeled and identified?
- Is ventilation adequate?
- Is temperature appropriate for these animals?
- Is humidity appropriate for these animals?
- Are floors and counters clean?
- Are supplies stored appropriately?
- Are log books orderly and up to date?
- Are the rooms generally clean and orderly?
- Are there any stains, leaks or other problems?
- Is equipment in good working order?
- Is there any evidence of insect or animal incursions?
- Are all lights functional, providing appropriate circadian lighting?

- Are there any other observations of note or concern?
- Is the facility properly secured?

Following inspection of the facilities, the IACUC chair generates a report of any noted deficiencies, including a plan for corrective actions and dates by which the issues will be resolved. The IACUC chair coordinates with investigators, facility managers, IACUC members, and the institutional official as needed to ensure that facility deficiencies are corrected in a timely manner.

- 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:

Criteria for the Semiannual Report

- a) The reports are updated at least once every six months upon completion of the required semiannual evaluations.
- b) The reports are maintained by the institution and are made available to OLAW upon request.
- c) Each report contains a description of the nature and extent of the Institution's adherence to the Guide, PHS Policy and to the AWA. The report identifies any specific departures from the Guide, PHS Policy and to the AWA and states the reasons/justification for each such departure.
- d) The report distinguishes significant/major deficiencies from minor deficiencies. A significant/major deficiency is one that, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency.
- e) If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by the PHS, the report identifies those accredited facilities.

Preparation of the Semiannual report. The Chair prepares a draft of the semiannual report before the meeting. Results from the meeting (such as the disposition of proposals) are annotated on the draft, and it is then signed by attending members. (During the pandemic, the committee met by zoom and signature authority was assigned to the chair). An appropriately edited and corrected semiannual report is then circulated by email and, when there are no further objections or corrections, or minority reports, the semiannual report is then forwarded to the Institutional Official.

Components of the semiannual report. The semiannual report contains the following components:

- a. Date
- b. Salutations
- c. Identification of the document as a semiannual report of the IACUC
- d. Citation of the controlling regulations and policies.
- e. Summary of any changes in the institution's program for animal care and use.
- f. Adherence/Departures from PHS Policy, the Guide, and the AWA (IACUC approved)
- g. Deficiencies in the IACUC Program (classify, describe & address)
- h. Deficiencies in the Institutions Animal Facilities (classify, describe & address)
- i. Disposition of any research proposals reviewed.
- j. Minority views (if any)
- k. Status of AAALAC accreditation (or lack thereof)
- l. Signatures of the attending members of the IACUC (must be a majority)

Significant/Major Deficiency

A **Significant/Major deficiency** is defined as a deficiency that may be a threat to the health and safety of animals. Other deficiencies are usually considered to be minor deficiencies.

Departures from the Guide

"Must"

The guide provides a variety of "must" statements. The IACUC may approve a departure from a "must" statement for any or all of the following reasons:

- scientific justification,
- veterinary reason, or
- animal welfare reason

Any IACUC approved departures from a "must" statement is to be noted in the semiannual report.

A departure from a "must" statement, without IACUC approval, is to be promptly reported to the IO and to OLAW.

"Should"

The guide provides a variety of "should" statements.

The IACUC may approve a departure from a "should" statement for any or all of the following reasons:

- scientific justification,
- veterinary reason, or
- animal welfare reason

An IACUC approved departure from a "should" statement for any of these reasons is to be noted in the semiannual report.

The IACUC may also approve a departure from a "should" statement for any or all of the following reasons:

- an IACUC approved performance standard
- a guide-approved specific exception

An IACUC approved departure from a "should" statement for any of these reasons is not considered reportable.

A departure from a "should" statement, without IACUC approval, is to be promptly reported to the IO and to OLAW.

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

Instructions on how to report concerns about animal welfare are prominently posted in the animal facilities and on the UAH IACUC website. Concerns may be communicated to the Chair of the IACUC, the Vice-Chair of the IACUC, the Institutional Official, or the Director of the Office of Sponsored Programs. The IACUC chair or designee will investigate all such concerns promptly, and will communicate the initial concern, the findings of the investigation, and any corrective actions taken, to the institutional official, to the UAH IACUC, and to the concerned party (when possible). Anyone making a good faith report is protected by UAH policy from any form of reprisal or discrimination. For details, see

<https://www.uah.edu/policies/06-09-03-duty-to-report-and-protection-from-retaliation>.

Instructions for anonymous correspondence and anonymous reporting are also provided. Any such reports and the resulting investigations and actions will be reviewed at the next IACUC meeting.

- 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:

Written outcomes and recommendations associated with semiannual program reviews and inspections are submitted to the Institutional Official by the IACUC chair via the semiannual report. Additional recommendations are made by the IACUC or the IACUC chair as needed. (For example, in July of 2019, the chair sent a two page white page to the Institutional Official and other interested parties outlining the case for an expansion of the vivarium capacity and capability. The work on this expansion was completed in August of 2022).

- 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:

Meeting format. If an in-person meeting is not possible or practicable, a hybrid or virtual meeting can be used. These meeting must be accessible to all members, must provide a comparable levels of participation and interaction, and must adhere to all other requirements outlined in [NOT-OD-06-052](#) (Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals). In particular, the following criteria must be met:

- All members are given notice of the meeting.
- Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
- All members have access to the documents and the technology necessary to fully participate.
- A quorum of voting members is convened when required by PHS Policy.
- The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
- If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
- Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but may not be counted as votes or considered as part of the quorum.
- Written minutes of the meeting are maintained in accord with the PHS Policy, IV.E.1.b.

Scope of the UAH IACUC.

The UAH IACUC oversees all use of vertebrate animals on the UAH campus, or in the field, under the supervision of UAH personnel. The UAH IACUC covers use of animals both for teaching and for research purposes. The scope of the UAH IACUC is not limited by the nature or source of research funding.

Solicitation of Proposals. In the month prior to an IACUC meeting, the chair may contact researchers to see if they have new proposals to submit and may remind them of when their current approvals expire.

Preview of the Proposals. Upon receipt, the Chair reviews proposals for completeness. If any omissions are found, the chair corresponds with the PI and suggests revisions before review. Following receipt and preview of a complete proposal, the Chair recommends to the IACUC a method of review. There are two basic review protocols, namely Designated Member Review and Full Committee Review, as described below.

Designated Member Review (DMR).

In the case of Designated Member Review, the chair circulates a complete copy of the proposal, by email, to the full committee and proposes a designated member review. If there are no requests for a full committee review within 48 hours, the chair then assigns the proposal to a single member of the IACUC for review. The chair of the IACUC can assign a DMR to any member of the IACUC (including the chair). The designated member

reviewer can approve the proposal, require modifications to secure approval, or refer the proposal for a Full Committee Review.

Full Committee Review (FCR)

In a full committee review, proposals are first circulated, by email, prior to the meeting. In the meeting, each proposal is given a short introduction by the chair or by another suitably qualified member of the committee. The committee then engages in a thorough, relatively slow-moving roundtable discussion of specific questions, concerns, and possible modifications. The discussions are followed, in parliamentary style, by a motion, a second, and votes on how to dispose of the proposal. A majority vote of the convened quorum is required to determine the outcome. There are three ways to dispose of the proposal:

1. approval
2. require modifications to secure approval
3. withhold approval

One of the above three outcomes is determined by a majority vote of the convened quorum. A quorum is defined as more than half of the IACUC. The quorum must be present or convened, no proxies are permitted.

If the IACUC has "required modifications to secure approval" then the modified proposal, once received, is sent to FCR or DMR as described above.

Alternatively, if the necessary conditions are met, then the IACUC can elect for a modified proposal, once received, to go to "DMR subsequent to FCR" as described below.

DMR subsequent to FCR

The establishment of "DMR subsequent to FCR" requires the unanimous consent of the entire IACUC and a written record of the same.

The election of "DMR subsequent to FCR" requires a unanimous vote of the convened quorum. Unanimous, in this case, means the positive assent of all members present, with no abstentions. Additionally, if even a single member present calls for the revised protocol to be sent to FCR, then that method of review must be used.

"DMR subsequent to FCR" differs from regular DMR only in that the distribution of the modified proposal to the entire committee is not required. Instead the modified proposal is sent immediately to the designated member, chosen by the Chair. The designated member reviewer can approve the proposal, require modifications to secure approval, or refer the proposal for a Full Committee Review, just as in ordinary DMR.

Establishment, Modification and Reaffirmation of the Assurance and IACUC policies. The assurance can be modified administratively as part of the application or renewal process. The written Assurance should be examined by the committee at least every three years, or more frequently, if needed. The assurance can be reaffirmed by a majority vote of the convened quorum. The assurance can be modified by a unanimous vote of a convened quorum. Any substantive changes to the assurance must be communicated to the entire IACUC. Additionally, any substantive changes to the Assurance must be communicated in the Annual Report to OLAW. Any changes in the Assurance and associated policies are contingent upon acceptance or approval by OLAW.

Conflicts of interest

If an IACUC member has a conflict of interest (typically because they are a PI or co-PI on a proposal) then they are recused from the review of that proposal and they leave the room (or go to a zoom meeting breakout room) until recalled back to the meeting. If the recusal would break quorum, then the proposal cannot be considered. A full quorum is required to consider each proposal.

"Renewals"

PIs are encouraged to submit an updated protocol circa six months to a year before the expiration. A "renewal" is treated in the same way as a new proposal.

Criteria for review of proposals

The IACUC uses a variety of external and internal guidelines to assist in the review of proposals. Among these are:

1st Excerpt from the Guide:

Animal Care and Use Protocols

The following topics should be considered in the preparation and review of animal care and use protocols:

1. Rationale and purpose of the proposed use of animals.
2. Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
3. Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (see Appendix A, "Alternatives").
4. Adequacy of training and experience of personnel in the procedures used.
5. Unusual housing and husbandry requirements.
6. Appropriate sedation, analgesia, and anesthesia. (Scales of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, "Anesthesia, Pain and Surgery.")
7. Unnecessary duplication of experiments.
8. Conduct of multiple major operative procedures.
9. Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
10. Postprocedure care.
11. Method of euthanasia or disposition of animal.
12. Safety of the working environment for personnel.

Note: Special concerns include physical restraint, multiple major surgical procedures, and food or fluid restriction.

2nd Excerpt from the Guide:

This Guide endorses the responsibilities of investigators as stated in the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985; see Appendix D). Interpretation and application of those principles and this Guide require professional knowledge. In summary, the principles encourage

1. Design and performance of procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society.
2. Use of appropriate species, quality, and number of animals.
3. Avoidance or minimization of discomfort, distress, and pain in concert with sound science.
4. Use of appropriate sedation, analgesia, or anesthesia.
5. Establishment of experimental end points.
6. Provision of appropriate animal husbandry directed and performed by qualified persons.
7. Conduct of experimentation on living animals only by or under the close supervision of qualified and experienced persons.

3rd Excerpt from the Guide:

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable Federal laws, guidelines, and policies.¹
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

- 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:

Any significant change in proposed animal use must be reviewed and approved by the IACUC. Examples of a significant change include:

- any increase in previously approved number of animals
- any alteration in the housing of the animals
- any relocation of animals to area not overseen by the IACUC
- any change from nonsurvival to survival surgery
- any change resulting in greater pain, distress, or degree of invasiveness
- any change in species
- any change in study objectives
- any change in Principal Investigator (PI)
- any change that impacts personnel safety
- any change in anesthesia, analgesia, sedation, or experimental substances
- any change in euthanasia methods
- any change in duration of procedures to be performed on an animal
- any change in the number of procedures to be performed on an animal
- any change in the type of procedures to be performed on an animal

To request approval for significant changes, the principal investigator must submit to the Chair of the IACUC a complete, revised IACUC proposal. The proposal will then be treated as a new submission and reviewed via the procedures detailed in section 6, above. Similar procedures are also used for submission and review of renewal and resubmission applications.

- 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:

Notification (approval, require modifications to secure approval or withhold approval). Principal Investigators are notified, by a letter attached to an email, of the disposition of their proposal.

Proposals are approved for a term of three years. PIs are instructed to contact the chair of the IACUC if any significant amendments are contemplated (as described above, in Part III. D. 7)

If approval is withheld, the problems or reasons for rejection are outlined so that the principal investigator can respond constructively to the rejection, and may resubmit. A re-submitted proposal is treated as a new proposal, and gets no special consideration.

The IO is notified in the semiannual report, by "carbon copying" the IO on the PI notification or by a separate communication. The Office of Sponsored Programs is notified by the IO or by the Chair of the IACUC, as needed.

- 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:

Protocols are approved for a three year period. PIs are encouraged to submit an updated protocol six months to a year before the expiration so that a new protocol can be approved before the old one expires. The review procedure for a previously approved activity is not different from the review procedure for a new activity, and must proceed, by DMR or FCR, in the usual manner.

If a protocol expires (without being re-approved), all animal experimentation must cease until a new approval has been obtained. The ordinary care of the animals from an expired protocol may continue, or the animals may be euthanized, at the discretion of the IACUC chair.

Postapproval Monitoring

Animal care workers, who check on animals daily and keep records of any unusual observations or circumstances, also report any concerning circumstances to the IACUC chair. Additionally, the IACUC Chair or designee periodically checks the animals and the animal quarters, interviews researchers and workers, and/or observes procedures.

- 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:

The IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, Guide, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur 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. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

Additionally, the IO (with advice from Chair of the IACUC and/or the Veterinarian) may, under exigent circumstances, unilaterally halt, terminate or impose sanctions on any animal activity.

- 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:

Oversight and management. The UAH health and safety program is a comprehensive and ongoing collaborative effort that is overseen and coordinated by the UAH Office of Environmental Health and Safety (OEHS). Environmental Health and Safety professionals are involved in planning and monitoring the program, as well as training activities, with advice and assistance from:

Office of the Vice-President of Research (OVPR) (Citi training)
UAH Facilities (environmental engineering, HVAC, etc)
Individual Principle Investigators (PIs) (project-specific knowledge)
UAH Office of Risk Management (legal advice)
UAH Institutional Animal Care and Use Committee (advice, training and intermediation)
UAH Health Services (vaccinations, medical assessment, medical clearance)

and other offices and individuals as needed.

Risk Assessment. The program is based on identifying, assessing and mitigating the hazards associated with specific materials, agents, activities and environments as well as considering the health, vaccination status and special vulnerabilities of the people engaged in these activities. Quantitative factors (amounts, concentrations, durations) may also be important considerations.

Risk Mitigation. Risk may be mitigated by environmental or engineering controls such as ventilation and Biological Safety Cabinets, by Personal Protective Equipment (PPE) such as safety glasses, respirators, lab coats, and gloves, by vaccination, or by task and hazard-specific training, or by limiting the duration or intensity of contact.

We have established four levels of exposure and risk with progressively more extensive levels of training and medical assessment.

Level 1. Occasional visitors who have **no direct contact** with animals, are accompanied by UAH personnel and are advised, before entering a facility, of hazards, precautions and conditions that might render them especially vulnerable. For example:

Warning

This facility may contain animal dust and dander which may lead to allergic reactions or infections in susceptible individuals.

Use of masks/respirators (N95, KN95, etc.) is recommended.

If you have any medical conditions that may increase your risk (allergy, asthma, pregnancy, immunodeficiency, etc.) you may wish to consult with your personal health provider before entering the animal facility.

Level 2. UAH employees, such as plumbers and electricians, who have **no direct contact** with animals, and who spend less than 4 hours per week in such an environment also receive general safety training from OEHS and learn about general hazards, precautions, PPE, warning signs and where to get more information.

Level 3. UAH students and employees, who have **minimal contact** with vertebrate animals (less than 4 hours per week) are given extensive activity-specific safety training, and sign an **acknowledgement** (indicating, for example, that they have received training on the relevant hazards and precautions, that they accept the inherent residual risks, that their continuing participation is voluntary, and that they can stop at any time).

Level 4. UAH students and employees who have **frequent and/or substantial contact** (more than 4 hours per week) with vertebrate animals are also required to obtain a **medical clearance**. They are given a form and referred to UAH Health Services, or, alternatively, to their personnel physician, for a medical assessment. The **medical history** stays with the person's medical records and is collected, maintained and stored in compliance with HIPAA requirements. A short **medical clearance**, which may give, or decline to give, a medical clearance for the relevant activity, is transmitted to the IACUC and the relevant supervisor(s).

For specific situations or hazards or projects, or for projects of lower intensity but longer duration (for example, greater than 4 months), the IACUC or the PI may choose to escalate a person or project or activity to a higher risk level.

1. Personnel will be instructed as to the nature of any biological, chemical or physical hazards to which they may be exposed during their work. This instruction will be provided by the chair of the IACUC or by other qualified members of the IACUC. Potential hazards of specific interest include:

Allergens (from Animal dander)

Asphyxiation (from carbon dioxide gas cylinders)
Burns (from Autoclave)
Caustic fumes (from bleach)
Explosion (from natural gas or gas cylinders)
Infection by Pathogens (from Animal bites or animal bedding)
Intoxication (from organic chemicals such as Isoflurane)

2. Personnel will be instructed as to the proper use of available personal protective equipment including laboratory coats or gowns, gloves, dust masks, safety glasses that might help to minimize or mitigate such hazards. Personnel will be trained, as needed, on use of BSC and other engineered safety equipment.

3. Reporting of injuries. In case of an injury, such as a bite wound, personnel will be instructed to: a) record the event in the log, b) notify the IACUC chairperson and the director of environmental health and safety of the injury, and c) seek treatment from their personal physician. If the injury is life-threatening or otherwise requires **emergency medical attention**, the employee should seek medical assistance and treatment without delay at the emergency room of a nearby hospital.

UAH maintains a listing of approved medical providers. This list includes multiple after-hours provider locations. The list is published at this URL: <https://www.uah.edu/rmi/injuries>. This link also contains instructions to both employees and supervisory personnel regarding handling of job-related injuries. If the lab-related injury / illness involves a non-employed student, the same process for obtaining medical treatment should be followed, but the non-employee accident report form should be used, and the student's healthcare insurance would be primary.

4. The IACUC chair, committee, or workers shall consult as needed with the director of occupational health and safety regarding ventilation, waste disposal, personal protective equipment and related safety issues or concerns.

5. Personnel are instructed to get a tetanus booster, and other vaccinations, as recommended. Additionally, employees are instructed to consult with the IACUC chair, the director of environmental health and safety, and/or their personal physician, if they have or develop a condition (such as pregnancy or infection or chemotherapy) that might render them more sensitive to biological, chemical or radiological hazards.

6. Personnel are required to refresh their institutional and IACUC specific training annually.

7. Principal Investigators may provide or require additional training for people working under their supervision.

8. A **Medical Clearance** is required for people with frequent and/or substantial contact (> 4 hr per week) with vertebrate animals (see details above).

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:

The training or instruction of scientists, animal technicians, and other personnel involved in animal care, treatment, or use will be provided in a half-day course provided by the IACUC, or by equivalent individualized instruction. This course will be offered at least once a year, and more often if warranted by the number of individuals requesting it. The course will be taught by one of the veterinarians on the committee and the chairperson (and/or other qualified individuals) in a lecture/ demonstration format. The course will follow the format outlined for a core module in instruction as described in "Education and Training in the Care and Use of Laboratory Animals" developed by the National Research Council, and published by National Academy Press, Washington, D.C., 1991. The participants will also be instructed

in the specific procedures to be followed according to this institution's Assurance. Information will be provided concerning research or testing methods that minimize the use of animals and minimize animal distress. Articles from ILAR Journal and other pertinent sources will be used. The participants will also be informed of the resource materials maintained on campus by the IACUC for use in assessing and designing animal protocols. Individuals completing this course will receive written documentation of completion. All individuals who will be working with animals will be required to receive this training.

Each animal caretaker will also be given detailed instruction concerning the feeding and watering of animals, cleaning of cages, cleaning of facilities, storage of food, bedding and supplies, and record keeping.

The Collaborative Institutional Training Initiative (CITI Program) may be used to supplement or replace components of our traditional training program.

IACUC evaluates the effectiveness of training by spot checks of task quality (did the task get done, was it done well), by direct observation of task performance, by oral examination (How do you) and by direct demonstration (Please show me how you). These assessments are performed periodically and opportunistically by the IACUC chair and other qualified individuals.

IACUC members are provided with ready access to the Guide, to the Animal Welfare Assurance (once approved) and to other relevant materials. The duties of the IACUC and the criteria for proposals are reviewed at the beginning of each IACUC meeting. Additionally, we are working to ensure that all IACUC members, including those outside the institution, will have access to the relevant CITI Training materials.

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) was 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, the Vice President of Research and Economic Development.
 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 federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 3. Any change in the IACUC membership
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, the Vice President of Research and Economic Development.
 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: Robert Lindquist	
Title: Vice President of Research and Economic Development	
Name of Institution: University of Alabama in Huntsville	
Address: <i>(street, city, state, country, postal code)</i> SSB 324 301 Sparkman Drive, Huntsville, AL 35899	
Phone: 256-824-6100	Fax: 256-824-6783
E-mail: robert.lindquist@uah.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: July 3, 2023

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
<p>Jane J. Na, DVM, CPIA / Director, Division of Assurances Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672</p>	
Signature:	Date: July 12, 2023
Assurance Number: D22-01154	
Effective Date: July 12, 2023	Expiration Date: July 31, 2027