

Kennesaw State University

D22-01145

Animal Welfare Assurance for Domestic Institutions

I, Karin Scarpinato, as named Institutional Official for animal care and use at Kennesaw State University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, National Science Foundation (NSF), and/or National Aeronautics and Space Administration (NASA). 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:

Kennesaw State University

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

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 President of Kennesaw State University (Dr. Kathy Schwaig) delegated authority through the Vice President for Research (Dr. Karin Scarpinato) to serve as the Institutional Official (IO). The Institutional Animal Care and Use Committee (IACUC) and Attending Veterinarian (AV) report directly to the IO. Members of the IACUC are appointed by the IO per a formal letter designating this responsibility.

The IACUC oversees the Institution's animal care and use program, facilities, and approved procedures. The IACUC advises the IO about problems or deficiencies and recommends steps for correction. The IACUC reviews all animal use protocols for consideration of humane animal care and use and performs semiannual reviews of the animal care and use program and facilities as required by federal regulations and Kennesaw State University policy. Dr. Jared Tagliatela (Associate Professor of Biology, Department of Ecology, Evolution, & Organismal Biology) serves as Chair of Kennesaw State University's IACUC.

Kennesaw State University has retained Dr. Wai Hung Hanson (Clinical Veterinarian, Emory University School of Medicine) on a contract basis, reporting directly to the IO, as Attending Veterinarian.

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

1) Name: Wai Hung Hanson

a. Qualifications

- Degrees:
DVM, PhD, DAACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Wai Hanson received her D.V.M. from the University of Georgia in 2018. She specializes in laboratory animal medicine having completed a residency program at Emory University and becoming a Diplomate of the American College of Laboratory Animal Medicine (DAACLAM) in 2021. Dr. Hanson is licensed to practice in the state of Georgia and is accredited with the USDA National Veterinary Accreditation Program. Having received her Ph.D. prior to veterinary medicine, Dr. Hanson remains heavily involved with research consultation, collaboration, and primary investigations. Her special interests include refinement of environmental-based methods for colony health surveillance and improvement of fur mite detection and treatment protocols.

- b. Authority: Dr. Wai Hung Hanson has been delegated program authority and responsibility for the Institution's animal care and use program including access to all animals and all animal use areas.

- c. Time contributed to program:

Approximately 5-10 hours per month on consulting basis

2) Name: Karen Strait

a. Qualifications

- Degrees: DVM, DAACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Karen Strait received her D.V.M. from the University of Georgia College of Veterinary Medicine in 2005 and completed her DAACLAM credentials in 2007. Dr. Strait is licensed to practice in the state of Georgia and is accredited with the USDA National Veterinary Accreditation Program. She has many years of clinical veterinary experience and currently serves as Attending Veterinarian at the Morehouse School of Medicine. Dr. Strait also served from 2010-2016 in

academic positions at Emory University School of Medicine in the Department of Pathology and Laboratory Medicine.

- b. Responsibility: Dr. Karen Strait has been designated as a backup veterinarian to be available when the Attending Veterinarian is not available. Dr. Strait will have access to all animals and all animal use areas.
 - c. Time contributed to program:
As needed on consulting basis
- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, professions, 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 quorum of the IACUC participates in the program review evaluation and discussion at a convened meeting of the committee. Recommended changes, if any, are passed by majority vote and the Committee documents any resulting programmatic changes. In the event that a substantive programmatic change is recommended, the IO is notified and a subcommittee of the IACUC may be appointed by the Chair to further investigate the recommendation and report back to the full IACUC for a determination. The semiannual program review also includes evaluation of the following:
 - IACUC membership and function
 - IACUC protocol review practices
 - IACUC records and reporting requirements
 - Veterinary care, including preventive medicine, animal procurement, transportation, surgery, pain, distress, analgesia and anesthesia, euthanasia, and drug storage and control
 - Research personnel qualifications and training
 - Occupational health and safety of personnel
 - 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:

At least once every six months, the IACUC inspects all Institutional facilities where animals are housed and/or used. A minimum of two voting members of the committee must comprise an inspection team. The IACUC utilizes the *Guide* and the Animal Welfare Act as the principal guiding documents in conducting the inspections.

Areas inspected include central animal housing facilities and related facilities such as, but not limited to, cage wash, aseptic surgery, procedure areas, necropsy, supplies and inventory storage, controlled substance storage and records, surgical suites, and recovery areas. No IACUC member wishing to participate in any review or inspection shall be excluded. The IACUC may invite *ad hoc* consultants to assist in the reviews and inspections. A checklist adapted from the PHS template is used to note any deficiencies.
 - 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:

Upon completion of the semiannual animal program and facilities reviews, the IACUC Chair prepares a written report. The report shall describe the Institution's adherence to the *Guide* and the Animal Welfare Act, rationale for any departures recorded, and a list of any deficiencies found. At the current time, KSU does not have AAALAC accreditation for any facilities; if such accreditation is received by any KSU facilities, this information will also be included in the report. Reports are distributed to all members of the IACUC for their review and discussion at a convened meeting of the committee where a quorum is present. The reports must be signed by a majority of the members of the IACUC and shall include minority views, if any. The IACUC shall submit the signed semiannual report to the IO. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

Deficiencies from *PHS Policy* and the *Guide* identified during review are categorized as either minor or significant, and they are so described in the written report. A significant deficiency is defined by USDA Regulations and *PHS Policy* as something that is or may be a significant threat to animal health or safety; such deficiencies require immediate attention and resolution. The report shall include a plan and schedule with dates for correction of each program or facility deficiency. The IACUC shall coordinate with the researcher or other responsible party on resolving the deficiency. Resolution may require notification of facilities management personnel, identification of resources (i.e., funding), and follow-up by the IACUC.

Any failure to adhere to the plan and correction schedule that results in a significant deficiency remaining uncorrected shall be reported by the IACUC through the IO within 15 days, in writing and as appropriate, to the Office of Laboratory Animal Welfare (OLAW). If the activity is federally funded, the relevant agency shall also be notified.

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

The details of the animal welfare concern policy are found in KSU document *IACUC-04: Animal Welfare Concern Reporting and Investigation*.

Any individual who has a concern regarding the care and use of an animal at KSU is encouraged to discuss concerns with the faculty member(s) or specific department (e.g., Ecology, Evolution, & Organismal Biology; Molecular & Cellular Biology) in charge of the animals. If the concern is not addressed adequately, or if there is fear of retribution for expressing a concern directly to the person in charge, an individual is encouraged to report through one of the alternative routes listed below.

- KSU Ethics and Compliance Reporting Hotline through an online report (<https://secure.ethicspoint.com/domain/media/en/gui/76605/index.html>) or by calling 877-516-3456. Reports may be anonymously submitted.
- Institutional Official (Vice President for Research), Dr. Karin Scarpinato, kscarpin@kennesaw.edu, 470-578-6046.
- Director, Office of Research Compliance, Dr. Kristine Nowak, knowak@kennesaw.edu, (470) 578-4941.
- IACUC Chair, Dr. Jared Taglialatela, jtaglial@kennesaw.edu, (470) 578-3678.
- Attending Veterinarian, Dr. Wai Hanson, whanson2@kennesaw.edu, (845) 527-0671.
- Any IACUC member. The names of current IACUC members are listed on the following webpage: <https://research.kennesaw.edu/iacuc/members.php>.

Moreover, this policy requires signs containing the mechanism for reporting concerns to be posted in all animal housing facilities and procedure locations at KSU. There is an anonymous survey offered via URL and QR code on this signage.

Concerns may be handled in a confidential or anonymous manner if requested by the originator. The IACUC Chair, at least one other IACUC member and, as necessary, the Attending Veterinarian (AV) will meet with the individuals against whom a complaint or concern is lodged. The purpose of this discussion is to allow the researcher an opportunity to respond to the claim and to clarify any misunderstanding. If the claim is found to have merit, the IACUC may further investigate and/or appoint a subcommittee of members to do so. The IACUC will consult with the Institutional Official (IO) to ensure that the rights and reputation of the accused individuals are protected. The Chair and the AV, in consultation with the Director of Research Compliance, will report findings of the investigation to the IACUC and the IO. The Director of Research Compliance, on behalf of the IO, will originate required reports to funding agencies.

Any individual who, in good faith, reports an animal welfare concern will be protected against whistleblower reprisals or discrimination as mandated by the University System of Georgia's Office of Ethics and Compliance

(<https://secure.ethicspoint.com/domain/media/en/gui/76605/faq.pdf>): "Employees may not interfere with the right of another employee to report concerns or wrongdoing, and may not retaliate against an employee who has reported concerns or wrongdoing, has cooperated with an authorized investigation, has participated in a grievance or appeal procedure, or otherwise objected to actions that are reasonably believed to be unlawful, unethical or a violation of USG policy. Violations of this policy may result in disciplinary action, which may include the termination of employment."

In addition, as an institution within the University System of Georgia, KSU has an established policy on whistleblower protection within the Employee Handbook:

1.9 Whistleblower Protection Statute

Kennesaw State University recognizes that an ethical, efficient, and effective work environment is essential to our continuing to successfully accomplish our mission. As a result, we have always placed a high priority on assuring that each member of our university community has the opportunity and means to convey any matter that could compromise that environment. Reporting through your supervisory chain frequently produces the most thorough and timely resolution of a matter and is encouraged. However, other reporting avenues, such as the University Police, Human Resources, and Internal Audit, have been and continue to be readily available. In keeping with our efforts to expand alternatives for reporting matters of significance, there is Hotline reporting through a service provided by an independent company. This service is available 24 hours a day, 7 days a week, and allows you to voice your concerns, and to remain anonymous if you prefer.

Of special concern are fraud, waste, and abuse as well as harassment of any kind, given that they so directly impact our stewardship responsibilities and the well-being of individuals within our campus community. Yet, we would encourage you to report any other significant issues as well through any of the methods available to you. Click here to [report](#) a concern.

- 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 are made to the IO in the semiannual reports as described above and at any requested meetings of the IO and the IACUC. If the IACUC has recommendations at other times of the year, or concerning matters not covered on the semiannual reports, they are made in the form of a letter to the IO. The letter is drafted by the IACUC Chair (or a designee of the chair) and submitted for review and approval by the entire IACUC membership.

- 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 details of protocol review are detailed in KSU Document *IACUC-13: Protocol Review Procedure*.

- A. **PRINCIPAL INVESTIGATOR PREPARES AND SUBMITS PROTOCOL:** The following describes the steps taken by the Principal Investigator to apply for IACUC approval.
1. **ANIMAL CARE AND USE PROTOCOL (ACUP) FORM:** The PI must fully complete an ACUP form. As of July 1, 2022, KSU uses Cayuse Research Suite for all ACUPs.
 2. **STATEMENT OF WORK OR PROJECT DESCRIPTION:** If external funding is associated with this protocol, a copy of the funding proposal or final grant pages sent to the funding agency must be sent to the IACUC along with the ACUP form. Federal regulations require the IACUC to compare the protocol to the funding proposal Statement of Work or Project Description. Substantive differences must be satisfactorily addressed prior to IACUC approval.
 3. **REQUIRED TRAINING:** Everyone named on the protocol (including students, post-docs, lab techs, Visiting Scholars, and affiliates) is required to complete the current prescribed training via the Collaborative Institutional Training Initiative (CITI). Instructions and access can be found at <https://research.kennesaw.edu/iacuc/online-training.php>. Other training for Occupational Health and safety purposes may also be required, depending on the specifics of the protocol and the assigned duties of the individual.
 4. **DEPARTMENTAL SIGN-OFF:** Submission of the ACUP via Cayuse includes an attestation that the PI has secured departmental approval for the proposed work. When the department chair is the Principal Investigator named in the ACUP, no other approval is required.
 5. **PROTOCOL UPDATES:** If ACUP modification or amendments are required, the PI should complete an Amendment submission in Cayuse. If necessary, the PI may consult with the IACUC Chair and/or Attending Veterinarian before submission.
- B. **ADMINISTRATIVE PROCESSING OF PROTOCOLS:** Upon receipt of an ACUP application, the IACUC follows this process to facilitate protocol review. (If the submission is a modification or amendment or a three-year renewal the same steps are followed).
1. **PROTOCOL TRACKING:** Applications are automatically assigned an IACUC number in the Cayuse Research Suite when initiated. Amendments and de novo three-year renewal applications are linked to the relevant ACUP by selecting the appropriate option from the currently approved protocol.
 2. **INITIAL REVIEW:** The application will be given a preliminary review by the IACUC Office and/or Chair to confirm that applications are complete and compare the proposed research procedures to those described in the funding proposal, if any. Completion of appropriate training for each named member of the research team will also be verified. Final IACUC approval will be withheld until these requirements are satisfied.
 3. **VETERINARY CONSULTATION:** If compliant, a consultation with the Veterinarian may be scheduled. The Veterinarian will contact the PI for discussion, clarification, or additional information as necessary. Following veterinary consultation, the ACUP will be returned to the PI for modifications, if necessary. If none are needed, the Veterinarian will inform the IACUC Chair and the ACUP application will be forwarded to the IACUC committee.
 4. **PROTOCOL DISTRIBUTION TO COMMITTEE:** After the ACUP application has undergone administrative and veterinary review and has been revised and resubmitted by the PI if needed, it is distributed to all members of the IACUC. IACUC members must respond within a prescribed number of days regarding a call for full committee review or their recommendation of designated member review. If a committee member calls for full committee review, then the protocol will be placed on the agenda for the next IACUC meeting, unless it was received without sufficient lead-time to allow for all committee members to review before the meeting in which

case it will be scheduled for a future meeting. On a case-by-case basis and based on researcher justification, a special meeting may be called to expedite full committee review of an ACUP protocol. Researchers should contact the IACUC well in advance of ACUP submission to coordinate their submission date with the current IACUC meeting schedule.

5. **DESIGNATED MEMBER REVIEW:** If no member of the IACUC identifies that an ACUP submission requires full committee review, then the IACUC Chair will designate one IACUC member to complete a review. The designated member may decide after their review that the submission requires full committee review, in which case it will be sent to the committee again and placed on a meeting agenda. The designated reviewer will assign one of three outcomes to the ACUP: approve, require modifications to secure approval, or refer to full committee review.

C. **COMMITTEE REVIEW PROCESS**

1. **FULL COMMITTEE REVIEW AT CONVENED MEETING OF COMMITTEE:** All applications requested for full committee review (new protocols, three-year renewals, or amendments) are considered for approval during regularly scheduled meetings of the IACUC with a quorum present. Occasionally, the PI will be invited to take questions from the IACUC at a convened meeting. The PI will not be present during deliberations and voting. Protocols that lack substantive information necessary for the IACUC to make a judgment (e.g., justification for withholding analgesics in a painful procedure) are considered incomplete and the IACUC defers review until the requisite information is provided by the investigator.
2. **IACUC MEETINGS:** Institutional Animal Care and Use Committee meetings are conducted in the manner described here.
 - a. **MEETING SCHEDULE:** The IACUC will meet at least quarterly, depending on the holiday schedule and whether there are matters to consider. Additional meetings will be called if necessary for the Committee to fulfill its responsibilities.
 - b. **QUORUM:** A quorum is required at any meeting at which formal action is taken by the IACUC. Any formal action taken by the IACUC (i.e., approval, suspension) must be approved by majority vote at a convened meeting with a quorum of IACUC members. A simple majority of the current members of the IACUC constitutes a quorum. If a quorum is lost at any time during the meeting, no further formal action will be taken until a quorum is attained. Any member who has a conflict of interest in a matter under consideration by the IACUC shall not be counted for establishing a quorum for that portion of the meeting.
 - c. **USE OF TELECOMMUNICATIONS FOR IACUC Meetings:** Through use of telecommunications (e.g., telephone- or video-conferencing), the Institution's IACUC may conduct official business without all members physically present. In concordance with PHS guidance, all virtual meetings are conducted via Teams or Zoom and adhere to the following criteria:
 - i. All members are given sufficient notice and provided with the meeting link.
 - ii. All documents are provided ahead of the meeting in the same manner as provided for an in-person meeting.
 - iii. All members have access to the documents and the technology necessary to fully participate.
 - iv. A quorum of voting members is verified before official business is conducted.
 - v. All members are able to interact verbally in real-time.
 - vi. Voting is verified by either chat, voice vote, or raised hands
 - vii. Any opinions presented in absentia are not counted as votes or considered for quorum.
 - viii. Written minutes are maintained in the same manner as for in-person meetings.
 - d. **CONFLICTS OF INTEREST:** Any member who is listed as personnel on a protocol may not participate in its discussion. The member may be present to answer any questions from the membership, as any PI/personnel are welcome to

do, but must leave the meeting for the duration of the discussion and vote on that particular protocol.

3. **DETERMINATIONS MADE BY MAJORITY VOTE AT CONVENED MEETING WITH QUORUM:** When full committee review of a protocol is undertaken, a meeting will be held with attendance by a quorum of voting members. Although the committee strives for consensus, majority rule will apply. IACUC determinations, reached by the full committee, shall result in the protocol application (or other action) being assigned to one of the following categories:
 - a. **APPROVED:** The application is approved as presented with no modifications required. The Cayuse System will send the PI an email indicating that the protocol was approved, and it will show status of "approved" in the list of protocols. If required, the IACUC Office can supply attestation of the approval status to any research funding agencies or other entities that request proof of review and approval.
 - b. **REQUIRE MODIFICATIONS TO SECURE APPROVAL:** Clarifications or minor modifications are required for approval. A majority vote of the quorum present is required for the protocol outcome of "require modification to secure approval." When the entirety of the IACUC committee membership is present at a meeting, and a majority of the committee votes to "require modification to secure approval," the committee may elect to review the revised protocol by DMR if the entire IACUC membership (all members) agree. The DMR is then designated by the IACUC Chair. When the entire committee is not present at a meeting, and a majority of the quorum present votes to "require modification to secure approval," the committee can only elect to use DMR once the revised protocol has been resubmitted by the PI, and the entire IACUC membership has been given a chance to review the revised submission. Any requests from the membership for Full Committee Review will be honored. Any designated reviewers must concur in their opinions before approval is granted.
 - c. **DISAPPROVED:** The IACUC will notify the PI in writing via email when an application is disapproved and will provide the basis for the committee's decision. The Cayuse Research Suite does not include a provision for communication when a protocol is "cancelled" (disapproved) by a vote of the committee. When circumstances warrant, the Chair may call the PI to discuss the review. If a protocol is disapproved, the PI has the right of appeal to the IACUC. The IACUC may, at its discretion, obtain external review of the application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field of that research. The Kennesaw State University IACUC, however, shall be the final authority in determining the acceptability of the protocol. A "disapproval" determination by the IACUC may not be overruled by any officer or employee of the University.

- 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:

Amendments to an existing ACUP must be reviewed and approved by the IACUC before the changes are implemented. The administrative and committee review process is virtually identical to that for new protocols, described above. Changes made to a protocol may be categorized as one of two types, significant or minor.

A. SIGNIFICANT CHANGES OR MODIFICATIONS

Significant changes follow the same procedures as new proposals (above) and may require full committee review at a convened meeting. The following actions (identified by the Office of Laboratory Animal Welfare as significant) generally require approval by the full committee (allowing for alternative Designated Member Review as decided by the Members as for any new protocol):

- change in objectives of a study
- proposals to switch from non-survival to survival surgery
- change in degree of invasiveness of a procedure or discomfort to an animal
- change in species or in the approximate number of animals used
- change in anesthetic agent(s)
- change in approved analgesia
- change in experimental substances used
- change in methods of euthanasia
- change in housing or use of animals in an area not previously designated for housing or animal use
- change in duration, frequency or number of procedures performed on an animal
- change in any element of the procedures that alter safety for protocol or facility personnel
- change in Principal Investigator (PI)

B. MINOR CHANGES OR MODIFICATIONS

Those actions that have no effect on the humane care and use of laboratory animals may be administratively reviewed and approved by the IACUC Chair and/or designated member of the IACUC. These include changes in personnel (other than the PI or co-PI), change in protocol title, and change in funding source. If the change in funding source includes any additional or different procedures, the amendment shall be distributed to the full committee for consideration.

Revisions to an existing protocol do not extend the current approval period.

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

The IACUC will mainly communicate with the PI via the Cayuse Research Suite, which automatically sends emails with notifications of decisions as they are confirmed by the IACUC Office (except for disapproval, as detailed in III.D.6 above). Comments that detail any required or requested edits are attached to each section of the protocol. Changes in the protocol are tracked by the system with each resubmission. Researchers may log in to Cayuse and view any comments that were made on the protocols. Because the email is automatically generated, it does not provide any detail about the decision. All notes regarding the decision will be part of the comment record in the protocol; this serves to facilitate any required edits by labeling the sections which need addressed.

Minutes of each meeting will be posted to the shared drive to which all IACUC members have access. Minutes include a list of agenda items (i.e., discussed protocols) and a list of the protocol actions taken since the last meeting (i.e., DMR, administrative reviews). The IO also has access to the shared drive, and thus will be able to see decisions and actions on all protocols both on and outside of the meeting agendas. In addition, the semi-annual report to the IO will contain a list of all submissions reviewed since the last report, including whether it was approved or disapproved.

- 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:

THREE YEAR RENEWAL

If a protocol will continue beyond the third year, the PI must submit a complete, new application to the IACUC prior to the three-year anniversary date. The IACUC will conduct a review which will proceed as it would for any new protocol submission, including any pre-reviews and consultations by the Attending Veterinarian before submission to the full committee per Animal Welfare Regulations (.

POST APPROVAL MONITORING

The KSU IACUC has a monitoring plan detailed in document *IACUC-05: Post Approval Monitoring Program*.

In summary, the PAM process includes:

- Semi-annual facility inspections of all animal housing and usage areas
- Regular monitoring of animal health and welfare (frequency varying depending on species)
- Investigation of any reports of noncompliance or animal welfare concerns
- Observation of each protocol at least once per active year
- Follow-up of finding with a written report approved by the IACUC and notification to the PI, IACUC Chair, and AV
- Prompt reporting of any findings or concerns to the animal care staff and AV, as well as notification to the IO and, if needed, to OLAW, USDA, or other research sponsor as required
- An appeal process for researchers regarding the findings, recommendations, and corrective actions of the IACUC
- Appropriate recordkeeping of all written reports and corrective actions

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 may suspend a protocol at any time if it determines that the activity is not being conducted in accordance with the protocol approved by the IACUC or not in accordance with the guidance from the AWA, *PHS Policy*, the *Guide*, or Kennesaw State University's Animal Welfare Assurance or policies. Suspension of a protocol requires a majority vote of IACUC members at a Full Committee meeting with a quorum of members attending. Such meetings may be held via teleconference to ensure a swift and appropriate response to serious concerns.

As an exception to the above: The Attending Veterinarian can halt work on a protocol on an emergency basis. The Attending Veterinarian has the authority to halt work on any protocol that does not follow AWA, *PHS Policy*, the *Guide*, or Kennesaw State University's Animal Welfare Assurance or policies. The Attending Veterinarian is authorized, in extreme situations, to confiscate animals, remove them from the control of the PI, treat animals, and/or euthanize them, pending an inquiry or investigation.

Any such halt or work stoppage will immediately be reported to the IO and the IACUC and will be the subject of a convened meeting with a quorum of committee members. The IACUC may additionally impose a period of suspension for some or all individual's ability to use animals until it is clear that the personnel and procedures have been brought into compliance with federal and Kennesaw State University policies and guidelines. The individuals involved may be subject to further disciplinary action by the institution.

The IO (or designee) will notify the Office of Laboratory Animal Welfare (OLAW) immediately by telephone or email. The IACUC will then prepare, for the IO's signature, a written notification to OLAW and any other appropriate federal agency.

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 Kennesaw State University (KSU) Office of Environmental Health & Safety (EHS) has established an occupational health and safety program for personnel working within the animal research facility (i.e., vivarium) and researchers who are exposed to animals, in partnership with Concentra Occupational Health. In addition, there are several engineering and programmatic controls KSU implements within the vivarium to mitigate or prevent the risk of occupational health concerns and exposures while working with animal models.

As an initial step, all animal users are required to enroll in Kennesaw State University's vivarium occupational health and safety program administered by EHS. This requires a basic health history, an annual animal allergy questionnaire, current Tetanus-diphtheria (Td) vaccination, the availability of Hepatitis B titer and/or primary titer series when working with any human tissues or other materials of human origin, and the disclosure of any immune compromising condition(s). Part of this assessment includes relevant exposure information for the user and an evaluation tailored to the proposed research species, as well as an assessment of any conditions that would affect their health status such as reduced immunocompetence or known animal allergies. This evaluation is completed at the Concentra Occupational Health Clinic. Concentra will then provide KSU EHS and the animal user with documentation indicating the release for work and suitability for job duties. This decision will include a plan for any animal staff or users who have complicating conditions requiring special monitoring or treatment. Animal care staff routinely working in the vivarium must have an annual audiogram and meet the 50lb weightlifting requirement, in addition to the general animal user occupational requirements. If further considerations beyond basic hygiene and exposure notification are needed, those are addressed during the proposal of a new animal use protocol by the Institutional Biosafety Committee (IBC), EHS, and IACUC. KSU EHS maintains a record of all personnel who have undergone Occupational Health screening. In addition, the date of evaluation and any expiration date are entered into the individual's Cayuse record by EHS or other personnel with administrative access (the end user cannot enter their training information). This information is verified by the IACUC Office along with required animal care and use training as well as vivarium orientation (see below) before any final protocol approvals are granted.

The Animal Care Facility Manager provides mandatory Vivarium Orientation for any visitors or users, which is offered after an individual has undergone Occupational Health evaluation. First time animal users must complete a walkthrough of the facility with the Animal Care Facility Manager to become familiar with the exit/entry procedures/pathways, location of common supplies, and review of emergency exits to gain independent access to the vivarium (card access to the facility). This also includes demonstration of proper donning and doffing of personal protective equipment (PPE). Any visitors are always escorted by The Animal Care Facility Manager or their designee. Independent of IACUC protocol status, access to the facility will not be granted until the Occupational Health screening and training and Vivarium Orientation are complete. Details are found in facility SOP *ACF-200-02: Vivarium Entry and Exit Requirements and Procedures*. Access and personnel records are reviewed annually. Annual occupational health assessment and refresher training is required to maintain access to the vivarium, which includes review of the current SOPs and IACUC policies. Training records must be maintained by lab heads for their own personnel, and by the Animal Care Facility Manager for vivarium staff and others. In addition, SOP *ACF-200-02* indicates that disclosure of immunocompromising conditions is required annually or as conditions arise, and that information on risks to pregnant women can be obtained upon request. After a request or notification is obtained from an animal user or care staff, then situationally appropriate training and advice will be delivered.

KSU housekeeping staff enters the clean anteroom and locker room spaces that do not require PPE. They do not enter the vivarium or other laboratory spaces. Any cleaning/disinfection within the vivarium is performed by the Animal Care Staff. Facilities Maintenance and Public Safety personnel attend a first-time vivarium orientation and an annual refresher. When areas require maintenance, the Animal Care Facility Manager is notified at a minimum of 24 hours in advance (when possible), the vivarium space is

decontaminated, and personnel don appropriate PPE if needed to enter and perform maintenance. Mechanical staff attend training on entry and exit so that they may assist with emergent issues. If vivarium maintenance, construction, or repair work is performed in animal housing and procedure areas, team members will don appropriate PPE and/or be enrolled in the EHS Occupational Health screening as appropriate.

The response to an incident or injury is detailed in KSU policy document *ACF-200-01 Occupational Incidents and Injury Reporting for the Vivarium*. When an incident or injury occurs, personnel will first secure any animal back into their cage, if possible. Then, they will remove any contaminated PPE and wash the site for 15 minutes with soap and water while encouraging blood flow to the site. If a spill or splash occurs, personnel should tell others to avoid the area. Remove any contaminated PPE. Then personnel should administer first aid, if necessary. If eyes, nose, or mouth were exposed, they should flush with large amounts of water for 15 minutes with use of eye wash station or emergency shower. After first aid is administered, personnel must alert their supervisor with as many details of the incident as possible. Common details to be provided should include type of injury and where it occurred on the body, animal IDs/protocol number/PI name (if involved), what type of PPE was worn at the time of injury, room where incident occurred, and any witnesses present.

If further medical attention is needed, personnel can report to the third-party contractor Concentra Urgent Care Clinic at 220 Cobb Pkwy NW Ste. 400, Marietta, GA 30062 for evaluation between 7:30 am – 6:00 pm Monday-Friday and 9:00 am – 3:00 pm Saturday. If an incident occurs after hours, then evaluation and treatment are available at the Wellstar Kennestone Hospital Emergency Room (115 Cherry St, Marietta, GA 30060). The incident must be reported through the [KSU Human Resources](#) website within 24 hours. Once reported, EHS will initiate a review to determine if additional safety procedures can be implemented to prevent any similar exposure or injury from occurring in the future.

When protocols are submitted to the IACUC or when risks are identified, EHS conducts a full risk assessment and implements any additional safety procedures or recommends additional personal protective equipment necessary to minimize the specific hazard(s). This may include input from the IBC, Fire and Life Safety, the Office of Emergency Management, Environmental Compliance, and other relevant departments concerning the risk or use of materials.

There is no food or drink permitted in the vivarium. When entering the vivarium, personnel must wear a single pair of nitrile gloves, surgical mask, safety glasses (or splash proof goggles if there is a potential for splashes), hair bonnet, shoe covers, closed toe shoes, and disposable gown. Before exiting the vivarium, all users must remove all PPE according to protocol and wash their hands with soap and water.

The vivarium is designed with the *Guide's* standards and suggestions. Engineering controls in place include individually ventilated rodent cages, cage changing station, and Class II biosafety cabinets for experimental manipulations. Rooms are kept under negative pressure with a minimum of 10-15 air changes per hour. Dirty disposable rodent cages are autoclaved then disposed of properly according to manufacturer's and KSU waste management specifications. In addition to engineering controls, several administrative controls are put in place to ensure the health and safety of those within the vivarium. Standard Operating Procedures (SOPs) and training are provided to all that enter the vivarium and are relevant to their work and duties. Additional controls include hazard signage postings, wearing of PPE, , regular decontamination of procedure rooms, regular sanitation of animal rooms, and autoclaving and disposing of contaminated waste materials or incineration by a third-party vendor.

If specific PPE or practices are necessary for handling a particular species or hazardous agent, PPE is provided and training on the species or special use of equipment will be provided prior to the initiation of the protocol.

Animal users must complete training through multiple online platforms internal to KSU and provided by third-party vendors. In addition to general work safety training modules, animal users must complete basic animal care and use training and applicable species-specific modules through the third-party CITI training platform and/or AALAS Learning Library. This training includes general information about allergies and zoonoses, safe animal handling, and use of infectious agents or recombinant DNA in animals. KSU internal OwlTrain modules include ergonomics training, sharps handling, hazardous chemicals and labeling systems, and compressed gas safety.

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

See the *Facility and Species Inventory* table in Part X.

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

There are multiple training options offered to those using laboratory animals including online training modules and hands-on training. Users are required to take a basic animal care and use course via CITI and/or the AALAS Learning Library which includes content on the 3Rs, pain categories, humane endpoints, and prolonged restraint. Animal users are also required to take an online module specific to their animal subject species. There is a specific course on reducing pain and distress in laboratory mice and rats that is required for researchers utilizing rodent species. In addition, hands-on husbandry, handling, and basic research technique trainings can be provided by the Laboratory Animal Care Facility Manager. Those working within the vivarium must complete a hands-on proficiency assessment if they do not already possess the skills listed in their protocol from previous animal research experience.

The IACUC Members are required to complete a specific training, through the CITI platform and/or AALAS Learning Library, which includes information about IACUC member responsibilities, meeting procedures, protocol review, suspension of animal activities, semi-annual evaluations, and facility inspections. KSU has access to the AALAS Learning Library, with accounts provided for all committee members and animal users on campus. Assigned training for each user will address all required topics based on role and animal species. IACUC members will be provided with access to KSU's approved Animal Welfare Assurance.

The IACUC maintains a website (<https://research.kennesaw.edu/iacuc/>) that provides basic information about animal care and use, such as the PHS Policy and the *Guide*. This site is updated when new resources are identified that can provide additional training in any area, such as published webinars. In addition, the IACUC has an internal, firewall protected SharePoint site (accessible to all university personnel with valid credentials) which contains all animal care and use program documentation such as the IACUC policies and Animal Care Facility SOPs.

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 approved by the IACUC prior to implementation and reviewed by the IACUC at least every three years. In addition, any departures from the *Guide* will be identified in the semiannual report with the reasons for each departure.

Reports will also distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

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

[Note: if there are no changes to report, provide written notification that there are no changes.]

- 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: Karin Scarpinato	
Title: Vice President for Research	
Name of Institution: Kennesaw State University	
Address: <i>(street, city, state, country, postal code)</i> 585 Cobb Ave NW MD 0111 Kennesaw, GA 30144	
Phone: 470-578-6354	Fax: 470-578-9110
E-mail: kscarpin@kennesaw.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: 3/26/2024

B. PHS Approving Official	
<p>Name/Title: 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) 402-1922 Fax: +1 (301) 451-5672</p>	
Signature:	Date: March 26, 2024
Assurance Number: D22-01145	
Effective Date: March 26, 2024	Expiration Date: March 31, 2028