

Animal Welfare Assurance for Domestic Institutions

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

I. Applicability of Assurance

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

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
UConn Health
- 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 chief officer responsible for compliance with this assurance at UConn Health is the Associate Vice President of Research Integrity and Regulatory Affairs. For the purposes of this Assurance, the Associate Vice President of Research Integrity and Regulatory Affairs is the Institutional Official (IO) responsible for the assurance of compliance with this Policy. The Associate Vice President of Research Integrity and Regulatory Affairs reports to the President of the University of Connecticut through the Vice President for Research and the Provost.

The position responsible for the animal care and use program at UConn Health is the Director of the Center for Comparative Medicine (CCM). The Director, who is also the institution's Attending Veterinarian (AV) reports to the Associate Vice President of Research Integrity and Regulatory Affairs. There is a direct and open line of communication between the IO and the AV. The IACUC also reports to the IO through the Chair of the IACUC. In addition, the IACUC administrator reports to the IO. The IO has an "open-door" policy and is available to any member of the IACUC should the member have concerns, questions, or opinions regarding the animal care and use program.

The Chief Executive Officer of UConn Health (the President of the University of Connecticut) has delegated, in writing, the responsibility for appointment of members of the IACUC to the IO. The IACUC is responsible for activities that are conducted at UConn Health.

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

1) Name: Ramaswamy Chidambaram

Qualifications

- Degrees:

BVSc, MSc, PhD, and an ACLAM Diplomate

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

Dr. Chidambaram has over 20 years of experience in the field of laboratory animal medicine. As the Director of CCM, Dr. Chidambaram serves in a full-time capacity as the institution's Attending Veterinarian and has direct program authority and responsibility for UConn Health's animal care and use program, including access to all animals, and to exercise duties required by UConn Health policy, professional standards, and applicable regulations to ensure adequate veterinary care and ethical and humane use of animals. Dr. Chidambaram is available by phone 24 hours a day, 7 days a week. Dr. Chidambaram is a full voting member of the UConn Health IACUC. Dr. Chidambaram is the full-time attending veterinarian at UConn Health.

2) Name: Steven R. Wilson

Qualifications

- Degrees:

BS, VMD, and an ACLAM Diplomate

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

Dr. Wilson has over 30 years of experience in the field of laboratory animal medicine. Dr. Wilson services in an on-call, back-up capacity at UConn Health and is a clinical veterinarian at Yale University. In the absence of Dr. Chidambaram, Dr. Wilson has direct program authority and responsibility for UConn Health's animal care and use program including access to all animals and to exercise duties required by UConn Health policy, professional standards, and applicable regulations to ensure adequate veterinary care, and ethical and humane use of animals. Dr. Wilson has been appointed as an alternate to the AV on the UConn Health IACUC.

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

See attached current IACUC roster.

- 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:

Whenever the written program description is revised, it is placed in a shared folder (a common access area of UConn Health's computer network system) for committee members to review. The non-affiliated member of the IACUC also has access to this network system. During the committee meeting, members discuss and update the information as necessary. The IACUC will meet at least once every six months to review the UConn Health program for humane care and use of animals. The committee uses the *Guide* and other pertinent resources (e.g., *PHS Policy*, USDA AWARS) as a basis for the review. To facilitate the evaluation, the committee uses a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) animal care and use program; b) disaster planning and emergency preparedness; c) IACUC overview; d) IACUC protocol review; e) IACUC membership and functions; f) IACUC training; g) IACUC records and reporting requirements; h) veterinary care; i) personnel qualifications and training; j) occupational health and safety requirements; k) personnel security; l) investigation and reporting animal welfare concerns; m) clinical care and management; n) animal procurement and transportation/preventative medicine; o) surgery; p) pain, distress, anesthesia, and analgesia; q) euthanasia; and r) drug storage and control. If program deficiencies are noted during the review, they will be categorized as significant or minor and the committee will develop a reasonable and specific plan for correction and a schedule for correcting each

deficiency. A significant deficiency is one that is, or may be, a threat to the health and safety of animals. No member will be involuntarily excluded from participation in any portion of the program review.

- 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:

The IACUC procedures for conducting semiannual facility inspections are as follows: at least once every six months, members of the IACUC will visit all of the institution's facilities where animals are housed or used. Inspection teams are composed of at least two IACUC voting members in an area where USDA-regulated species are used and generally two IACUC voting members in all other areas. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the committee will develop a reasonable and specific plan for correction and a schedule for correcting each deficiency. A significant deficiency is one that is, or may be, a threat to the health and safety of the animals. No member will be involuntarily excluded from participation in any portion of the inspections.

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

Individual IACUC members will give their written observations to the IACUC administrator who will draft a written report summarizing the semiannual facilities inspections and program review. The report will contain a description of the nature and extent of the institution's adherence to the *Guide*, *PHS Policy*, and *AWARs*, identify specifically any departures from the provisions of the *Guide*, *PHS Policy*, and *AWARs*, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. UConn Health facilities are accredited by AAALAC-i and the report will identify the facilities as such. The report will be reviewed and signed by a majority of the IACUC members and will include any minority reports; if there are no minority opinions, the reports will reflect such. The completed reports will generally be submitted to the Institutional Official within 30 days following the evaluation.

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

The UConn Health IACUC has a policy regarding the handling of concerns or complaints involving animal care and use at this institution. Personnel, whether internal or external, have multiple ways to report any concern regarding animal care and use at UConn Health. Procedure notices are posted in all animal user areas (including the animal facility and the animal use common elevator). Personnel have the ability to lodge a formal written complaint (to the IACUC Chair, the IACUC administrator, the IO, or the AV), an anonymous complaint (this is generally through the IACUC administrator, but it may be to any agent listed above), or lodge a complaint to a toll-free reporting hotline.

When a complaint is reported, the IACUC Chair is informed. In general, the Chair informs the IACUC administrator who may collect initial information to bring to the IACUC for review and discussion. On a case-by-case basis, relying on the Chair's judgment, and that of

the IACUC and the AV, a minimum of a 3 member *ad hoc* subcommittee, consisting of members of the current IACUC, may be convened to investigate the complaint. The subcommittee is charged with reviewing the available data and interviewing all parties involved in the complaint. They are to determine whether the violation(s) are:

- 1) serious or continuing non-compliance with *PHS Policy*;
- 2) serious deviation from the provisions of the *Guide*; and/or
- 3) sufficiently serious to require that they be reported to NIH (via OLAW) and the USDA (if applicable).

The AV may be called upon as a consultant to the subcommittee in veterinary issues. A full report of the subcommittee's findings, plus recommendations for any action, will then be submitted to the IACUC via the IACUC administrator. When the IACUC has accepted the report and has agreed to the recommended action(s), the Chair reports to the IO and, as warranted, to OLAW and/or USDA. This same procedure would be used for both internal and external complaints. Reported concerns and all associated IACUC actions will be recorded in IACUC meeting minutes.

UConn Health has an institutional policy (2003-40, last revised on 2/17/15) that states: "The University encourages individuals to bring forward information and/or complaints about violations of state or federal law, University policy, rules or regulations. Retaliation against any individual who, in good faith, reports or who participates in the investigation of alleged violations is strictly forbidden. This policy does not protect an individual who files a report or provides information as part of an investigation that he or she knows is false, files a bad faith retaliation claim or participates in any illegal conduct. The University will take appropriate action, up to and including dismissal, against any employee who violates this policy."

- 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 regarding any aspects of the institution's animal program, personnel training, or facilities are discussed and developed by the IACUC. The committee's recommendations are included in IACUC meeting minutes or report of IACUC evaluations in a separate letter. Any recommendations are reported in the semi-annual report to the IO.

- 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 process for reviewing and approving programs using animals is initially based on completion of an Application for Animal Care and Use form. Information required for the application is consistent with requirements detailed in the *PHS Policy* and AWARs. We currently use an electronic animal protocol development and review system, Topaz Elements; therefore, all documentation is maintained in an electronic database.

The Principal Investigator (PI) completes an application form and it is submitted via Topaz. This submission goes to the IACUC administrator who generally reviews it for completeness

and accuracy (a pre-review). If there are significant problems with the submission, it is returned to the PI with a list of changes and/or clarifications that are required for a committee review.

When an adequately completed protocol is submitted, it is assigned as a full committee review (FCR) or a designated member review (DMR) by the IACUC administrator based upon criteria established by the IACUC. For all protocols, a veterinarian, the Institutional Biosafety Officer (BSO) and/or Committee Chemical specialist, the IACUC administrator, and one other primary scientific reviewer are assigned responsibility for the formal review.

For a protocol assigned a review assignment of FCR, the full IACUC meets on a monthly basis throughout the year. At least one week prior to the meeting, an agenda listing the protocols to be reviewed that month is placed in the IACUC computer network shared folder and posted in Topaz Elements. At each meeting, the IACUC is presented with a synopsis of the purpose of the study and the proposed animal use by the primary scientific reviewer. The IACUC may invite consultants to assist in the review of complex issues, but consultants do not have voting privileges. Possible outcomes of an FCR IACUC review include approval; modifications required, subsequent review by DMR; modifications required, subsequent review by full committee review; or disapproval of the application. As *PHS Policy* dictates, a quorum (defined as 50% of voting members plus one) of the IACUC must be present to conduct official business. A vote is taken after the discussion of the protocol of the IACUC members eligible to vote on any particular protocol.

For all review outcomes other than approval, the PI is sent a list of items which require changes in order to secure the approval of the submitted protocol through Topaz Elements.

An initial review of “modifications required, subsequent review by DMR” allows the re-review of the protocol to be done by a DMR review from the primary reviewers as per our IACUC Policy on Utilizing Designated Member Review which is compliant with the OLAW Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR), NOT-OD-09-035. All IACUC members have agreed in advance and in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modifications are necessary to secure approval. Any member of the IACUC has access to the revised protocol via the electronic protocol development and review system used at UCH and may request a FCR review of the revised protocol. Once the PI submits the required changes, it is sent to the primary reviewers for approval. All reviewers must be unanimous in their approval. An initial review designated “modifications required, subsequent review by FCR” requires the revision to be sent to the full committee and is reviewed as stated above.

Should a review designated “disapproved” occur, the PI is given the decision of the IACUC with a list of concerns that the IACUC had with regard to the protocol via the electronic protocol review system. The PI has the opportunity to request that the IACUC reconsider its decision via a written request sent to the IACUC administrator.

For a protocol assigned a review assignment of DMR, the IACUC administrator assigns the primary reviewers. The IACUC Chair is notified and either approves the review assignment or changes the assigned reviewers. At the same time, the full committee is notified via the Topaz Elements protocol system that there is a protocol they need to review to determine if anyone wishes to call for a full committee review. Committee members are asked to complete their Topaz Elements reviews, by a certain date, to indicate if they wish to call for a full committee review. Until the application is actually approved by all reviewers, it can be called to a full committee review if any committee member calls for it. The assigned reviewers may recommend approval, modifications required to secure approval, or they, themselves, may call for full committee review. DMR reviewer decisions must be unanimous; if not, the protocol will be referred to the full committee for review. No protocol for DMR review can be assigned a status of not approved; if any reviewer wishes to disapprove the protocol, the protocol must be assigned to a full committee review. Because of the use of Topaz Elements at UConn Health, all reviewers of a protocol have access to everyone else's review and can comment on whether or not they agree with a particular review comment. Each reviewer is aware of, and is required to agree with, each other's review and this is accomplished by the Topaz Elements system and the documentation efforts by the IACUC office. Only one version of the protocol can be reviewed at any time and this version contains reviewer comments. Though this has never been an issue to date, if the review opinions were subject to concern by any individual reviewer, all assigned DMR reviewers would meet to come to a consensus about the review of the protocol.

For all review outcomes other than approval, the PI is sent a list of items which require changes in order to secure the approval of the submitted protocol through Topaz Elements. The revised document, when received by the IACUC office, is sent to all DMR reviewers for their re-review and ultimate approval.

In order to approve proposed protocols, the IACUC conducts the review of those components related to the care and use of animals and determines that the proposed protocols are in accordance with PHS Policy. In making this determination, the IACUC shall confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity and that the protocol is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals and be consistent with sound research design;
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator;
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

- d. The living conditions of the animals will be appropriate for their species and contribute to their health and well-being. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;
- e. Medical care for the animals will be available and provided as necessary by a qualified veterinarian;
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures; and
- g. Methods of euthanasia used will be consistent with the recommendations of the *AVMA Guidelines on Euthanasia*, unless a deviation is justified for scientific reasons in writing by the investigator.

Any IACUC member who is listed as personnel on an animal care and use protocol cannot vote on the protocol. If an IACUC member is the PI on a submitted animal care and use protocol, s/he is asked to leave the room when the protocol is discussed by the committee. Should an IACUC member have a conflict of interest, even if they are not listed in the protocol, they are typically asked to leave the room while the discussion of the protocol is being performed by the committee unless the committee has some questions that this individual may be able to clarify. It is up to the IACUC administrator to ensure that a quorum of the committee is still present. If leaving the room results in a lack of a quorum, the protocol will be tabled until the next committee meeting.

- 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:

Modifications to approved protocols must be appropriately documented, reviewed, and approved. Modifications are submitted to the IACUC through Topaz Elements. The IACUC administrator, based on IACUC policies, determines if the modifications are minor or significant. Minor modifications are approved administratively, though this does not necessarily mean by the IACUC administrator; the IACUC administrator will send the modification to the appropriate administrative reviewer for review and approval. If the modification is determined to be major (significant), then the modification is reviewed by Designated Member Review (DMR), Full Committee Review (FCR), or Veterinary Verification and Consultation (VVC) review methods. Criterion for each route of review is detailed in IACUC policies. The policy on modifications to protocols has been carefully considered by the IACUC, taking into account any actions of the proposed changes that could have any negative impact on animal welfare. This policy is reviewed and re-approved by the IACUC every 3 years. If there are any questions regarding the modification's status as a minor or significant – or the route of review required – the IACUC Chair will make the final decision.

Minor modifications would include addition of qualified personnel, addition or deletion of funding sources, addition or deletion of room locations, <100% increase in rodent animal numbers, <25% increase in non-rodent animal numbers, the need to repeat an experiment, and the addition of animal strains (including the addition of transgenic or gene targeted lines). Minor modifications that are solely administrative in nature (addition of funding

sources, addition/deletion of personnel, changes in room assignments, addition/deletion of accounts, etc.) are reviewed by the IACUC administrator. Other minor modifications typically would be reviewed by the IACUC member who reviewed the original document or, if they are not available, by the IACUC Chair. Major (significant) modifications would include a change in the purpose or aim of the study, change in PI, $\geq 100\%$ increase in rodent animal numbers, $\geq 25\%$ increase in non-rodent animal numbers, addition of survival surgery, addition of painful procedures, housing of animals in a location that is not part of the animal program overseen by the IACUC, any changes that have the potential to impact personnel safety, and changes in – and additions of – new experimental procedures.

FCR review criteria of major modifications would include addition of major survival surgery, addition of painful procedures, use of death as an endpoint, and requests for exemptions to any regulations (including IACUC policies). DMR review criteria would include change in purpose or specific aim of a study, change in PI, housing of animals in a location that is not part of the animal program overseen by the IACUC, changes that have the potential to impact personnel safety, and addition of minor survival surgery.

VVC review criteria of major modifications would include changes to anesthesia and analgesics, addition of non-invasive sampling, addition of experimental substances (note: this may also require a safety review), change of euthanasia to any AVMA-approved method, and addition of sample collection times. These changes regarding duration, frequency, type, and number of procedures formed that have been assigned a VVC review cannot be new procedures. A policy detailing the evaluation criteria for a FCR/DMR/VVC review has been written and approved by the IACUC.

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

The IACUC, via the administrator, notifies investigators of its decision to approve or disallow approval of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval, by email once the review of a protocol or modification to an approved protocol is completed via the Topaz Elements electronic protocol development and review system. This system automatically generates an email to personnel listed on the protocol of the committee's decision. If the IACUC decides to deny approval of a protocol or modification request, it includes, in its written notification, a statement of the reasons for its decision and gives the investigator an opportunity to respond in person or in writing. The institution is notified via the IO who is sent the approved committee meeting minutes which contain all decisions of the IACUC by the IACUC administrator.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

All approved protocols are subject to annual review and, if active long enough, renewal every 3 years (33 months). The annual review is conducted as follows: the PI is sent an email, through the Topaz Elements system, that an annual review of the protocol is required. This email details the procedures to be used to start an annual review. In general, the annual review requests the following information: status of the project (active, inactive); any change in personnel; of any problems or adverse events; declaration of continuing check of availability to alternatives to animal use and potentially painful procedures and duplication of experiments; and future plans for the protocol.

All continuing reviews are performed by the full committee review method. Annual reviews are due in the 11th and 22nd month of life of the protocol. For example, if a protocol was approved in December 2017, the first annual review is due in November, 2018 and the second annual review is due in October, 2019 and it would expire in September, 2020.

All protocols expire in the 33rd month. In the above example, a PI would be sent notification in May of 2020 indicating that his protocol would need to be submitted as a “new” protocol by July of 2020. The submission would be reviewed as a new protocol in the manner described as above in section III.D.6. No work may occur after the expiration date of the protocol is reached. If a “renewal” protocol has not yet been approved, the animals are transferred to the institutional holding protocol and kept – this includes husbandry and veterinary care, but no experimental 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 may suspend an activity that it has previously approved if it determines that the activity is not being conducted in accordance with the description of that activity as provided by the PI in the Animal Use Protocol, applicable provisions of the Animal Welfare Act, the *Guide*, the institution's assurance, or the *PHS Policy*. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

The Institutional Official may temporarily halt an activity that the IACUC has previously approved in the case of serious or continuing non-compliance with IACUC approved protocol or governmental law or regulation, misuse or mistreatment of research laboratory animals, or previously unanticipated risk to the laboratory research personnel. The PI will be notified verbally or electronically with a follow up letter after the IACUC meets (generally within 3 business days) to discuss the temporary halt and determine if a suspension by the IACUC is warranted or if the temporary halt is lifted by the IACUC. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC

and with the suspension vote of a majority of the quorum present. The IACUC will review the reasons for suspension with the Institutional Official, take appropriate corrective action, and the Institutional Official will report that action with a full explanation to OLAW.

The AV may temporarily suspend an activity that the IACUC has previously approved in the case of serious misuse or mistreatment of research laboratory animals. The PI will be notified verbally or electronically with a follow up letter after the IACUC meets (generally within 3 business days) to discuss the temporary halt and determine if a suspension by the IACUC is warranted or if the temporary halt is lifted by the IACUC. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. The IACUC will review the reasons for suspension with the Institutional Official, take appropriate corrective action, and the Institutional Official will report that action with a full explanation to OLAW.

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

The Occupational Health and Safety Program (OHSP) is in accordance with the *Guide* and is extended to all personnel having contact with animals or animal tissues, including animal facility staff, investigators, students, and technicians. All individuals who will be handling animals at UConn Health are required to enroll in the Occupational Health Surveillance (OHS) program. The OHSP is under UConn Health Policy #2005-13 “Occupational Health Surveillance Program for Principal Investigators (PI), Researchers, Technicians, Center for Comparative Medicine (CCM) Staff, and Students Utilizing Animals in Research or Educational Programs”, last revised on 7/8/14. The Employee Health Service (EHS) provides pre-placement and periodic surveillance screenings, immunizations, and other procedures as recommended and required. All individuals meet with a physician or an APRN from the Employee Health Service/Department of Occupational Medicine (EHS) prior to working at UConn Health. During this visit, discussions regarding the use of animals are performed at that time. Every individual who uses laboratory animals is required to submit a form, supplied via the web from EHS, called a “Mandatory Annual Certificate of Enrollment” (MACE) form which will detail any changes in an individual’s status with regard to working with animals and hazardous substances and any health changes they might be experiencing. Individuals may be asked, by EHS personnel, to make an appointment at EHS as a result of their review of the MACE form.

The following table summarizes key aspects of the program:

Type of Contact	Reference
Rodents, Rabbits, and Birds	1, 2, 4, 5
Fish	1, 2, 4, 5
Animal Tissues	4, 5
Human Tissue in Animal Models	3, 4, 5

<u>Reference #</u>	<u>Measures To Be Provided</u>
1	Physical Exam (Mandatory for CLAC Employees, Offered to All Employees)
2	Tetanus Immunization (Every 10 years or after known injury on advice of physician)- recommended to all animal users (as shown above, this includes all vertebrate animals- warm and cold blooded including fish)
3	Hepatitis B Immunization
4	Annual OHS Enrollment
5	Post Exposure Incident Evaluation (Bites, Scratches, etc.)

Species currently used at UConn Health include mice, rats, hamsters, guinea pigs, frogs, fish, and rabbits.

In certain instances, non-animal users working in specific positions may have only incidental contact with animals. For example, Facilities Management personnel may briefly encounter animals while performing duties in the animal facility. Individuals who need access to the animal facility are provided with an informational handout which describes the risks associated with exposure to animals and their housing areas and how to get additional information on animal issues and health risks.

All protocols and modifications to approved protocols are reviewed by the Biological Safety Officer (BSO, a Certified Industrial Hygienist and Registered Biosafety Professional and the Institutional Biosafety Committee Coordinator) or the Chemical Safety Specialist (CSS) to identify potential hazards (such as infectious agents, chemical hazards, radionuclides, and/or toxins) associated with the submitted documents. A hazard assessment is performed based on what procedures with hazardous materials are required by the protocol. This also identifies if monitoring may need to be performed in anticipation of exposures to researchers. Should a hazard be identified by the BSO or CSS, an IACUC safety protocol (IACUCSP) may be required prior to IACUC approval of the proposal or modification. Control of routine hazards, such as perfusions with paraformaldehyde and exposures to anesthetic waste gasses, are not written up in IACUCSPs but are documented within the IACUC animal care and use protocol. The IACUCSP serves several purposes: a) as an OSHA hazard assessment to comply with the Personal Protective Equipment Standard (29 CFR 1910.132(d)); b) as a hazard warning and information to/for researchers about hazards with which they are working; c) as documentation of measures that will be taken to protect researchers from hazards; and d) how to properly dispose of soiled bedding and animal carcasses. Door signs provide a list of personal protective equipment that must be donned prior to entering the room. The IACUCSP is prepared by the PI in conjunction with the BSO or chemical safety specialist. Each IACUCSP is unique to the experiments being covered.

Personnel involved in incidents at UConn Health that result in personal injury report to their supervisors and then to the UConn Health Emergency Department. An incident report is filed with Human Resources after injuries are treated and every accident/incident report is reviewed by the EH&S office. The Environmental Health & Safety (EH&S) office may be called to assist with spills and exposures that researchers feel are beyond their capacity to address. Major or

life-threatening emergencies are responded to by on-campus fire, EMS, and/or police by dialing x7777.

UConn Health's OHSP is monitored at multiple levels. The UCH OHSP is under the direction of the UCH Employee Health Service/Division of Occupational Medicine. Occupational physicians and nurses have primary responsibility for the OHSP and evaluates all yearly OSH forms submitted by animal users. The CCM Director supervises the day-to-day operational aspects of CCM safety and compliance procedures. EH&S, represented by the BSO and CSS, oversees the occupational safety aspects. The IACUC administrator documents enrollment in the occupational health and safety medical surveillance program since enrollment in the program is a condition of protocol approval.

In addition to safety education and specific safety protocols for specific experiments, described above, UConn Health has comprehensive policies/guidelines on the use of hazardous materials that include:

- A comprehensive OSHA mandated Chemical Hygiene Plan that provides specific requirements on the controls that must be taken during the use of hazardous chemicals;
- UConn Health has adopted the CDC/NIH Guidelines, *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition, as its supplemental biosafety manual which, with the laboratory's IACUCSP and/or IBC registration, constitutes the biosafety manual for a given laboratory. The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2016, provides the basis for the operation of the Institutional Biosafety Committee (IBC);
- An OSHA mandated Bloodborne Pathogen Exposure Control Plan provides specific controls to be implemented during use of human materials; and
- A Radiation Safety Notebook for authorized users of radioactive materials that provides special guidance to the users on actions they must follow in order to comply with safety and Nuclear Regulatory Commission requirements;

General UConn Health safety policies have also been established by EH&S for other activities including policies on lockout/tagout of equipment, confined space entry, chemical hood performances checks, etc; and UConn Health's Hazardous Materials Waste Management Plan.

There are no institutional policies in place for personal hygiene, per se; however, this topic is part of the Chemical Hygiene Plan which details requirements on this matter. In addition, training in personal hygiene is given at three levels: during new employee orientation (required for all new employees), laboratory safety training (required for all new employees working in a laboratory setting), and during initial animal user training (required for all new employees who use animals).

Training is provided in the area of zoonoses via three routes. Zoonoses are discussed during initial animal user training (required by every individual who uses laboratory animals), it is

discussed during laboratory safety training, and it is discussed on our occupational health webpage. Every individual who uses animals is given the link to this webpage on a yearly basis and is asked to review the potential illnesses to which they may be exposed when using laboratory animals. Precautions to take during pregnancy, illness, or decreased immunocompetence are discussed during the initial animal user training to a limited extent; individuals are notified that they should contact EHS if they have questions related to these health conditions. Precautions for these populations are also discussed in animal safety protocols and on signage posted on specialty rooms.

- 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 attached current facility documentation.

- 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 program for the Humane Care and Use of Laboratory Animals is offered with the intent to certify attendance by all investigators, technicians, and personnel who handle or use laboratory animals and ensure that they are qualified to perform their duties. A new training handbook was written and approved by the IACUC in September 2004 and updated in January 2017 and is posted on the Health Center website. The overall training program provides guidance on the following:

1. Humane methods of animal maintenance and experimentation including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care of the various species used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals;
 - d. Aseptic surgical methods and procedures;
 - e. Euthanasia.
2. The concept, availability, and use of research or testing methods that limit the use of animals and minimize animal distress.
3. The proper use of anesthetics, analgesics, and tranquilizers for the animals.
4. Methods whereby deficiencies in animal care and treatment may be reported by UCHC employees.
5. Utilization of services available to provide information on:
 - a. Appropriate methods of animal care and use;
 - b. Alternatives to the use of live animals in research;
 - c. Prevention of unintended and unnecessary duplication of research involving animals; and,

- d. The intent and requirements of the Animal Welfare Regulations, US Government Principles, the *Guide*, and PHS Policy.
6. Moral and ethical considerations in the conduct of animal experimentation.
7. Instruction on the proper completion of the Application for Animal Care and Use form.
8. Occupational Health and Safety
 - a. Identification of hazards
 - b. Risk assessment / hazard control
 - c. Personal protective equipment and engineering controls
 - d. OHS oversight by IACUC
 - e. Laboratory animal allergies
 - f. Hazardous waste
 - g. Institutional safety resources (other trainings from the Office of Research Safety)
9. Working in the Animal Facility
 - a. Animal facility access
 - b. Facility security
 - c. Use of personal protective equipment
 - d. Requirements for cage identification
 - e. Working with hazardous substances
 - f. Animal imports and exports

Supplementary training, including hands-on training in the proper handling of animals, is provided by CCM as deemed necessary by the attending veterinarian and/or the IACUC. Additionally, the CCM and the IACUC both operate a World Wide Web server (<http://research.uchc.edu/animal/>) that provide investigators detailed information about UConn Health's animal care and use programs and includes several links to other information pertaining to the humane care and use of animals.

All PIs and their staff must renew their training every year. The IACUC develops a PowerPoint training every year that is uploaded to the UConn Health server. This training contains varying topics about which all animal users should be reminded. UConn Health also utilizes the Collaborative Institutional Training Initiative (CITI) web training. The IACUC office will notify researchers when training is required and will assign a module from the CITI program the researcher must complete. Records are maintained in the Topaz Elements system; therefore, all training records are linked to protocols so that when new protocols are submitted, or when protocols are being reviewed or modifications to add personnel to the protocol are being considered, the IACUC can see the training status of every person involved in the protocol and/or modification request.

The training of IACUC members is detailed in our IACUC Policy on Training IACUC Members. Once the individual is appointed to the IACUC, they will meet with the IACUC administrator. In this discussion, the new committee member will be introduced to the federal and state laws

and regulations which govern the use of laboratory animals as well as institutional policies and procedures.

The new committee members are given a copy of the following:

- The UCHC IACUC Committee Member Handbook;
- *The Guide for the Care and Use of Laboratory Animals*;
- Public Health Service Policy on Humane Care and Use of Laboratory Animals. This document includes the Health Research Extension act of 1985 and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- Animal Care (USDA) Policies;
- AVMA Panel on Euthanasia Guidelines;
- *Institutional Animal Care and Use Committee Guidebook*; and
- As a hard copy of the Animal Welfare Act and Animal Welfare Act Regulations are no longer readily available, the new committee member is provided with the link to these documents on the web.

The new committee member will be required to complete two training modules through CITIProgram.org. These include “Working with the IACUC” and “Essentials for IACUC Members”. The new committee member will be required to pass the examinations associated with these training modules. The new committee member will be trained on how to access the IACUC committee shared folder and how to access and use the Topaz Elements electronic protocol development and review system by the IACUC administrator.

UCH participates in webinars (OLAW, PRIM&R, and AAALAC) for continuing education of committee members. In addition, educational materials may be brought to committee meetings.

The IACUC office will be responsible for documenting all training activities of IACUC members here at the Health Center.

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 1 — 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.

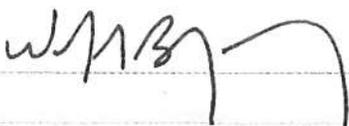
V. Recordkeeping Requirements

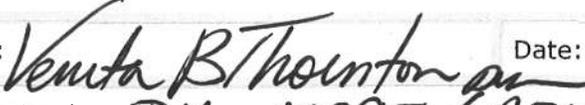
- A. This Institution will maintain for at least 3 years:
 - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Wesley Byerly.
 - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official.
 - 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: Wesley G. Byerly, Pharm.D.	
Title: Associate Vice President of Research Integrity and Regulatory Affairs	
Name of Institution: The University of Connecticut Health Center (dba UConn Health)	
Address: (street, city, state, country, postal code) 263 Farmington Avenue Farmington, CT 06030-1524 USA	
Phone: 860-679-6568	Fax: 860-679-2670
E-mail: byerly@uchc.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: 5/8/2018

B. PHS Approving Official (to be completed by OLAW)	
<p>Dr. Venita B. Thornton-Veterinary Medical Officer Office of Laboratory Animal Welfare National Institutes of Health RKL1, Suite 360-MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982</p>	
Signature: 	Date: 5/8/2018
Assurance Number: D16-00295 (A3471-01)	
Effective Date: 5/8/2018	Expiration Date: April 30, 2022

VIII. Membership of the IACUC

Date: July 18, 2017			
Name of Institution: The University of Connecticut Health Center (dba UConn Health)			
Assurance Number: A3471-01, D16-00295			
IACUC Chairperson			
Name*: Joseph Lorenzo			
Title*: Professor		Degree/Credentials*: MD	
Address*: (street, city, state, zip code) 263 Farmington Avenue Farmington, CT 06030-5456 USA			
E-mail*: jlorenzo@uchc.edu			
Phone*: (860) 679-1899		Fax*: (860) 679-1040	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
D. Bayarsaihan	Ph.D.	Assistant Professor	Scientist
M. Caimano	Ph.D.	Assistant Professor	Scientist
R. Chidambaram	BVSc, Ph.D.	Director, CCM	Attending Veterinarian
S. Clark	Ph.D.	Associate Professor	Vice-Chair
S. Crocker	Ph.D.	Assistant Professor	Vice-Chair
L. Haynes	Ph.D.	Professor	Scientist
K. Hoyt	BS, rLATg	Asst. Director, CCM	Scientist
T. Jensen	MHS	Research Associate	Scientist
E. Krisiunas	MPH	CEO WNNW International	Non-affiliated member
A. Medvedev	Ph.D.	Associate Professor	Scientist
A. Pohl	MS, rLATg, CPIA	IACUC Administrator	Scientist
L. Puddington	Ph.D.	Associate Professor	Scientist
D. Sasso	BS	Safety Specialist	Scientist
T. Sutak	Deacon	Deacon	Non-affiliated member, non- scientist
R. Wallace	Ph.D., CIH, RPB	Biosafety Officer	Scientist
C. Wu	Ph.D.	Professor	Scientist
S. Yee	Ph.D.	Director, GTTF	Scientist
S. Wilson	VMD	Back-up Veterinarian	Alternate for AV

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** [PHS Policy](#) Membership Requirements:

- Veterinarian* veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
- Scientist* practicing scientist experienced in research involving animals.
- Nonscientist* member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
- Nonaffiliated* individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

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

IX. Other Key Contacts (optional)

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

Contact #1	
Name:	Alison D. Pohl, MS, rLATg, CPIA
Title:	IACUC Administrator
Phone:	(860) 679-4129
E-mail:	pohl@uchc.edu
Contact #2	
Name:	
Title:	
Phone:	
E-mail:	

