

From: [AWAS Application](#)
To: [Samuel Traina](#); [REDACTED]
Cc: ThorntoV@mail.nih.gov
Subject: Assurance Renewal Clarification Letter - D16-00791
Date: Wednesday, July 10, 2019 1:02:32 PM
Attachments: [UnivofCaliforniaMerced-#D16-00791\(A4561-01\)-renewa.docx](#)

Assurance Clarification Letter

Thank you for your application for an Animal Welfare Assurance (Assurance). So that the processing of the Assurance can continue, we request clarification of the items listed in the attached document.



DEPARTMENT OF HEALTH and HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700-B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6700-B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

Date: July 9, 2019

Reference: Animal Welfare Assurance
Clarification Letter for **D16-00791 (A4561-01)**

Samuel J. Traina, Ph.D.
Vice Chancellor for Research and Economic Development
Institutional Official
University of California- Merced
5200 North Lake Road
Merced, CA 95343

Dear Dr. Traina:

Thank you for your correspondence of March 26, 2019 regarding the renewal of your institution's Animal Welfare Assurance (Assurance).

We request clarification of the items listed below, and ask that you submit your response to OLAW *by July 31, 2019*. Please submit a revised Assurance document with your current signature and date, incorporating the changes / clarifications described below. The revised Assurance document can be submitted by email as a scanned PDF attachment (signed and dated by the Institutional Official), to me at thorntov@od.nih.gov or to the Division of Assurances email at olawdoa@mail.nih.gov.

If, after reviewing the comments below and referring to the PHS Policy, and the OLAW website, you have any questions or desire assistance, please do not hesitate to contact us.

1. Part I. – Applicability of Assurance

a) Please update the Applicability section of the Assurance to include this statement:

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, DHHS, and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

b) **Part B. > “Institution” also includes the following names of any other institution, or branch and components of any other institution, covered by the Assurance:**

> Please indicate **“NONE”** in this section if it does not apply.

2. Part III. Section C. – Institutional Program for Animal Care and Use, IACUC Composition.

a) The IACUC members listed as **“# 3692 & # 3198” - (Non-scientist)** – may not meet the qualifications of the Designated Non-scientist IACUC member. The PHS Policy describes this member as *“one whose primary concerns are in a non-scientific area. The intent of the Policy is to have an individual with naïve attitude with regard to science and scientific activities.”* Please indicate if you feel that these individuals meet the qualifications as the Non-scientist member. However, this does not prohibit them from serving as a ‘general’ member on the IACUC. Please provide a revised IACUC Membership Roster.

3. Part III. Section E. – Occupational Health and Safety Program.

The “Guide for the Care and Use of Laboratory Animals” (“the Guide”) states that “an occupational health and safety program must be part of the overall animal care and use program.” Personnel would include the investigators, students who work with animals, the facility manager or supervisor and anyone else involved in the care and use of animals.

Please describe how the OS&H Program at your institution addresses the following issues / items ~

- a) Does the medical evaluation or collection of a health history meet federal, state and local [HIPAA regulations for privacy](#), as part of the risk assessment process? This is a required component of the occupational health and safety program. Please state this specifically in the description.

Again, if you have questions or desire assistance, please do not hesitate to contact me by phone at (301) 451-4208 or by email: thorntov@od.nih.gov . I look forward to receiving your institution's revised Animal Welfare Assurance document soon.

Sincerely,

X

Venita B. Thornton, DVM, MPH

Venita B. Thornton, DVM, MPH
Senior Assurance Officer
Office of Laboratory Animal Welfare

cc:
IACUC Chairperson
Regulatory Compliance Officer / Administrator

From: [REDACTED]
To: ThorntoV@mail.nih.gov
Cc: [Samuel Traina](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00791
Date: Tuesday, July 30, 2019 10:30:00 AM
Attachments: [image001.png](#)
[Revised Assurance renewal A4561-01 \(D16-00791\).pdf](#)

Dear Dr. Thornton,

Please find attached the revised assurance from UC Merced (D16-00791/A4561-01) addressing all matters identified in the clarification letter (dated 7/9/19).

Kind regards,

[REDACTED]



[REDACTED]
[REDACTED]
5200 Lake Road | Merced, California 95343
[REDACTED]

BUILDING THE FUTURE IN THE HEART OF CALIFORNIA

From: AWAS Application [mailto:donotreply@mail.nih.gov]

Sent: Wednesday, July 10, 2019 1:01 PM

To: Samuel Traina <straina@ucmerced.edu>; [REDACTED]

[REDACTED]
Cc: ThorntoV@mail.nih.gov

Subject: Assurance Renewal Clarification Letter - D16-00791

Assurance Clarification Letter

Thank you for your application for an Animal Welfare Assurance (Assurance). So that the processing of the Assurance can continue, we request clarification of the items listed in the attached document.

Domestic Assurance Sample Document

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. U.S. institutions receiving PHS funds through a grant or contract award are to use the Animal Welfare Assurance for Domestic Institutions (Domestic Assurance).

The Domestic Assurance should **not** be used by:

- Foreign institutions
- Institutions that currently do not have their own animal care and use programs
- Institutions that are proposing animal activity to be conducted solely at a collaborating institution

If one of these bullets describes your institution or if you don't know whether your institution is required to submit an Assurance, contact us at olawdoa@mail.nih.gov for guidance.

How to use the sample document

We have provided this sample document to help you develop an acceptable Domestic Assurance. Specific instructions, information, and recommended references are provided in italicized text and should be deleted from the final document. Please strive for clear concise text. It will be easier for you to complete and for us to review the Assurance if you follow the format of this sample.

One or two page attachments can be used to provide the following:

- Organizational structure of the animal care and use program
- IACUC membership roster
- Facility and species inventory
- Most recent semiannual report of program and facilities. This is needed **only** for Category 2 programs, those not accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

All other program elements are to be described in the body of the Assurance. Do not send any other attachments. We do not accept additional documents, appendices, binders, or manuals.

Tip: If you are not familiar with the PHS Policy or are preparing an Assurance for the first time, we encourage you to visit the [PHS Policy Tutorial](#).

How to submit

Fax your completed Assurance to 301-915-9465 or e-mail to olawdoa@mail.nih.gov

Questions?

Contact the Division of Assurances by phone at 301-496-7163 or e-mail olawdoa@mail.nih.gov

Additional references

- Domestic Assurance webpage, <http://grants.nih.gov/grants/olaw/sampledoc/assur.htm>
- OLAW Online Seminar "Writing a Good Assurance," http://grants.nih.gov/grants/olaw/educational_resources/webinar_06092011.htm
- OLAW homepage, <http://grants.nih.gov/grants/olaw/olaw.htm>
- PHS Policy, <http://grants.nih.gov/grants/olaw/references/phspol.htm>

Animal Welfare Assurance for Domestic Institutions

I, [Samuel Traina](#), as named Institutional Official for animal care and use at [University of California, Merced](#) 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, DHHS, and/or NSF. This Assurance covers only those facilities and components listed below.

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

[Office of Research and Economic Development](#)
[Department of Animal Research Services \(DARS\)](#)
[School of Engineering](#)
[School of Natural Sciences](#)
[School of Social Sciences, Humanities and Arts](#)

[University of California Agriculture and Natural Resources](#)

- B. The following are other institution(s), or branches and components of another institution:
NONE

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:

See Attachment 1

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

- 1) Name: Katherine Wasson Clark

Qualifications

- Degrees: DVM, PhD, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Clark is a diplomate in good standing in ACLAM and has worked in laboratory animal medicine since 1995. Her experience includes regulatory, clinical and research duties as pertains to laboratory animal medicine in academic and private research settings.

•

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

Time contributed to program: Dr. Clark is a part time employee, working 20 hours per month. She contributes 100% of her time to the animal care and use program

Backup veterinary medical care is provided by the University of California Davis, Teaching and Research Animal Care Services (TRACS) Veterinary Services by the following individuals:

- 2) Name: [REDACTED]

Qualifications

- Degrees: DVM, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: [REDACTED] has 21 years' experience in laboratory animal medicine.

Responsibilities: [REDACTED] provides management and oversight of TRACS Veterinary Services (e.g., staff, budget), directly supervises staff veterinarians, and acts as a liaison between TRACS Veterinary Services and TRACS Husbandry Services. As a clinical veterinarian, [REDACTED] covers approximately one-third of the animal areas providing clinical care, project support, veterinary pre-review of protocols, and serves as an alternate to the Attending Veterinarian on the UC Davis IACUC and Institutional Biosafety Committee.

[REDACTED] is an Associate Clinical Professor in the Department of Medicine and Epidemiology, School of Veterinary Medicine, and serves as [REDACTED]

Time contributed to program: On an as-needed basis for emergency backup veterinary care

- 3) Name: [REDACTED]

Qualifications

- Degrees: DVM, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: [REDACTED] has 13 years' experience in laboratory animal medicine.

Responsibilities: [REDACTED] provides clinical management of animals, regulatory compliance, research support as needed to numerous investigators and teaching and training of veterinary students, residents, veterinary pre-review of protocols, and rotating interns. [REDACTED]

[REDACTED] serves as an alternate to the Attending Veterinarian on the UC Davis IACUC

Time contributed to program: On an as-needed basis for emergency backup veterinary care

4) Name: [REDACTED]

Qualifications

- Degrees: DVM, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: [REDACTED] has 6 years' experience in laboratory animal medicine.

Responsibilities: [REDACTED] manages the TRACS veterinary clinic, provides clinical management of animals, veterinary pre-review of protocols, and regulatory compliance. [REDACTED] provides research support as needed to numerous investigators and teaches veterinary students, residents, and rotating interns. [REDACTED] serves as an alternate to the Attending Veterinarian on the UC Davis IACUC.

Time contributed to program: On an as-needed basis for emergency backup veterinary care

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.

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:

The Institution's program for humane care and use of animals is reviewed at least once every six months at a convened IACUC meeting. The OLAW checklist is used when conducting semiannual program evaluations. IACUC membership and functions, records and reporting, veterinary care, personnel qualifications and training, and the institutional occupational health and safety program are categorized in writing as acceptable or having minor or significant deficiencies. Each deficiency is further annotated with a plan for correction and date that the correction is completed. All IACUC members are given the opportunity to participate in the semiannual evaluations/program reviews. The program findings are reviewed and approved by quorum at a convened IACUC meeting.

- 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 Institution's animal facilities, including animal housing, support and procedures areas; aseptic, non-survival and rodent surgeries; and laboratories are inspected at least once every six months. The OLAW checklist is used when conducting semiannual facility inspections. All IACUC members are given the opportunity to participate in the semiannual facility inspections however, a minimum of two voting IACUC members is required to conduct the inspection. These voting IACUC members inspect all areas of the animal facility including those areas that may house USDA covered species. Inspection findings are categorized in writing as acceptable or having minor or significant deficiencies. Each deficiency is further annotated with a plan for correction and date that the correction is completed. Inspection findings are reviewed and approved by quorum at a convened IACUC meeting.

- 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:

Reports are submitted in memo form to the Institutional Official. This memo includes a summary of evaluation of the animal care and use program, inspection of the facilities, minority views and IACUC member signatures. Deficiencies are described as minor or significant and include a reasonable and specific plan and schedule for correction for each deficiency. When deficiencies are found during semi-annual inspections, if possible, they are corrected immediately, on site, in view of the inspecting IACUC members. If correction cannot be done immediately, the IACUC director, the IACUC chair and facility director discuss a reasonable time period in which the deficiency can be corrected. The semiannual reports to the Institutional Official reflect whether a deficiency has been corrected or the timeline/deadline for correction. A description of the nature and extent of the institution's adherence to the *Guide for the Care and Use of Laboratory Animals* is included in the semiannual report. Any departures from the *Guide* are identified specifically and reasons for each departure are stated and reported to the Institutional Official each six-month reporting period during which the IACUC approved departure is in place.

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

Concerns regarding the care and use of animals at the Institution can be submitted verbally, in writing or anonymously to any IACUC member, Attending Veterinarian, Institutional Official, or the individual's supervisor. In the latter case, supervisors are required to relay concerns to any IACUC member, Attending Veterinarian or Institutional Official. The IACUC chair in consultation with the Attending Veterinarian and Institutional Official will immediately address concerns. Results of investigation, communication and resolution will be discussed and documented in the minutes at the next IACUC meeting. Significant deficiencies and issues of noncompliance will be reported to the Office of Laboratory Animal Welfare in a timely fashion. The Institution follows the University of California Policy for Protection of Whistleblowers from Retaliation and Guidelines for Reviewing Retaliation Complaints (<http://www.ucop.edu/uc-whistleblower>). The mechanisms for reporting concerns, including contact information of whom to report to and instructions on how to report, are posted in the animal facility as well as on the DARS and Office of Research Compliance & Integrity (RCI) websites (<http://rci.ucmerced.edu/iacuc/reporting-animal-concerns>).

- 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:

All recommendations from the IACUC regarding the animal program, facilities, personnel training or other animal-related issues are made in memo form to the Institutional Official.

- 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:

An IACUC-reviewed and approved animal care and use protocol must be in place prior to any animal procurement or activity. The "Animal Use Protocol Application" is available electronically to all animal users on the Institution's website, and includes information on number, type and source of species used; description of proposed animal use; search for alternatives; summary of procedures; drugs to be used and method of euthanasia. Once completed, the protocol is submitted electronically to the IACUC staff office. It is assigned a tracking number and distributed to all committee members by use of the institution's project collaboration and courseware system. E-mails are generated when new material is added to the system, and all members receive e-mail reminders prior to each IACUC meeting. Two IACUC members are assigned as primary and secondary reviewers and present each protocol at the next scheduled IACUC meeting. All protocols also undergo a veterinary review.

IACUC meetings are scheduled in advance at the start of each semester and held every month of the year. In addition to the electronically distributed material, hard copies of protocols are distributed at every meeting. Each protocol is presented and discussed at the meeting. If a quorum of voting members is present ("full committee review"), the committee may vote by simple majority to approve, require modifications in order to secure approval, or withhold approval of the protocol. If a quorum of voting members is not present, the protocol or modified protocol (once received back from the

investigator) is redistributed electronically to all committee members. Members are given 72 hours to request full committee review. If full committee review is not requested, the IACUC chair assigns two committee members to review the protocol or modified protocol ("designated member review"). They may approve the protocol, require additional modifications in order to secure approval, or request full committee review. Designated review may not result in withholding of approval. If the designated reviewers differ on their protocol decision, the protocol goes back for full committee review.

If an IACUC member has a conflict of interest with a protocol, they are excused from the room during discussion of and voting on that protocol.

This Institution does not conduct alternate processes, procedures, or expedited reviews of protocols.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Changes in ongoing research projects are handled as protocol amendments at this institution. Amendments are submitted on the "Project Revision/Modification Form", available electronically on the institution's website. Significant changes to a protocol include, but are not limited to, changes in animal species used; requests for additional animals; changing from non-survival to survival surgery; or changes in method of euthanasia or anesthesia. Significant changes must not be implemented without review and approval by the IACUC. Once received by the IACUC staff office the amendment is assigned a tracking number and distributed to all committee members by use of the institution's project collaboration and courseware system. The process for reviewing and approving amendments is similar to that for protocols. Each amendment is presented and discussed at the meeting. If a quorum of voting members is present ("full committee review"), the committee may vote by simple majority to approve, require modifications in order to secure approval, or withhold approval of the amendment. If a quorum of voting members is not present, the amendment or modified amendment (once received back from the investigator) is redistributed electronically to all committee members. Members are given 72 hours to request full committee review. If full committee review is not requested, the IACUC chair assigns two committee members to review the amendment or modified amendment ("designated member review"). They may approve the amendment, require additional modifications in order to secure approval, or request full committee review. Designated review may not result in withholding of approval. If the designated reviewers differ on their decision, the amendment goes back for full committee review.

- 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 investigator is notified in writing of the results of the IACUC protocol review, with an explanation of needed modifications if appropriate. If the IACUC withholds approval of a protocol, no animal work or procurement can begin. In addition to receiving written explanation as to why approval is withheld, the investigator is encouraged to consult with the IACUC Chair and/or Attending Veterinarian prior to resubmitting the protocol. All communication to the investigator regarding protocol decisions is made available electronically to the IACUC and the Institutional Official. In addition, the Institutional Official is kept informed of the IACUC's decisions and program as a whole through regularly scheduled meetings with the Attending Veterinarian, Director of the Department of Animal Research Services and the IACUC Executive Committee. The IACUC Executive Committee consists of the Institutional Official, Attending Veterinarian, IACUC Chair, IACUC Vice Chair, Director of Animal Research Services, Animal Care Supervisor and the Director of Research Subject Protection.

- 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 animal protocols go through an annual review process by either full committee review or designated member review (see section 6 above). The annual review process involves obtaining paperwork from the principal investigator that documents any potential changes to procedures or personnel. These annual reports are discussed at a regularly convened IACUC meeting.

Additionally, all proposed changes to a protocol are reviewed through an amendment process prior to initiation (see section 7 above). Amendments are reviewed by the IACUC by either full committee review or designated member review.

Postapproval monitoring of ongoing and previously approved animal activities is performed through a variety of mechanisms, including annual review of approved protocols and amendments to approved protocols described above. Laboratory and procedure space where animal work is performed is inspected twice a year by a minimum of two voting IACUC members as part of the semiannual inspections. Monthly veterinary rounds are performed by the Attending Veterinarian. These rounds include assessment of animal care; inspection of surgical and procedure areas; and review of health, anesthetic and surgical records. Rounds are documented and a copy provided to the vivarium director. In addition, vivarium staff have access to and monitor protocol procedures as they take place in the facility and report all instances of where they might think there are unapproved deviations from documented protocol. This is done on an ad hoc basis.

All protocols expire three years after initial approval date. The investigator will be contacted prior to the expiration of the protocol and will be required to rewrite, update (as needed) and resubmit the protocol if animal use is ongoing. The resubmitted protocol is considered a new animal care and use protocol, assigned a new tracking number, and undergoes full IACUC review (see section 6 above).

- 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 Attending Veterinarian has the authority to stop animal use for humane reasons or protocol deviations pending IACUC review of an incident. Upon review, the IACUC has the authority to suspend animal activity after a majority vote at a convened meeting involving a quorum of members. In consultation with the Institutional Official and Attending Veterinarian, the IACUC will determine and execute appropriate corrective action. These will be documented in meeting minutes. The investigator is informed of the IACUC's decision and action(s) in writing. An electronic copy is made available to the Institutional Official. The Institutional Official, in conjunction with the IACUC, will review the reasons for suspension of animal activity and protocols, take appropriate corrective action, and report that action with a full explanation to OLAW in a timely fashion.

- 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:

A number of institutional programs and service organizations have been established to address injury and illness prevention and to mitigate specific concerns relating to maintaining and promoting a safe and healthy environment for the campus community. The three primary occupational health and safety organizations are the UCM Office of Environmental Health & Safety (EH&S), Occupational Health Services (UC Davis), and Olivewood Meadows Occupational Health Clinic.

EH&S is responsible for tracking developments in environmental health and safety laws and regulations. Detailed descriptions of how specific risks are managed for individuals working with animals and hazardous agents are presented in the appropriate sections below.

Occupational Health Services at UC Davis is a UC systemwide medical clinic (based on the UC Davis campus) that offers work-related preventive medicine and injury & illness prevention services, and OSHA- and departmentally-mandated medical surveillance programs. Medical surveillance is provided by Occupational Health Medical Professionals. The system meets the federal, state and local HIPAA regulations for privacy.

Olivewood Meadows Occupational Health Clinic provides treatment for work-related injuries and illness as well as preventive treatments outlined by UC Davis Occupational Health Services physicians.

1) Personnel Training

a) EH&S provides training in general laboratory safety, hazardous materials spill, biological safety, blood-borne pathogens, field safety, and several other in-person or online courses, with refresher training as required by law. Additional courses include hazardous waste disposal, personnel health, and use of fume hoods and biological safety cabinets.

EH&S and the IACUC provide guidance on wildlife studies, teaching protocols and assists with the development of field safety plans.

The Department of Animal Research Services (DARS) provides an Occupational Health and Safety Manual to faculty using animals in research and teaching. The manual covers: the University Policy; description of the OHSP; staying healthy in the vivarium; asthma and allergy in animal handlers; common zoonotic agents; a species specific guide; and safety procedures in the use of laboratory animals.

b) EH&S and DARS staff provide training for animal care staff on the safeguards that should be observed when working with animals exposed to hazardous agents, as well as other facility and task-specific safety topics. In addition, pregnancy and health/immune status are addressed during safety training for DARS staff.

c) Investigators receive initial training from EH&S; however, investigators are responsible for providing research personnel with lab-specific training regarding chemical safety, microbiologic and physical hazards, handling of waste material, and personal hygiene as appropriate for the risks imposed by their work environments. The need for specialized training regarding the use of hazardous agents in animals is also evaluated by the IACUC and DARS during the protocol review process and communicated to animal care supervisors and/or investigators as needed so that laboratory SOP's are developed to ensure health of personnel and lab safety practices.

2) Personal Hygiene and Protection

a) Animal care personnel are provided with scrubs worn only while working in the animal facilities. The clothing is laundered in house or by a commercial laundry service. Additional protective clothing is provided as needed and includes dedicated safety work shoes or boots, eye goggles, face shields, work/exam gloves, disposable coveralls, facemasks, head covers, and shoe covers. The EH&S Respiratory Protection Program provides fit testing of respirators and training in their proper use. All outer protective clothing worn in rooms where hazardous or infectious agents are used is handled as hazardous waste as outlined in the various EH&S Use Authorizations and the Animal Room Safety Sheet. There are no facilities for the use of BSL3 or BSL4 level agents at this institution.

b) There are sinks in procedure rooms, the cage wash facility, and the office and locker room area. Employees remove gloves and wash their hands as they leave the animal housing area, procedure rooms, and cage wash facility. Locker rooms with showers are also provided. Employees change into street clothes before leaving the facility. DARS policies prohibit eating or drinking in any of the animal facilities or support areas. A dedicated lunch room area is located in the facility. Currently, institutional policy prohibits smoking anywhere on campus property.

3) Medical Evaluation and Preventive Medicine for Personnel

a) The occupational health program for persons with animal contact is administered by the IACUC, DARS, and EH&S. Enrollment in this program is currently free to the participant and required for all faculty, students and staff, volunteers, visiting researchers, and non UC collaborators who are listed on an Animal Care and Use Protocol or work with live vertebrate animals in research or teaching whether they are on campus or in the field. All DARS personnel who work in animal facilities or have contact with laboratory animals or animal tissues are required to participate in the program. The DARS Director is responsible for ensuring that all DARS employees participate in the program. DARS funds the program for all DARS participants. All individuals (including investigators) must be cleared through the Occupational Health Services system prior to initiating any work with animals.

b) Initial Medical Assessment Process

1. Create Risk Assessment – The supervisor creates a Risk Assessment (RA) for the participant.
2. Review Risk Assessment – The participant reviews the RA and accepts or rejects it if changes are needed.
3. Health Questionnaire – After accepting the RA, the participant fills out the confidential Health Questionnaire (HQ) and submits for review by Occupational Health Medical Professional.
4. Medical Assessment – The Occupational Health Medical Professional reviews the participants' RA and HQ and sends a medical assessment for the participant to review.
5. Review and Acknowledge – The participant logs into Occupational Health Services system and reviews/acknowledges the medical assessment. If there are questions from the health professional on either the HQ or RA, or if services are needed, a response from the participant will be needed to complete the process.

c) On-going Assessments

1. The need for additional reviews, evaluations, and services will be determined by the Occupational Health Medical Professional, based on the current assessment, the individual's annual injury records, and reported health status changes.
2. The Investigator is responsible for updating the risk assessment when there are changes in work assignments (i.e., change in species, contact levels) for participants.
3. Individuals listed on Animal Care and Use Protocols are responsible for updating their personal health records.

d) Ancillary personnel will be provided information on their need for entry into animal care facilities. This training will include the following: 1.) availability of and the option to request medical evaluations and treatment; 2.) general information on potential hazards (zoonoses, allergies and injuries); 3.) universal precautions and personal hygiene; 4.) other potential health and safety hazards; 5.) link to Hazard Analysis Tool (<http://safety.ucdavis.edu/IACUC/risktool/index.cfm>); 6.) advice to contact the occupational health care provider for consultation if they are pregnant, immuno-compromised, diabetic, or have a history of allergies or other significant medical conditions.

4) Animal Experimentation Involving Hazards

a) Institutional policies governing experimentation with hazardous agents are as follows:

- i. Biologic agents: Individuals using infectious or toxic biological materials must obtain prior approval and a Biological Use Authorization (BUA) from the institutional biosafety committee. Infectious or toxic biological materials include microorganisms pathogenic to humans classified at or above Biosafety Level 2, recombinant DNA experiments covered by the NIH Guidelines Involving Recombinant DNA Molecules, human fluids or tissues for which Cal/OSHA requires the observance of universal precautions under the Blood-borne Pathogens Standard, and toxins. The Occupational Health Medical Professional will assess the need for serum-banking and serological surveillance when a substantial risk of illness is associated with the agent and methods are available to measure immunologic response to the agent.
- ii. Chemical agents: A written plan that describes procedures for the safe handling of regulated carcinogens must be developed in consultation with the chemical hygiene officer in EH&S. Animal research involving other suspect carcinogens, teratogens and mutagens is subject to review by EH&S, which provides requirements for the safe handling and disposal of the materials involved. Safety programs for the use of

hazardous chemicals are also mandated by state law. Each department must establish a written Injury and Illness Prevention Program that includes the following elements: identification and evaluation of workplace hazards; proper labeling of hazardous chemicals; availability of Safety Data Sheets; periodic self-inspections; and training of all personnel who handle hazardous substances. State law also requires each laboratory that uses hazardous chemicals to develop a Chemical Hygiene Plan that defines procedures for handling chemicals, controlling exposure, and informs personnel that medical consultation is available. The plan must also describe emergency procedures, and special safeguards for handling highly toxic chemicals, reproductive toxins, and regulated carcinogens. Standard Operating Procedures for these latter materials must be developed in consultation with EH&S.

iii. Physical agents: Individuals using radioisotopes or ionizing radiation must obtain prior approval and an annual permit from the Radiation Safety Officer in EH&S. Sites where radioisotopes are used are inspected quarterly by technical staff of the EH&S to evaluate compliance with use permits, and sealed sources are inspected semiannually. Persons who could reasonably be exposed are subject to personal monitoring. Purchase and distribution of isotopes are controlled centrally by EH&S to ensure that only approved agents and quantities are obtained.

b) All proposed uses of hazardous agents in animals must be described in the animal use protocol and are preliminarily screened by DARS and the IACUC. However, the investigator is responsible for submitting protocols or other necessary documentation to the respective committee or EH&S safety officer responsible for ensuring compliance (i.e. Institutional Biosafety Committee, Chemical Hygiene Officer, or the Radiation Safety Officer). Review and approval for the use of hazardous substances in animals will not begin until the Investigator and the IACUC have been notified that approval has been obtained from the other appropriate office or committee.

An additional mechanism for ensuring that proposed uses of hazardous substances receive prior review and approval involves the forwarding by the Sponsored Projects Office to EH&S of all grant applications that propose the use of infectious agents, radioisotopes, and toxic gases. EH&S staff bring these applications to the attention of the appropriate safety committee for review and approval.

Husbandry practices to ensure personnel safety include proper labeling of cages, double-bagging and labeling of contaminated waste, and monitoring and disposal of waste by EH&S.

d) Personnel working with radioisotopes must comply with the handling precautions described in their Radiation Use Authorization (RUA). Handling and containment of hazardous chemicals must conform to the laboratory's Chemical Hygiene Plan.

e) Anesthetic gases are scavenged by fume hoods, dedicated exhaust systems, or with activated charcoal canister filters in all procedure areas. All hoods and cabinets are used according to the manufacturer's specifications for effective protection. All fume hoods are checked by EH&S annually. All biosafety cabinets are certified at least annually by a contract service. Any failure of a hood, cabinet or their components must be reported to EH&S or DARS immediately and work stopped until properly functioning equipment is available.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

The IACUC ensures that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This is implemented through job training (for animal care staff), the UC Merced Animal Care and Use Training Manual

(distributed to all research staff), and a web-based lab animal course that is mandatory for all animal users (administered by subscription to the Collaborative Institution Training Initiative; see <http://www.citiprogram.org>). In addition, hands-on laboratory animal skills classes, aseptic techniques courses for rodents, and one-on-one veterinary assistance or training tailored to investigators' needs or at the IACUC's request are offered. IACUC members are given a copy of the UC Merced IACUC Handbook and enroll in a mandatory, web-based IACUC course (administered by subscription to the Collaborative Institution Training Initiative; see <http://www.citiprogram.org>). IACUC members also attend an orientation presented by RCI staff prior to attending their first meeting. During this orientation, the IACUC members are presented with information including but not limited to the key components of the UC Merced program, responsibilities of the IACUC, Veterinary Care Program, Occupational Health and Safety Program, researcher responsibilities, regulations governing animal research, history and background, the three Rs, and IACUC review process. At the time of this orientation, the new members are provided the PHS Policy, OLAW/ARENA IACUC Guidebook, AVMA Guidelines on Euthanasia, Guide for the Care and Use of Laboratory Animals 8th Ed., additional related background materials and a quick reference guide with links to all key resources. All IACUC members are provided electronic access to the Animal Welfare Assurance, AAALAC Program Description, UCM IACUC handbook and all materials related to the UCM program. Physical copies of these documents are provided during regularly scheduled IACUC meetings. Additionally it is recommended that all IACUC members attend IACUC Basics or IACUC 101 and other offered trainings and workshops. RCI staff, the AV, Director of DARS and subject matter experts provide continuing education and training session during convened IACUC meetings and scheduled workshops. Training of all scientists, research technicians, animal technicians and IACUC members is documented in employee training records, animal care and use protocols and/or IACUC training records (as appropriate) and maintained by the IACUC Office. Qualifications of personnel using animals are reviewed regularly to fulfill the research Institution's responsibilities.

The IACUC ensures that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility is fulfilled in part through the provision of training and instruction to those personnel.

Animal Care and Use Training Manual

All investigators involved in the care and use of animal subjects have access to a copy of the "UCM Animal Care and Use Training Manual." Investigators are required to keep a copy of the manual in his/her laboratory for the use of all personnel. Investigators are expected to review the manual prior to completing Animal Care and Use Protocols and to ensure that all staff and students under their supervision are also familiar with the regulations and policies outlined in the manual. The manual is a key component of the IACUC's training program as it describes: (a) applicable regulations and policies governing the use of animal subjects; (b) animal acquisition, housing and husbandry practices; (c) the occupational health and safety program; (d) veterinary care; (e) guidance on selecting the most appropriate animal models; (f) the availability and consideration of alternatives to the use of laboratory animals; and (g) ethical and humane considerations in the use of animals for research. The manual is also an important reference tool for animal researchers with its various supplements including: (a) guidelines for the choice and utilization of tranquilizers, analgesics and anesthetics in laboratory animals; (b) the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition; (c) IACUC guidelines of acceptable standards for various commonly used procedures involving animals; and (d) a copy of the Institution's Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals.

Training for Department of Animal Research Services Staff

Training of animal care staff is provided in house. Department of Animal Research Services (DARS) staff may also be sent to other campuses for formal training. Training conducted at DARS staff meetings covers such topics as safety in the workplace, general zoonoses, overall health surveillance of the colonies, record keeping requirements, barrier and containment essentials, and rodent research techniques including collection of genotyping material from rodents, blood collection, timed mating techniques, rodent rederivation procedures, and regulations pertaining to the animal research program. DARS also offers preparatory courses that will provide the instruction and guidance necessary to successfully sit for AALAS Certification exams. This is voluntary training but is closely tied to career

development. The campus Environmental Health and Safety office conducts additional formal training. DARS staff conducts training of husbandry staff in day-to-day job duties.

Collaborative Institutional Training Initiative (CITI)

The Institution subscribes to the Collaborative Institutional Training Initiative (CITI). CITI Laboratory Animal Welfare courses meet federal (USDA, PHS) requirements for basic training in the humane care and use of animals in research and teaching. Personnel are required to complete the modules for the species they are working with. Basic courses include "Working with the IACUC" (for Investigator, Students and staff) and "Essentials for IACUC Members" (for IACUC members). Species-specific modules include:

- Post-Procedure Care of Mice and Rats in Research
- Wildlife Research
- Working with Amphibians in a Research Setting
- Working with Fish in a Research Setting
- Working with Mice in a Research Setting
- Working with Rats in a Research Setting
- Working with Reptiles in a Research Setting
- Working with Zebrafish in a Research Setting

The IACUC maintains a list of all personnel and a record of modules completed. All personnel listed on an Animal Care and Use Protocol must complete the appropriate basic course and species-specific modules.

Laboratory Animal Skills Classes

On a semester basis UCM provides laboratory animal skills classes for rodents. These classes focus on the practical handling, restraint, gavage, injection, and blood collection techniques commonly performed in these species. Following a lecture, demonstration and discussion, participants practice what they have learned during the hands-on session. Every attempt is made to tailor classes to the specific needs of participants.

Aseptic Surgical Techniques for Rodents

On a semester basis the institution provides a class on aseptic surgical techniques for rodents. This class focuses on anesthesia, advanced blood collection techniques, analgesia, aseptic technique, humane endpoints and euthanasia. Following demonstration and discussion, participants practice what they have learned during the hands-on session on non-animal models. Participants must have experience handling, restraining and giving basic injections prior to taking this class.

One-on-One Training Sessions for Investigators/Research Personnel

One-on-one veterinary assistance or training is available upon the request by the investigator or at the recommendation of the IACUC. Frequently, during the review of an Animal Care and Use Protocol, the IACUC may designate the veterinarian to counsel an investigator and to ensure that he/she and his/her personnel are experienced and qualified to conduct the research and associated animal care and treatment.

IACUC Information and Training Workshops

The IACUC offers workshops dedicated to provide continuing training and instruction to the research community. These workshops may be taught in house or may be taught by a guest instructor. Workshop topics include but are not limited to: (a) humane methods of animal maintenance and experimentation; (b) the intent and requirements of the AWA, PHS Policy and Institution's policies governing the use of laboratory animals; (c) the concept, availability, and use of research methods that limit the use of animals or minimize animal distress; (d) the proper use of anesthetics, analgesics, and tranquilizers for specific animal species; and (e) the utilization of literature databases available to

provide information on appropriate methods of animal care and use or alternatives to the use of live animals in research.

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, [Samuel J. Traina](#).
 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, [Samuel J. Traina](#).
 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: Samuel J. Traina	
Title: Vice Chancellor for Research and Economic Development	
Name of Institution: University of California Merced	
Address: (street, city, state, country, postal code) 5200 North Lake Road Merced, CA 95343	
Phone: (209) 205-6469	Phone:
E-mail: straina@ucmerced.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: 7/30/19

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

Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: March 19, 2019			
Name of Institution: University of California Merced			
Assurance Number: A4561-01			
IACUC Chairperson			
Name*: Jack L. Vevea			
Title*: Associate Professor		Degree/Credentials*: PhD	
Address*: (<i>street, city, state, zip code</i>) 5200 North Lake Road Merced, CA 95343			
E-mail*: jvevea@ucmerced.edu			
Phone*: (209) 658-1706		Fax*: (209) 228-4007	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Jack Vevea	PhD	Associate Professor	Chair, Scientist
3025	PhD	Assistant Professor	Vice Chair, Scientist
Katherine Wasson Clark	DVM, PhD	Attending Veterinarian	Veterinarian
8643	BS	CEO/Principle, Agrecom, Inc	Nonaffiliated
9532	MLIS	Librarian	Nonaffiliated, nonscientist
1771	BS RLATg	Director, DARS	Scientist
3547	PhD	Assistant Professor	Scientist
1754	MLIS	Instruction & Scholarly Communications Librarian	Nonscientist
3692	RLATG	Animal Care Supervisor	Scientist
3198	MS	EH&S Specialist	Scientist
3697	MS	Dairy Farm Advisor	Scientist

* 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: [REDACTED]	
Title: [REDACTED]	
Phone: [REDACTED]	E-mail: [REDACTED]
Contact #2	
Name: [REDACTED]	
Title: [REDACTED]	
Phone: [REDACTED]	E-mail: [REDACTED]

X. Facility and Species Inventory

[illegible]

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

Attachment 1

