The University of California, Davis D16-00272 # (A3433-01)

ANIMAL WELFARE ASSURANCE In accordance with the PHS Policy for the Humane Care and Use of Laboratory Animals

I, Prasant Mohapatra, as named Institutional Official (IO) for animal care and use at the **University of California, Davis (UC Davis)**, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. Applicability of Assurance

This assurance applies whenever this institution conducts the following activities: all research, research training, experimentation, biological testing, teaching, and related activities involving live vertebrate animals supported by PHS, DHHD, and/or NSF (if applicable). This assurance covers only those facilities and components listed below.

A. "Institution" includes the following branches and major components of UC Davis:

School of Medicine
School of Veterinary Medicine
College of Agricultural and Environmental Sciences
College of Biological Sciences
College of Engineering
College of Letters and Science
Office of Research
Office of Student Affairs

B. "Institution" also includes the following institutions/locations:

Shriner's Hospitals for Children - Northern California VA Northern California Health Care System (VANCHCS) including their nonprofit group: East Bay Institute for Research and Education

We have several investigators that hold joint appointments with UC Davis and the Shiner's Hospital for Children in Sacramento. Many of these investigators have their laboratories in the Shriner's Hospital building. UC Davis maintains a room in Shriner's Hospital that is used to house animals as well as several laboratory areas where animals are used. The UC Davis Institutional Animal Care and Use Committee (IACUC) inspects the holding room on a semiannual basis and conducts routine inspections of the laboratory space.

UC Davis also has a number of faculty that hold joint appointments with the VANCHCS. All PHS-supported work conducted by VANCHCS or their non-profit group, East Bay

Institute for Research and Education, will be conducted under the jurisdiction of the UC Davis IACUC and in facilities inspected and approved by the UC Davis IACUC.

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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this assurance as well as all 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 in accordance with the *ILAR 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 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 provided in the attached organizational chart and described as follows.

The animal care and use program on the UC Davis campus functions within a centralized, in-house regulatory structure under a single campus IACUC and the Research and Teaching Animal Care Program Executive Director (ED) who is the Attending Veterinarian. The UC Davis central animal care provider, Teaching and Research Animal Care Services (TRACS), reports directly to the ED. Some academic centers, departments, and PIs manage their own animal facilities under the oversight of the ED and IACUC.

Animal Care Leadership Team: The current IACUC Chair, Vice Chair, two former IACUC Chairs, ED, IACUC Director and Assistant Director, Research Compliance and Integrity Director, Associate Vice Chancellor for Safety Services, Executive Associate Vice Chancellor for Research, and Vice Chancellor for Finance, Operations and Administration meet approximately monthly to discuss the animal care and use program. The IO joins these Animal Care Leadership Team meetings at least quarterly. The ED

and IACUC Director also meet approximately monthly with the IO to keep him informed of the program's activities.

The lines of authority and responsibility for administering the institutional animal care and use program and ensuring compliance with this policy are summarized in the attached organizational chart (Attachment 1: "UC Davis Animal Care and Use Program Regulatory Oversight").

The Deans of the schools and colleges and Vice Chancellors determine the specific organizational structure of the animal facilities under their purview. According to UC Davis IACUC policy, each animal facility must be supervised by a "Scientist-in-Charge" with the assistance of a supervisory "Technician-in-Charge". These individuals are responsible for ensuring facility operation is consistent with IACUC policy, facility Standard Operating Procedures (SOPs) are consistent with the ED Standards of Care, and that any animal health concerns are promptly communicated to a clinical veterinarian. The ED holds meetings approximately every other month with the Technicians-in-Charge to review policy changes, training, and discuss other animal program related items.

- **B.** The qualifications, authority, and percent time contributed by the veterinarian that participates in the program include the follows:
 - 1) Research and Teaching Animal Care Program Executive Director (ED) Dr. Laurie Brignolo

Qualifications:

- DVM, DACLAM Certification
- University of Wisconsin School of Veterinary Medicine
- University of California Davis Laboratory Animal Medicine
- 35 years of experience in laboratory animal medicine including 25 years as a laboratory animal veterinarian

Authority: Dr. Brignolo has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. The ED is responsible for the campus veterinary care program. As per the Animal Welfare Act regulations, the ED, as Attending Veterinarian, is directly responsible for the oversight of animal disease control and prevention, euthanasia, the appropriate use of pain-relieving drugs, and other aspects of veterinary care. Dr. Brignolo is an Associate Clinical Professor in the Department of Medicine and Epidemiology, School of Veterinary Medicine, and is a voting member of the IACUC.

Time contributed to the program: Full time employee with 100% time dedicated to the animal care program.

- 2) Veterinary Care is provided by the following units:
 - a. Campus Veterinary Services (CVS)

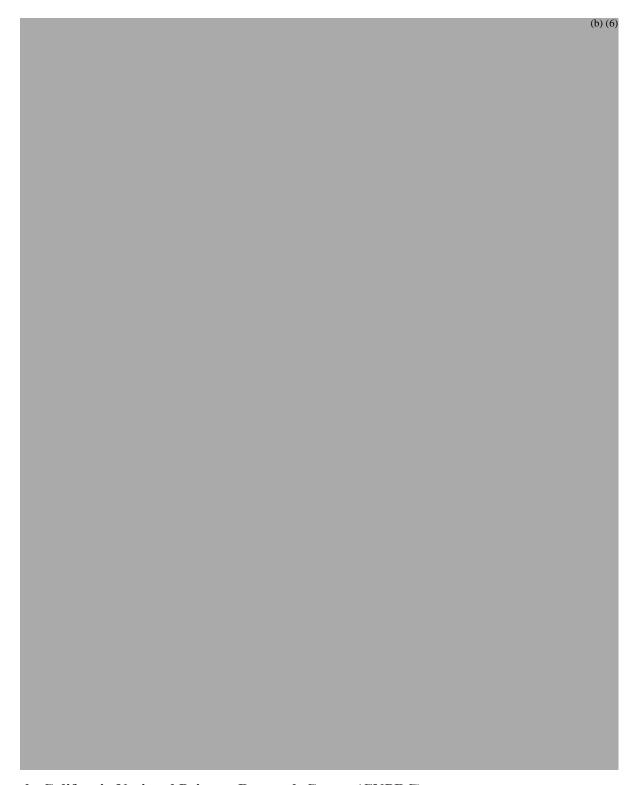
CVS is under the direction of the ED and is a full service laboratory animal veterinary clinic. CVS provides clinical care, research services, and project consultation for the majority of the biomedical research projects on campus, excluding the California National Primate Research Center (CNPRC). Four laboratory animal veterinarians and one to three resident veterinarians in CVS, in addition to the CNPRC veterinary staff, provide veterinary pre-review of all animal care and use protocols submitted to the UC Davis IACUC.

In addition, CVS veterinarians provide veterinary advice and consultation to the facility managers and husbandry units through the veterinary visit program. The assigned clinical veterinarian also takes any day-to-day calls referred by the animal health technicians through the triage system.

Rodent and Aquatic Health Surveillance is also addressed under direction of the ED. CVS utilizes DVMAX Veterinary Health Management Software (Electronic Health Record).

CVS Veterinarians





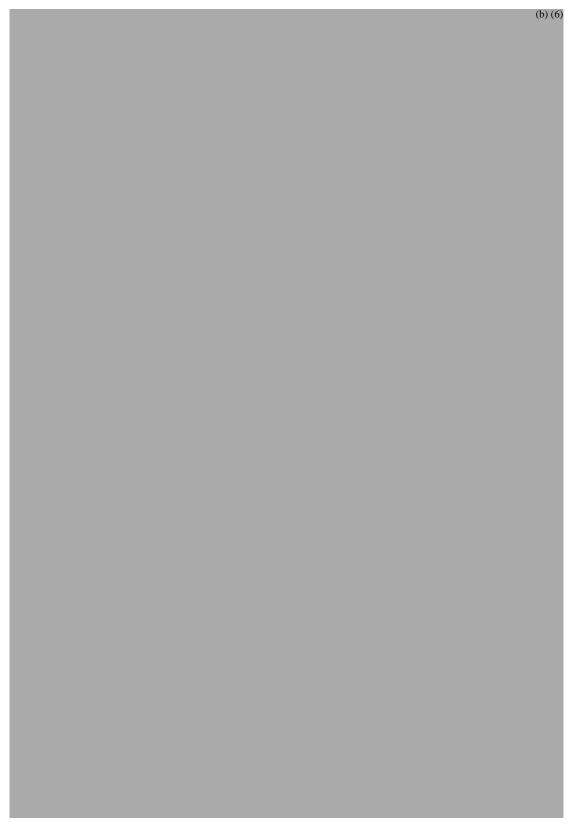
b. California National Primate Research Center (CNPRC)

The CNPRC veterinarians provide veterinary care for all nonhuman primates housed at the CNPRC. The CNPRC has six full time laboratory animal veterinarians and operates a full-service veterinary hospital and provides health care

and centralized surgical facilities for nonhuman primates housed within the CNPRC.

CNPRC Veterinarians

b) (6)



The CNPRC also typically employs one to three Residents in Laboratory Animal Medicine who provide veterinary care.





C. The IACUC at UC Davis is appropriately appointed according to the 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 five members, and its membership meets the compositional requirements set forth in the PHS Policy section IV.A.3.b. Attachment 2 provides the names of the Chairperson and Attending Veterinarian along with a coded list of the IACUC members including titles, earned degrees, or other relevant credentials, and institutional affiliation.

D. The IACUC will:

1. Review at least twice yearly the institution's program for humane care and use of animals, using the ILAR Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

Since many of the programmatic elements requiring review are integral to the management programs within each animal facility, the IACUC reviews the programs within each of those facilities at the same time that it conducts facility inspections (see section 2, below). Examples of programmatic elements connected with the management of each facility include provision of veterinary care, maintenance of records, and participation in the occupational health program. The written report of each facility inspection includes both the programmatic and facility-related elements.

On a semiannual basis a program review subcommittee composed of IACUC members, the ED, the IACUC Director, and IACUC staff conduct a program evaluation using a modified version of the "Semiannual Program Review Checklist" provided by the Office of Laboratory Animal Welfare (OLAW). During this review the subcommittee discusses

IACUC membership, functions, training, records, and reporting requirements as well as the Veterinary Care Program, personnel qualifications and training, the Occupational Health and Safety Program, disaster and emergency planning, security and animal welfare concerns, and investigations to ensure that the program meets the requirements set forth in the Animal Welfare Act Regulations and PHS Policy. The meeting times are circulated to the entire committee and any member is allowed to participate. If deficiencies are noted, they are included in the report with a corrective action plan and timeline. The subcommittee then presents the program evaluation to the entire committee during a convened IACUC meeting.

The evaluation, including programmatic issues, are merged with facility inspections, study area inspections, and post-approval monitoring reports. This comprehensive report is presented to the IO twice yearly. This report includes corrective action plans for any noted program deficiencies, suggestions for improvements to the animal care program, minority reports, and is signed by a majority of the IACUC.

2. Inspect at least every six months all of the institution's animal facilities, using the Guide as a basis for evaluation.

UC Davis has a large number of animal-related areas (e.g., over 2,300 rooms for animal housing, procedure areas, food storage, investigator laboratories) that require inspection by the IACUC. All animal housing areas are inspected by members of the IACUC and/or members of the IACUC staff every six months. A list of facilities and the dates scheduled for inspection is sent to all members for opportunities to participate. Any IACUC member that wishes to participate in any evaluation is included. Facilities holding USDA covered species are inspected by at least two voting members of the IACUC.

After conducting an inspection, the IACUC staff prepares a draft inspection report which is reviewed by the IACUC and revised if necessary. Deficiencies are categorized as either minor or significant. The Scientist-in-Charge and/or Technician-in-Charge formally respond to each inspection report with their corrective action or plan for correction and correction date. Confirmation of a Facilities Management work order with an assigned task number also meets these criteria for any deficiencies identified related to building maintenance (e.g. rusted doorframes, peeling paint, pitted floors). A convened quorum of the IACUC reviews and votes on the final facility inspection reports.

The IACUC and/or members of the IACUC staff inspect laboratories where work with live, vertebrate animals is conducted and also conducts post-approval monitoring on approved protocols on a regular basis to ensure compliance with PHS policy. Similar to facility inspections, the IACUC staff prepares a draft inspection report which is reviewed by the IACUC and revised if necessary. Deficiencies are categorized as either minor or significant. The Principal Investigator (PI) formally responds to each inspection report with their corrective action or plan for correction and proposed correction date. A convened quorum of the IACUC reviews and votes on all final reports. Post-approval monitoring conducted through protocol annual review is summarized at each convened IACUC meeting and any action required is voted on by the IACUC.

3. Prepare reports of the IACUC evaluations as set forth in the PHS policy section IV.B.3. and submit the reports to the IO.

The development, approval, and submission of the semiannual report and the process for facility and laboratory inspections are discussed in more detail in sections III D, 1 and 2 above. Briefly, the semiannual report contains any programmatic deficiencies noted during the semiannual review process conducted by the semiannual program review subcommittee. The semiannual report also contains a summary of all the facility and laboratory inspection reports prepared by the IACUC staff and reviewed by the IACUC during the six-month reporting period. Any programmatic deficiencies or deficiencies noted during facility inspections are categorized as either minor or significant. Corrective actions or a corrective action plan and schedule are provided and documented in individual facility and laboratory inspection reports. These reports are included in the semiannual program review that is submitted to the IO.

The semiannual report also contains a summary of protocols that have completed post approval monitoring, any inspections by regulatory bodies, protocol suspensions, minority reports, departures from the PHS policy and the Guide, and any USDA approved Animal Welfare Act exemptions. Departures from the PHS Policy and the Guide or exceptions to internal policies and standards of care are reviewed and approved by the committee. The semiannual program review report contains a summary of active protocols with approved departures or exemptions.

4. Review concerns involving the care and use of animals at the institution.

All concerns about the use of animals in research or teaching, whether they originate from animal care staff, students, researchers, or from the general public, are routed to the IACUC Office or the Attending Veterinarian. Individuals also have the ability to report an animal welfare concern to the University of California system-wide or UC Davis whistle-blower hotline. Information for individuals on how to report a concern is available on the UC Davis IACUC website and is posted near animal facilities and procedure spaces. Once a concern report is received, the IACUC Chair, IO, ED, and the entire Animal Care Leadership Team are notified. The IACUC, IACUC staff, and/or the ED review all concerns, gather information as necessary from all involved parties, and then report their findings to the IACUC. The IACUC reviews the reports at a convened meeting and determines if any further action is needed. Concerns are maintained anonymously to the extent possible. Results of concern investigations are discussed with the ED, IACUC Chair, and IO at regularly scheduled meetings.

5. Make written recommendations to the IO, regarding any aspect of the institution's animal care program, facilities, or personnel training.

Written recommendations to the IO are generally included in the semiannual program review. If they fall outside the semiannual reporting period, recommendations are made in writing from the IACUC Chair, ED, or IACUC Director.

6. Review and approve, require modification in (to secure approval), or withhold approval of those sections of applications or proposals to PHS related to the care and use of animals as set forth in the PHS Policy at IV.C.

The IACUC procedure for the review of submitted protocols is as follows:

Each investigator or instructor in charge of any research or teaching activity involving live, vertebrate animals prepares and submits a *Protocol for Animal Care and Use*. The form contains all the information mandated for IACUC review by PHS Policy and the Animal Welfare Act regulations. No research or teaching activity involving live, vertebrate animals may be initiated until the protocol has been reviewed and approved by the IACUC.

Protocols for Animal Care and Use are submitted to the IACUC Office via an online system where they are subjected to an extensive pre-review process. The IACUC staff ensures that the submitted protocols are clear, internally consistent, and fulfill all regulatory requirements for review. Veterinary staff pre-review all submitted protocols to ensure that any veterinary-related concerns are addressed. If biological, chemical, or radiological hazards are identified in the protocol, these are routed to the appropriate UC Davis Environmental Health and Safety group for their review. The IACUC staff communicates with the investigators and helps them prepare documents for IACUC review.

After the submitted protocols are pre-reviewed by the IACUC staff and veterinary staff, and recommended modifications have been made by the investigator/instructor, the protocols are either placed on the agenda for the next upcoming convened meeting to be reviewed by the full committee or assigned to Designated Member Review. Agendas and copies of all of the protocols are made available online to the IACUC members approximately one week prior to each meeting.

Designated Member Review (designated review or DR): Typically, protocols that include nonhuman primates, survival surgery, or USDA category E are reviewed by the full committee at a convened IACUC meeting. Other protocols are typically reviewed using a DR process. After pre-review, a link to these protocols, along with a summary, are sent to all committee members via electronic mail with at least one member assigned under the IACUC Chairperson's authority, as designated reviewer(s). All committee members have the equivalent of two working days to review and request full committee review if they deem review by the entire IACUC to be necessary. If full committee review is not requested within two working days, the designated reviewer(s) may approve the protocol as presented (decision must be unanimous if more than one reviewer is assigned), request modifications, or request full committee review. All members have full access to the current version of the protocol as well as access to the reviewer comments and requests for revisions. Designated Member Review cannot result in withholding approval.

Full Committee Review: Full Committee Review occurs at a convened meeting of a quorum of IACUC members and with a formal vote. During the week prior to the meeting, members who have questions related to any of the protocols listed on the agenda communicate those questions to the IACUC staff via the online system. The staff relays the questions to the investigator and the investigators responses are made available to the full IACUC via the online review system. At the convened meeting each full committee protocol will be brought forward for any additional committee discussion and voted on to approve, deny, or request modifications to secure approval. Designated member review procedures may be used to review modifications (process described below). If significant modifications are required, the IACUC may also choose to table the protocol for a future meeting. A quorum is required for all actions on full committee protocols and approval or denial requires a majority of the quorum. Members who have a conflict of interest must abstain from voting and are required to step out during the discussion if they are involved in the project. Members who have a conflict of interest would not be counted towards the quorum for that vote.

Designated Member Review subsequent to Full Committee Review: If the committee has requested modifications to secure approval during the meeting, the IACUC can send the protocol to designated member review with a unanimous vote of the quorum. At least one IACUC member will be assigned by the chair during the meeting as a designated reviewer. If the protocol is sent to designated member review, upon securing the revisions the assigned reviewer(s) can then approve the proposal as presented, ask additional questions, or send the protocol back to full committee. Any member of the IACUC may, at any time, request to see the revised protocols and/or request full committee review. The IACUC has an approved policy describing the IACUC review process and covers designated review subsequent to full committee review. This policy is included in all new IACUC member training.

Beginning October 2018, protocols listing external funding must also list the corresponding university Cayuse datasheet number assigned by Sponsored Programs. This Cayuse number, along with a signed statement provided by the PI, is tracked by Sponsored Programs to establish grant-to-protocol congruency.

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 as set forth in the PHS Policy at IV.C.

Investigators are required to submit proposed significant changes in ongoing protocols as amendments for the IACUC's review and approval prior to initiating the change. Amendments are received by IACUC staff and processed in the same manner as protocols, receiving both IACUC staff and veterinary staff pre-review. The amendments along with the original protocol are made available to the IACUC members online and are reviewed for approval at convened meetings by full committee, or by the designated review method described above.

Changes determined not to be significant (e.g. staff roster additions and deletions, approved location changes) may be approved administratively.

Other minor changes consistent with pre-established approved guidelines as described in IACUC Policy 7 may be approved administratively following veterinary review, verification, and consultation.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4.

After each meeting, the IACUC staff notifies the investigators of the actions taken with respect to their protocols via electronic mail. Investigators have the ability through the online protocol and amendment system to print a "letter of verification" which the investigator can forward to the NIH or other funding agency as evidence that the project has been reviewed and approved by the IACUC. If the IACUC denies a protocol the investigator will receive the reason for the denial and options for appealing to the IACUC.

The IACUC Office also provides access to a list of approved protocols to University business officers and campus entities to verify that a particular project has been reviewed and approved by the IACUC.

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 every 3 years according to PHS Policy IV.C.1.-5.

Approval of protocols is granted in one-year increments for up to three years. At one-year intervals PIs must indicate whether they would like to have their active protocol expire or be renewed. If renewal is requested the PI is asked, via electronic mail, to review the current procedures, numbers of animals, and staff listed on the protocol for accuracy. Changes to renewed protocols are made through submission of an amendment or modifications to the staff roster. Annual renewal is required for all protocols regardless of the species used. Protocols that have been requested to be renewed are placed on the IACUC agenda for full committee review or designated member reviewer(s) are assigned according to the process described in point # 6. IACUC members have access to the full current copy of the protocol as well as a history of amendments to the protocol.

At the third year, a *de novo* protocol review is required. The PI is sent reminders starting approximately 90 days prior to expiration and asked to submit a new protocol incorporating any relevant amendments from the prior three years as well as any new procedures planned for the next three years. The IACUC addresses an updated protocol as a new protocol submission which goes through the standard review process as described in D.6., above (Full Committee or Designated Member Review).

Post-approval monitoring is completed through a variety of methods. Protocols may be randomly selected for review, however "for cause" review takes precedent. Post-approval monitoring may be conducted during protocol annual review or in conjunction with laboratory and facility inspections. Post-approval monitoring can be accomplished either through electronic mail or telephone conversation (e.g., for field studies) or may require in-person meetings, records review, and/or cage-side observations. Depending upon the format and circumstances surrounding the post-approval monitoring review, the IACUC staff member may prepare a draft inspection report that is reviewed by the IACUC, or findings and recommendations may be verbally presented at a convened meeting, as in the case of annual review reports. Deficiencies are categorized as either minor or significant. The PI formally responds to each inspection report with their corrective action or plan for correction and correction date. A convened quorum of the IACUC reviews and votes on all final reports. Post-approval monitoring conducted as part of the protocol annual review process may or may not be documented via the described formal reporting mechanism. IACUC meeting minutes document any PI or IACUC protocol updates or action items.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6.

The IACUC is authorized to suspend any activity involving animals, as set forth in the PHS policy. Any suspension would be voted upon at a convened meeting with a quorum present. The IACUC would then notify the PI, the IO, and OLAW. The vivarium manager would also be notified to ensure the investigator is not able to order animals. If animals are currently on the project they are transferred to the Campus Animal Holding protocol until the project is reactivated by the IACUC. While on the holding protocol, the animals may not be used for research or teaching purposes.

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:

All employees planning to work with live, vertebrate animals for research or teaching must participate in the UC Davis Occupational Health program, administered through the University of California system-wide Occupational Health Surveillance System (OHSS). This includes both a risk assessment form and a health questionnaire form. The risk assessment form is completed by the PI or supervisor and identifies risks in the work place. The employee then fills out a confidential medical history questionnaire. The questionnaire captures information such as vaccination and allergy history as well as immune status, pregnancy, and illness history. Visiting researchers and volunteers may elect not to fill out the questionnaire but at a minimum are provided information about the system and information about their risks and zoonoses while working with animals from the PI. Ancillary personnel who do not work directly with animals but may enter the facility (e.g., facilities maintenance personnel) are provided training on zoonoses, asthma and allergies associated with laboratory animals, and proper conduct when working in an animal facility.

The health history and risk assessment forms are submitted to Occupational Health Services through an online system for review. The forms are reviewed by an Occupational Health Professional and they make recommendations for each employee based on the employee's risk and health history. The IACUC database is tied into the Occupational Health database and only individuals enrolled in the program can be added to an IACUC protocol. Individuals or supervisors are required to update risk assessment forms if there are significant changes in employee health or a significant change in risk, respectively. Otherwise, health assessments are updated every three years or more frequently if required by the Occupational Health Physician.

Occupational Health Services is a campus-based medical clinic that offers treatment for work-related injuries and illness, work-related preventive medicine and injury and illness prevention services, and OSHA- and departmentally-mandated medical surveillance programs. Medical care is provided by physicians that are board certified in Occupational and Environmental Medicine. UC Davis Occupational Health Services offers vaccinations, such as Tetanus and Hepatitis B, or any vaccination deemed appropriate for the risks and health history of an individual. Individuals at a high risk due to pregnancy, illness, or decreased immune competence receive information specific to their pregnancy status or condition and related risks. Environmental Health and Safety (EH&S) also has a number of online safety nets that provide information on topics such as pregnancy in the work place.

Individuals working with nonhuman primates are prescreened for tuberculosis (TB) and documentation of measles titer or vaccination. Individuals working with nonhuman primates receive training on proper procedures for bites, scratches, splashes, and other potential exposures to the Macacine herpesvirus1 (formerly known as Herpes B virus). Treatment for injuries occurs at the UC Davis Occupational Health Services Clinic. For injuries or illnesses outside of normal business hours, employees are instructed to be seen at Davis Urgent Care. If Davis Urgent Care is closed workers are instructed to go to the Sutter Davis Hospital Emergency Room. The campus has mechanisms in place for reporting injuries.

Individuals working with sheep are prescreened for Q-fever titer.

Supervisors are responsible for providing employees with information about animal-related risks, including zoonoses, specific to their workplace and to the related research projects. Supervisors are provided with further information including a web-based "Risk Assessment Tool" on the UC Davis Occupational Health's website. Supervisors are also provided with information on training in universal precautions and personal hygiene which includes proper hand-washing techniques, appropriate protective clothing, use of personal protective devices, when to seek medical attention, and where to find species and project-specific hazard information. Information on animal allergies, such as allergy symptoms, how to limit exposure to allergens, and how to seek advice and treatment for allergies can also be found in the vivaria.

Animal care protocols involving hazardous agents are reviewed by EH&S to ensure the appropriate safety measures are in place and that other required approvals (e.g., Biological Use Authorization/Radiation Use Authorization) are in place. For all protocols utilizing hazardous material in the vivarium, a Vivarium Hazard Safety Sheet (VHSS) is included with the protocol identifying the hazardous material, potential risks associated with the hazard, appropriate personal protection equipment (PPE), and the disposal of cage bedding and animal carcasses. The VHSS are developed by EH&S professionals and displayed outside of animal housing rooms to inform vivarium staff of any hazard under use in the room.

The appropriate PPE may vary between vivaria and rooms located within a given vivarium due to the use of different species, biosafety levels, potential hazardous material, or the health status of the animals. In all cases, the required PPE is posted and readily available at all animal facilities on campus. The Occupational Health Clinic also manages the Respiratory Protection Program if it is determined that a respirator is needed for a specific type of work.

F. Animal Facilities under the Auspices of the UC Davis Campus

Administrative Unit	Vivarium Code	Assignable Square Footage
Office of Research	1	225,505
	Subunits 2 - 13	Inc. in code1
	33	22,297
	34	10,170
	35	611,029
	36	13,329
School of Veterinary	14	732
Medicine	15	16,085
	16	33,600
	17	5,692
	18	2,833
	19	Inc. in code 1
	20	Inc. in code 1
	21	29,458
	22	8,300
	23	2,800
	24	Inc. in code 1
	25	Inc. in code1
	26	Inc. in code1
	27	3,126
	28	5,715
	29	1,188
	30	5,553
	31	40,071
	32	5,504

College of Agricultural	37	13339
and Environmental		
Sciences	Subunits 38-51	250,557
		(square footage of offsite
		rangeland and pastures not
		included)
	52	10,204
	53	1,669
	54	15,762
	55	155
	56	2,560/Feedlot
	57	3,460
	58	Rangeland
	59	167
College of Letters and	60	2,779
Science	61	70
	62	1,799
School of Medicine	63	9,196
	64	3,069
	65	4,489
	66	Inc. in code 1
	67	Inc. in code 1
College of Biological	68	2,951
Sciences	69	1,257
	70	1,879
	71	1,513
	72	3,608
	73	3,453
Office of Student Affairs	74	55,813

Approximate Annual Animal Usage:

The approximate number of animals used by this institution during 2018 is shown below. This includes animals used for research or teaching on campus as well as studies conducted in the field:

2018 Annual Usage			
Alpaca	0		
Bat	20,900		
Bearded Dragons	31		
Capuchin	8		
Cats	469		
Cattle	4,116		
Chickens	5,224		
Chipmunk	116		

Coati	10
Cockatiel	14
Cynomolgus Macaque	20
Deer Mouse	179
Dogs	84
Donkey	11
Duck	322
Ferret	0
Fish	713,866
Frog	475
Gerbil	0
Goat	234
Gopher	0
Guinea Pigs	95
Hamsters	10
Horses	1,419
Llama	6
Lizard	34
Love Birds	0
Mice	245,820
Opossum	42
Other bird	1,423
Owls	11
Parrot	8
Peromyscus	655
Pigeon	124
Quail	4,245
Rabbits	229
Rats	9,027
Rhesus Macaque	9,741
Sea otter	30
Sheep	693
Shrew	4
Snake	6
Squirrel	218
Swine	1,764
Tortoise	132
Titi Monkey	95
Vole	2,128
Wild bird	1,525
Wild mouse	40
Xenopus	13,763
P***	

G. Training:

The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use consists of a variety of formal classes and on-the-job training. Subject areas include: animal care and use, practical technique methodology, safety, occupational health, and the handling of biohazards, blood-borne pathogens, chemical carcinogens, and radioisotopes.

IACUC Classes

Animal Care and Use 101 (ACU 101): The IACUC "Animal Care and Use 101" course is required for all faculty, staff, and students (employees or volunteers) who are named on an animal care and use protocol. ACU101 provides an introduction to the PHS Policy, Animal Welfare Act, Animal Welfare Regulations, California Fish and Wildlife Permitting, Occupational Health, and IACUC and University policies. The course covers the 3 R's including minimizing pain and distress as well as minimizing the number of animals used. The class is offered online through the UC Davis Learning Management System. Researchers and staff must renew this course every three years via an online renewal exam or by retaking the online course.

Rodent Survival Surgery Course: The "Rodent Survival Surgery Course" is required for all personnel performing survival surgery in rodents. This course provides animal users with the required information for performing rodent survival surgery. The topics covered are: aseptic technique, surgery area preparation, patient prep, surgeon prep, PPE, sterile instruments and re-use, anesthesia and analgesia, patient monitoring and post-operative care, as well as record documentation. The class is offered online through the UC Davis Learning and Management System.

Lab Animal Skills: These three-hour classes focus on the handling, restraint, gavage, injection, and blood collection techniques commonly used with laboratory rats and mice (classes for other species can often be scheduled upon special request). Following a video demonstration and discussion, participants practice what they have learned during the hands-on session with animal mannequins and/or live animals. Classes include a brief discussion of laws and regulations, animal health and welfare, and occupational health requirements. Every attempt is made to tailor classes to the specific needs of participants. Faculty, staff, and students working with laboratory rodents are encouraged to enroll to learn new skills or update techniques.

Rodent Aseptic Technique: This three-hour class focuses on anesthesia, advanced blood collection techniques, analgesia, aseptic technique, humane endpoints, and euthanasia. Classes that focus on the use of mice and rats are offered monthly (classes with other species can be offered upon special request). Following a video, demonstration, and discussion, participants practice what they have learned during the hands-on session on non-animal models, animal mannequins, cull, and/or live animals. Participants must have experience handling/restraining and giving basic injections to the designated species prior to taking this class.

Submandibular Blood Collection for Mice and Rats: This online course was designed to familiarize researchers with different blood collection techniques in mice and rats. The course focuses on the Submandibular/Facial Vein technique but also explains some of the advantages and disadvantages of the most commonly used blood collection techniques in rodents. The IACUC office provides training for any of the techniques discussed in the course.

American Association of Laboratory Animal Science (AALAS) Certification Preparatory Classes: These in-person classes are provided to help UC Davis employees and students pass the AALAS technician exams offered by the AALAS. Classes cover all three levels of AALAS certification.

AALAS Learning Library: UC Davis also has a membership to the AALAS Learning Library which all employees who work with research and teaching animals have access to. The Learning Library provides a wide range of online learning in the field of Laboratory Animal Science to our employees.

Other Classes

Library Classes: The UC Davis Carlson Health Sciences Library and the UC Davis Shields Library offer formal classes in the effective use of library resources and computerized searching of scientific literature. Every faculty and staff member of UC Davis can search the National Library of Medicine's PubMed database directly from their own computer, without charge to the individual user.

Departmental Short Seminars: Laboratory animal veterinarians at CVS and the Primate Center, as well as members of the IACUC staff, offer one hour presentations on request to various departments to provide overviews of research, current issues regarding animal care or use of animals in research. These are usually specifically tailored to the needs of the particular units.

Primate Center Classes: The CNPRC offers a Good Laboratory Practice class annually. They also regularly conduct continuing education courses on topics such as infection control, radiation safety, and other current issues.

Ad Hoc Training: Ad hoc training in a variety of animal procedures is offered by CVS and IACUC staff. Topics have included swine anesthesia, rabbit blood collection, maintenance of rodent colonies, physical methods of euthanasia, or specific procedural or surgical techniques. Such training is conducted whenever special research needs arise.

On-the-Job Training: On-the-job training is offered on a continuing basis by all departments that use animals. Such training is provided through supervisory channels to newly hired individuals, and whenever special needs arise. Supervisors are responsible for ensuring that all personnel in their unit or facility are provided with adequate training.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accordance with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accordance with the 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 "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 and when program 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 IO. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the <u>AAALAC International</u>. 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 three years:
 - 1. A copy of this assurance and any modifications thereto, as approved by 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 given or withheld.
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) are forwarded to the IO, Prasant Mohapatra, Vice Chancellor for Research.
 - 5. Records of accrediting body determinations.
- **B**. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three 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. This Institution's reporting period is January 1 to December 31. The IACUC, through the IO, will submit an annual report to OLAW on January 31 of each year. The report will include the following:

- 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 IO, Prasant Mohapatra, Vice Chancellor for Research.
- 5. Any minority views filed be members of the IACUC.

If there are no changes to report, this Institution will provide written notification that there are no changes.

- **B**. The IACUC, through the IO, 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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Prasant Mohapatra, PhD Title: Vice Chancellor for Research Institution: University of California, Davis Address: 1850 Research Park Drive

University of California, Davis

Davis, California 95616

Phone:

Email: pmohapatra@ucdavis.edu

Acting officially in an authorized capacity of 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 <u>4/12/19</u>

B. PHS Approving Official

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health 6700B Rockledge Drive

Suite 2500 - MSC 6910

Bethesda, Maryland 20892 Email: thorntov@od.nih.gov

Phone: (301) 451-4208

Fax: (301) 480-3421

Venita Digitally signed by

Venita B.

Thornton -S

Thornt Date: 2019.04.17

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Signature Date

C. Effective date of assurance: April 17, 2019

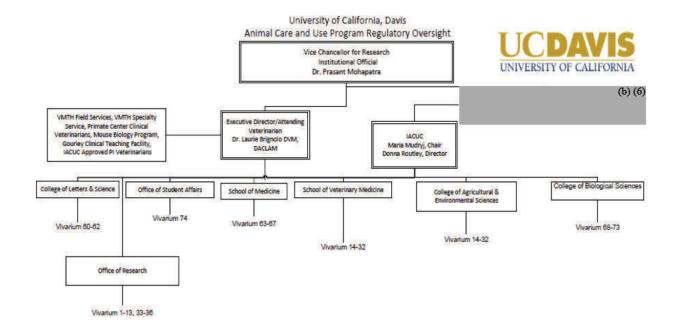
D. Expiration date of assurance: March 31, 2023

Attachments:

Attachment 1: UC Davis Animal Care and Use Program Regulatory Oversight

Attachment 2: Membership of the IACUC, 2018-2019

Attachment 1: UC Davis Animal Care and Use Program Regulatory Oversight



VIII. Attachment 2: Membership of the IACUC

I. Date: 01/28/2018					
Name of Institution: University of California, Davis					
Assurance Number: D	16-00521 # (A343	3-01	l)		
IACUC Chairperson					
Name*: Maria Mudryj					
Title*: Professor				Degree/Cre	edentials*: PhD
Address*: (street, city, state, zip code) UC Davis School of Medicine Department of Microbiology and Immunology 1 Shields Avenue Davis, CA 95616					
E-mail*: mmudryj@uc					W. (O
Phone*:) (6)		Fax*:		(b) (6)
IACUC Roster					
Name of Member/ Code**	Degree/ Credentials	Position Title***		itle***	PHS Policy Membership Requirements****
Maria Mudryj	PhD	Professor			Scientist
Laurie Brignolo	DVM, DACLAM	Attending Veterinarian		an	Veterinarian
				(b) (б	Scientist
					Scientist
					Scientist
Member					Member
					Member
Alternate for (b) (6)					
					Member
Alternate for (b) (6)					
Scientist, Vice Chair					
					Scientist
Alternate Scientist					Alternate Scientist
					Alternate Scientist

(b) (6)	Alternate for Attending
	Veterinarian
	Scientist
	Member
	Scientist
	Nonaffiliated, Nonscientist
	Scientist
	Alternate for (b) (6) and
	Member
	Scientist
	Alternate for (b) (6)
	Scientist
	Scientist
	Alternate Scientist
	Alternate for Attending Veterinarian
	Nonaffiliated
	Member
	Alternate Scientist
	Scientist
	Scientist
	Scientist

^{*} This information is mandatory.

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.

^{**} 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:

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.

IX. Other Key Contacts

Contact #1		
Name: Donna Routley		
Title: Director, IACUC		
Phone E-mail: dmroutley@ucdavis.edu		
Contact #2		
Name: Dr. Laurie Brignolo		
Title: Executive Director of the Research and Teaching Animal Care Program		
Phone (b) (6)	E-mail: llbrignolo@ucdavis.edu	

X. Facility and Species Inventory

Previously provided in section III F.