

From: [REDACTED] on behalf of [REDACTED]
To: olawdoa@mail.nih.gov
Cc: [Besselsen, David G - \(besselsd\)](#); [ORCR iacuc](#)
Subject: PHS Assurance Renewal for D16-00159 (A3248-01) University of Arizona
Date: Tuesday, March 12, 2019 9:38:35 AM
Attachments: [2019 PHS Assurance D16-00159 \(A3248-01\).pdf](#)

Good Morning,

The University of Arizona's PHS Animal Welfare Assurance renewal document is attached.

Best regards,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

University of Arizona
Tucson, AZ 85721

The University of Arizona
D16-00159 (A-3248-01)

ANIMAL WELFARE ASSURANCE

I, [REDACTED] as named Institutional Official for animal care and use at The University of Arizona, 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 and/or the National Science Foundation (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:

University of Arizona Health Sciences Center facilities, Phoenix Biomedical Campus facilities, Main Campus facilities, and Agricultural Research Center (ARC) facilities that house PHS- or NSF-funded animals and animal research.

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

Not applicable

II. INSTITUTIONAL COMMITMENT

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*.
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with 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 (sub-award) 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:
 - 1. The President of the University of Arizona is the Chief Executive Officer (CEO).
 - 2. The Vice President for Research (VPR) serves as the Institutional Official (IO).

3. The IACUC oversees the Animal Care and Use Program (ACUP). The IACUC is appointed by the IO, as per written authority from the CEO. The IACUC Chair reports to the IO. In addition, there are open lines of communication between the IACUC and the IO.
 4. The Attending Veterinarian (AV) reports directly to the IO. The AV has been given the authority and responsibilities outlined by the Animal Welfare Act, PHS Policy, and the *Guide* to ensure the welfare of all animals at the Institution. The current AV is the Director of University Animal Care (UAC).
 5. UAC is responsible for overseeing all veterinary care and husbandry functions for the Institution. The Director of UAC reports to the VPR.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: David G. Besselsen

Degrees: DVM, PhD, DACLAM, DACVP

Training and/or experience in laboratory animal medicine: Dr. Besselsen completed his DVM (1988), laboratory animal medicine residency program (1994), and PhD in Pathobiology (1995) at the University of Missouri. He joined UAC in 1995. He obtained board-certification in Laboratory Animal Medicine in 1995 and Veterinary Pathology in 2004. His specialties are rodent medicine, pathology, quality assurance, and facility design. He is experienced with all traditional laboratory animal species.

Authority: Dr. Besselsen has direct program authority and responsibility for the Institution's ACUP, including access to all animals, as AV.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from the University of [REDACTED] joined UAC in 2012, and obtained ACLAM board-certification in 2013. [REDACTED] specialties are clinical medicine, non-human primate medicine, large animal surgical models, anesthesia, and analgesia. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from [REDACTED] became a researcher at the University of Arizona, completed an MS in Animal Science (1992), and joined UAC in 1996. [REDACTED] obtained [REDACTED] CPIA credentials in 2018. [REDACTED] specialties are regulatory affairs, rodent and large animal experimental surgery, analgesia, and public outreach. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] VMD from The University of [REDACTED] and completed [REDACTED] MS and laboratory animal medicine residency at the University of [REDACTED] joined UAC in 2015 and obtained ACLAM certification in 2016. [REDACTED] specialties are rodent medicine, surgery, biometrics, and gnotobiology. [REDACTED] is experienced with all traditional laboratory animals.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: MS, DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] MS in Pathobiology from the UA [REDACTED] and [REDACTED] DVM from [REDACTED]. He practiced mixed, large and companion animal medicine and surgery in [REDACTED]. [REDACTED] joined UAC in 2016. He specializes in clinical farm animal medicine and management, with an emphasis on production agriculture and large animal surgical models.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] DVM at [REDACTED] and a laboratory animal medicine residency program at [REDACTED]. [REDACTED] joined UAC in 2018. [REDACTED] specializes in general laboratory animal medicine and management, with an emphasis on rodent medicine, surgery, and biometrics, non-traditional laboratory animal species and environmental enrichment.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

- 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 ACUP 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:
 - a. Review of the ACUP occurs at six month intervals (currently May and November), generally 2-3 weeks after the semi-annual inspection of PI locations, at a convened IACUC meeting with a quorum present. At the meeting, the IACUC reviews the UAC Program Description, which is updated every six months to reflect any programmatic or procedural changes. The IACUC is also apprised of major changes to UAC SOPs. The IACUC reviews the semi-annual inspection findings, departures from the *Guide*, adverse events and any IACUC programmatic changes for the preceding six months. A representative from the Institution's Occupational Health Program provides the IACUC with an overview of the Animal Hazards Program, including emergent issues requiring IACUC input. The IACUC documents its review of the Institution's ACUP using the *OLAW Semi-Annual Program Review Checklist*.
 2. Inspect at least once every 6 months all of the Institution's animal facilities, including satellite animal housing facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - a. Inspections are performed at six month intervals, with 4 inspection cycles per year. PI use location inspections are performed during the spring and fall inspection cycles (currently April and October). UAC location inspections are performed in summer and winter inspection cycles (currently January and July). Due to the size and complexity of the ACUP, different inspection teams inspect locations within a 2-4 week period. Any IACUC member may take part in any inspection. Generally, an inspection team consists of two or more IACUC members. Occasionally, inspections involving non-

USDA regulated species may be performed by a single inspector. Inspection teams visit locations where animals are maintained for ≥ 12 hours (USDA-regulated) or ≥ 24 hours (non-USDA-regulated) and all areas where survival or non-survival surgery is performed. The inspection team uses a checklist, based on the *Guide*, to ensure consistency. Any deficiencies are noted, and those that have the potential to significantly impact the welfare of animals are reported to the AV for immediate resolution.

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:
 - a. Following the IACUC meeting at which the ACUP is reviewed, a draft report is written using the NIH-OLAW Sample *Semi-Annual Program and Facility Review Report*, and this is circulated to all members for comment. At a convened IACUC meeting with a quorum present, the draft is reviewed, approved and signed by a majority of IACUC members. This meeting is generally held the month after the ACUP review meeting (currently December and June). The written report is sent to IO, generally less than a week after approval, and the IACUC Chair and AV review the report with the IO.
 - b. PIs may request a departure from PHS Policy or the *Guide* during protocol submission or by amendment to the protocol (note that we currently do not have any departures from PHS Policy). Using the review procedures outlined below (III.D.6), the IACUC determines whether there is a scientific justification for the departure and may approve it as part of the protocol. A summary of all the departures from the *Guide* are discussed at the ACUP review meeting and included in the *Semi-Annual Program and Facility Review Report*, along with the reasons for the departures.
 - c. The IACUC discusses all deficiencies identified during the semi-annual inspection at the corresponding ACUP review and categorizes them as minor or significant. For deficiencies already corrected by the PI, the IACUC makes a determination as to whether the corrective action is sufficient or additional actions are needed. For uncorrected deficiencies, the IACUC approves a plan and schedule for correction. Minor deficiencies are generally handled by email correspondence. Re-inspections are required for significant deficiencies. The re-inspection may be by an IACUC member, a UAC veterinarian, or designee. The IACUC is responsible for ensuring all deficiencies are corrected according to the plan and schedule. All deficiencies are reported to the IO in the *Semi-Annual Program and Facility Review Report*. If follow-up is required, the IACUC Chair and/or AV will work with the IO to resolve any issues. The IO reports serious, uncorrected deficiencies to the appropriate regulatory agencies. For significant UAC facility issues, the UAC Director works with the IO to obtain funds for renovation, construction and/or equipment.
 - d. The *Semi-Annual Report of the Program Review and Facility Inspection* contains a discussion of the ACUP's adherence to PHS Policy and the Guide, and the reason for any departures, identification of deficiencies and designation as either minor or significant, a schedule and plan for correcting deficiencies and minority views (if any).
4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
 - a. The Institution has mechanisms in place for members of the public, faculty, staff and students to report concerns involving animal care and use. Individuals may contact the IACUC or UAC, verbally or in writing; the IACUC maintains a webpage for anonymous reporting of concerns; the Institution offers a hot line maintained by a third party. This information is widely disseminated and is posted in all locations where animals are used. The Institution has a whistleblower policy to protect employees or students from retribution for expressing concerns.
 - b. All concerns are forwarded to the IACUC Chair and AV, usually via IACUC Office staff. Depending on the nature of the concern, the IACUC Chair assigns an IACUC member, UAC veterinarian, or IACUC Office staff to further research the concern. If the concern is validated by the research, the IACUC prepares a report that documents the issue and includes a corrective action plan and schedule.
 - c. The IO is notified in writing of all validated concerns, the corrective action plan and schedule.

Corrective actions are overseen by the IACUC and the IO, in consultation with other institutional units, as appropriate. The IO reports any issues identified to the appropriate regulatory agencies, as applicable.

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:
 - a. As part of the *Semi-Annual Report of the Program Review and Facility Inspection*, the IACUC makes recommendations to the IO related the ACUP. The IACUC Chair and/or AV will provide additional information and/or meet with the IO, if assistance is needed in the decision making process.
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:
 - a. Protocols and supporting documentation are submitted to the IACUC Office staff.
 - b. The IACUC Office staff perform an administrative pre-review.
 - c. IACUC members are notified of incoming protocols by email. The notification includes a summary of the protocol. IACUC members have 2 business days to review the notification, request additional information and/or call for Full Committee Review (FCR). If there is no call for FCR, incoming protocols are sent to the IACUC Chair for assignment of at least one Designated Member Reviewer (DMR). The DMR process has been agreed to by all IACUC members in writing.
 - d. Protocols and supporting documentation are available on request to all IACUC members, either by email or access through an electronic system.
 - e. IACUC meetings are routinely held once a month. A quorum of the full committee is required prior to conducting official business. The IACUC Chair and AV set the agenda, in consultation with IACUC Office staff. The agenda generally consists of approval of minutes, announcements, member training, old business, new business (e.g., review and approval of SOPs, discussion of adverse events), review of protocols and/or amendments, and membership training. Minutes are circulated to the IACUC members for comment prior to the next meeting.
 - f. If a protocol undergoes FCR, the IACUC Chair appoints one or more IACUC members to review the protocol. The primary reviewer and consulting veterinarian may work with the PI, through the IACUC Office staff, to address any issues prior to FCR. The primary reviewer presents the protocol at an IACUC meeting. The UAC veterinarian that consulted on the protocol also provides their opinion. The Committee discusses the protocol and votes to 1) approve, 2) require modifications to secure approval or 3) withhold approval. If the IACUC votes to send a protocol to DMR following FCR, the convened quorum of the IACUC appoints one or more IACUC members as DMR, by a simple majority. If more than one DMR is appointed, the DMRs review identical copies of the protocol and all DMRs must be unanimous in their decision to 1) approve or 2) require modifications to secure approval. In the event that the DMRs do not agree, or at least one DMR calls for FCR, the protocol is returned to FCR.
 - g. The IACUC Office staff identify conflicts between an IACUC member and a protocol submission. Conflicts include an IACUC member being a spouse or close family member of a protocol participant or a protocol participant themselves. The IACUC Chair is apprised of these conflicts and does not assign a DMR or primary review to a conflicted member. If the DMR or primary reviewer has an unidentified or perceived conflict of interest, they are instructed to notify the IACUC Chair so that the review can be reassigned. The IACUC Chair also instructs IACUC members to recuse themselves from participation in the IACUC review or approval of a protocol in which the member has a conflicting interest, except to provide information requested by the IACUC.
 - h. Following discussion of a protocol at FCR, IACUC members record a written vote to 1) approve, 2) require modifications to secure approval by DMR or 3) withhold approval. A decision to approve (1) or withhold approval (3) is based on a simple majority of the convened quorum of IACUC members. If the majority of IACUC members vote for modifications to secure approval by DMR (2), a DMR is nominated by an IACUC member and the IACUC members present vote unanimously for this

individual by a show of hands/voice vote. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting of the IACUC may decide by unanimous vote to use DMR subsequent to FCR when modifications are needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- i. If there is a recognized need, a quorum of the full IACUC will convene to discuss and vote on a protocol in the absence of prior written notification of the IACUC members. At the convened meeting, IACUC members are notified of the protocol(s) to be reviewed and are provided with written documentation relating to the protocol(s). Time is allocated at the meeting for review of the documents prior to any discussion. Protocols are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above).
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:
 - a. Significant changes are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above). In addition, the IACUC has voted to use an SOP process for veterinary verification and consultation (VVC) of significant changes, as outlined in NOT-OD-14-126. VVC can be used for significant changes to anesthesia, analgesia, sedation, experimental substances, or euthanasia method or in the duration, frequency, type or number of procedures and/or changes in animal numbers. Any UAC veterinarian can consult and verify these changes. Verification of all changes made through this process are documented on the request form and become part of the electronic protocol record. The SOP describes specific evaluation criteria for each type of change and the IACUC reviews and approves the SOP no less than once every three years.
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:
 - a. The IACUC Office staff notifies investigators in writing of the IACUC's decision to approve or withhold approval of those activities relating to the care and use of animals, or of modifications required in the document to secure IACUC approval. The written notification includes the reason for the IACUC's decision to withhold approval and provides information on how the PI may respond to the IACUC's decision. The AV and IO are regularly notified of the IACUC's decisions to approve or withhold approval for animal activities.
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:
 - a. Protocols are reviewed by the IACUC each time an amendment is submitted. Protocols with USDA regulated species, or USDA, DoD, or VA funding undergo continuing review (CR) at years 1 and 2, with De Novo review at year 3. The IACUC membership is notified when the protocol is within 30 days of the annual approval date and is given the opportunity to call for FCR. The IACUC Chair assigns a member to perform DMR in the absence of a call for FCR. The CR process consists of a full review of the protocol and subsequent requirement for protocol modification via amendment or veterinary verification and consultation if deemed necessary (i.e.: to address changes in IACUC standards since the last review). Additional post-approval monitoring occurs on an *ad hoc* basis and consists of protocol review and/or in person visits by IACUC members, UAC veterinarians and/or IACUC Office staff. At these visits, records and drugs may be inspected, personnel interviewed and/or procedures observed. Satellite facilities undergo additional oversight by a UAC veterinarian or designee and are inspected biannually while animals are housed within these facilities.
 - b. The IACUC requires submission of a new protocol and supporting documentation every three years. The protocol renewal is reviewed as described for a new submission in Part III.D.6, with the addition that progress on the current protocol must be included in the protocol renewal.
 - c. The annual review process for USDA-regulated species is described in Part III.9.a (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:
 - a. If the IACUC determines that an approved activity is not being conducted in accordance with federal regulations, the *Guide*, institutional policies and/or approved protocol, the IACUC may decide that the activity should be suspended. In this case, the IACUC reviews the issues at a convened meeting with a quorum present and votes whether or not to suspend the activity. A simple majority vote passes. In the event that the IACUC votes to suspend the activity, the PI and the IO are notified of this decision.
 - b. Once the IACUC has notified the IO of suspension of an activity, the IO in consultation with the IACUC will review the reasons for suspension and take the appropriate corrective action. A report is sent to OLAW detailing the reason for the suspension and the corrective action taken to address the issue and prevent a reoccurrence.
- 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. The Animal Hazards Program (AHP) is the occupational health program for personnel caring for, or using animals in research or teaching. The AHP includes hazard identification and risk assessment, personnel training, personal hygiene, facilities, procedures, and monitoring, personal protection and medical evaluation and preventive medicine. Participation in the AHP is required for individuals caring for or using live animals in research or teaching, and for those who perform necropsy. The following personnel may be required to also participate in the AHP, depending upon the assessment of risk: those working with unfixed animal tissues, cells, fluids or wastes or having environmental contact with live or dead animals; those who perform their duties in laboratory animal facilities, such as maintenance, police and safety, security and custodians; and non-affiliated students, consultants, volunteers or visiting scholars who will be performing animal activities as defined above. Oversight for the AHP is as follows:
 - i. The UA Committee on Occupational Health and the IACUC provide oversight of the AHP, which is managed by Research Laboratory Safety Services (RLSS). Programmatic decisions are based on current occupational health best practices, as recommended by Occupational Health and a working group consisting of the Senior Director of RLSS, Occupational Health medical providers and staff, stakeholders and subject matter experts. Each unit maintains policies, guidance documents, and standard operating procedures specific to their areas of expertise and responsibility. The Basic Occupational Health Care (BOHC) requirements are based on current occupational health recommendations and best practices identified from a number of sources and are used to reduce the health risks associated with specific animal activities. The BOHC requirements include clinic visits, immunizations, diagnostic tests and or counselling, as appropriate for the species used, the types of activity and the individual's medical history. The BOHC requirements are reviewed at least every six months by the Occupational Health working group. Changes are reviewed and approved by the IACUC prior to implementation.
 - ii. UAC provides expertise in animal hazards (zoonoses, bites, physical injuries), as well as current animal husbandry engineering standards that reduce exposure to allergens and prevent personnel exposure to pathogens and chemicals used in experimental studies.
 - iii. Occupational Health currently conducts medical surveillance for the AHP. Occupational Health providers use the Risk Assessment Questionnaire (RAQ) as the primary instrument for obtaining information to determine the risk associated with a participant's animal activities.
 - iv. Research Laboratory Safety Services (RLSS) administers three specific laboratory compliance programs; radiological, chemical and biohazard safety. Each compliance program is led by a responsible officer and appointed committees (several Radiation Safety Committees and the Institutional Biosafety Committee) that grant approval/authorization to those PIs requesting to use regulated hazardous materials under the Institution's licensure, registration, permit, or possession. RLSS provides all-inclusive services that include publishing required program rules,

plans and specific procedures, conducting hazard assessments, performing exposure monitoring, routine on-site inspections, incident investigation, spill response assistance, hazard communication signs and labels, and emergency response and training. RLSS reviews and approves all hazard use listed in IACUC protocols and amendments before work with hazardous materials commences. Locations are routinely inspected by RLSS personnel to evaluate and ensure continued compliance.

- v. Risk Management Services (RMS) administers the Institution's overall risk management effort by providing occupational health and safety services/programs and insurance coverage for property, liability, and workers' compensation. Those enrolled in the AHP receive support from RMS in the event of occupational illness or injury as a result of bites, scratches, needle sticks and exposures to infectious agents, including blood borne pathogens. RMS also provides support related to disposal of hazardous waste, facility air quality, fire safety, emergency response, respiratory protective equipment fit testing and training, and ergonomics.
- b. Individuals participate in the AHP by submission of the RAQ, which includes the individual's medical history, pregnancy status, current and prior illnesses and immunocompetence. After reviewing the RAQ, and in accordance with the BOHC requirements, the Occupational Health provider may require a clinic visit. The clinic visit is used to further determine the need for immunizations, diagnostic tests, personal protective equipment and/or counseling related to the individual's medical history, including pregnancy, current and prior illness and immunocompetence. As part of the counselling, individuals are provided with the specific precautions to reduce the risk associated with working in laboratory animal facilities, depending on their medical history and/or pregnancy status. Participants may be periodically recalled for medical follow-up, depending on the type of animal exposure and the BOHC requirements. Participation in the AHP is required (submission of the RAQ), but medical surveillance can be declined. Note that when working with certain species, immunizations, diagnostic tests and/or personal protective equipment are required and cannot be declined. Personnel choosing to decline any or all medical surveillance must sign a Medical Surveillance Program Declination form documenting an understanding of the risks associated with their declination.
- c. The BOHC (Part III.E.a.i) and the RAQ are used as the basis for medical evaluation and preventive medicine for individuals participating in the AHP. The specific BOHC requirements depends on the species used, the types of activity and the individual's medical history. For a typical rodent user, the individual's tetanus immunization status is assessed and the individual may be counselled on PPE to reduce exposure to allergens. For individuals working with sheep, the individual will also be counselled on Q Fever. All individuals have their tetanus immunization status evaluated and are offered immunization, as appropriate.
- d. Individuals working with or caring for *Macaca* spp. must undergo specialized training with a UAC veterinarian, or designee, to understand the special risks and procedures associated with these animals. The training includes a description of the PPE that must be worn when in animal rooms (fluid resistant gown or coveralls, mask, face shield, 2 pairs of gloves, 2 pairs of shoe covers) and procedures to prevent bites and scratches, including bite proof gloves and use of chemical restraint. Individuals are counselled on the risk of Macacine herpesvirus 1 by a UAC veterinarian, or designee and an Occupational Health provider, including the procedure for cleaning wounds, immediate prophylaxis and medical attention and reporting. All non-human primate areas have a Monkey Exposure Kit which contains detailed instructions, an anti-viral agent for prophylaxis and a thumb drive with information for the medical provider. Exposures must be reported to the individual's supervisor, Occupational Health, the facility coordinator and the UAC Director. All individuals must have an annual test for tuberculosis and may not work with these animals if suffering from an active case of measles.
- e. UAC is responsible for training employees that care for animals. All UAC employees receive training regarding zoonoses, allergens, injuries, personal hygiene and personal protective equipment (PPE) as

part of their new employee orientation. The IACUC is responsible for animal hazards training of individuals using animals in research or teaching. The CITI species specific modules taken by individuals using animals provide information on the risks associated with that species, including zoonoses, allergens and physical injuries. For higher risk activities (e.g., primate care and use), individuals meet with an Occupational Health provider and a UAC veterinarian for one-on-one counselling. RLSS and RMS have the responsibility for training of personnel related to non-animal hazards, such as blood borne pathogens, other biohazards, radiation and chemicals. The PI and RMS are responsible for training on reporting of occupational illness or injury as a result of physical injuries (e.g., bites, scratches, needle sticks, a fall, muscle strain, etc...) and/or exposures to infectious agents, including blood borne pathogens. Any individual with an occupational illness or injury is directed to contact Occupational Health for evaluation. After hours, individuals are directed to their personal physician, an Urgent Care Clinic, Corval, or the emergency room at Banner - University Medical Center Tucson.

- f. Any animal activity involving a hazard is routed to RLSS for review. RLSS works directly with researchers and UAC personnel to ensure that animal activities are conducted in a safe manner and in accordance with all applicable local, state and federal regulations. In addition, UAC facility coordinators provide one-on-one training for use of a particular hazard within UAC facilities. Hazardous material is collected and disposed of by RMS, in accordance with all applicable local, state and federal regulations.
 - g. UAC employees working in central animal facilities wear surgical scrubs provided by UAC. A combination of gloves, gowns, coveralls, N95 respirators, masks, face shields, goggles, safety glasses, ear protection, bonnets, rubber boots and/or shoe covers must be worn depending upon the species, housing requirements and activities being performed. These items are provided by UAC for use by their staff or researchers when in UAC facilities. RLSS oversees the requirements for personal protective equipment (PPE) such as gloves, safety glasses and lab coats for individuals performing animal activities outside of UAC.
 - h. All clothing provided by UAC is laundered in-house, by UAC employees. A commercial laundering service may be used for certain items such as lab coats. Shower facilities are available in all UAC facilities. The ARC has in-house laundry and shower facilities. RLSS is responsible for the procedures for laundering lab coats or other work clothing for individuals performing animal activities outside of UAC. A commercial laundering service is used for researcher lab coats or scrubs.
- 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:
- a. Prior to the start of animal activities, faculty, staff, students and volunteers who care for or use animals in research or teaching are required to complete all applicable certification and training. The Institution uses the Collaborative Institutional Training Institute (CITI) for training related to 1) humane animal care and use, including the applicable laws and regulations and the 3R's 2) species specific information, including animal care and handling and occupational health issues (e.g., zoonoses, allergens) and 3) activity specific information, including aseptic surgery. UAC provides facility orientation and hands-on training for safe animal handling, routine husbandry procedures, and hazard use within the animal facility. Individuals working with non-human primates have additional hands-on training requirements, including the risk of occupational hazards. A UAC veterinarian or designee provides hands-on training and certification for individuals performing physical euthanasia without pre-anesthesia. Completion of training and certification is confirmed by the IACUC Office staff.
 - b. All individuals working with animals in research or teaching must pass the CITI *Working with the*

IACUC: Investigators, Staff and Students course with a score of $\geq 80\%$. This course specifically addressed methods that minimize the number of animals used to obtain significant data. The course also addresses the need to minimize pain and distress. Each species-specific module describes the need to search for alternatives to animal use, humane standards and detecting pain and distress in that species. In addition, all laboratory rodent users must complete the CITI *Reducing Pain and Distress in Laboratory Mice and Rats* course which describes the responsibilities for minimizing animal pain and distress, the signs of pain and distress and methods for controlling pain and distress. Similarly, individuals listed on a protocol where survival or non-survival surgery is approved must pass the CITI *Aseptic Surgery* course, which includes information on surgical pain and distress, as well as analgesia and anesthesia. Individuals performing pre-operative procedures, survival or non-survival surgery and/or post-operative care must complete the *General Rodent Surgical Training* which is taught by a UAC veterinarian or designee. This class covers all aspects of rodent pain and distress, including signs and methods for alleviation with analgesia or other palliative care. UAC also provides optional hands-on training for rodent biometrics and advanced rodent surgery.

- c. Training for new IACUC members includes the CITI module for IACUC members and a one-on-one orientation with the IACUC Officer or designee. As part of the orientation, IACUC members receive written documentation, which includes links to online copies of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the OLAW/ARENA IACUC Guidebook and the Animal Welfare Act/Regulations. IACUC members are also provided the opportunity for mentoring and/or training with an experienced IACUC member. The Institution's IACUC website also provides extensive institutional and regulatory information, which the members can access at any time. IACUC members receive regular training at monthly Committee meetings and are encouraged to attend local training opportunities.

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.

The 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 semi-annual 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 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 IO [REDACTED]
 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 IO, [REDACTED]
 - 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: [REDACTED]
Title: Interim Vice President for Research
Institution: University of Arizona
Address: PO Box 210066
Tucson, AZ 85721
Phone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

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: [REDACTED]

Date: 3/11/19

B. PHS Approving Official

Name/Title:
Address: Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
Phone: 301-496-7163
Fax: 301-915-9465

Signature: _____

Date: _____

Assurance Number:

Effective Date:

Expiration Date:

VIII: MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Name of Institution: The University of Arizona			
Assurance Number: D16-00159 (A3248-01)		Date: 3/4/2019	
Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson	
Name: [REDACTED] Title: Professor Degree/Credential: PhD		School of [REDACTED] University of Arizona P.O. Box 210090 Tucson, AZ 85721 Phone: [REDACTED] Email: [REDACTED]	
Name of Member/Code	Degree/Credentials	Position Title	PHS Policy Membership Requirements
David G. Besselsen	DVM, PhD, DACLAM, DACVP	Director of University Animal Care, Attending Veterinarian	Veterinarian
3	PhD	Associate Professor, English	Nonscientist
4	DVM, PhD	Research Assistant Professor, Medicine	Alternate, Scientist
5	PhD	Research Assistant Professor, Pharmacology	Scientist
6	DVM, DACLAM	Associate Director, University Animal Care	Veterinarian
7	BS	Research Specialist Senior, Research, Discovery & Innovation	Alternate, Member
8	PhD	Professor, Psychology	Scientist
9	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
10	PhD	Professor, Basic Medical Sciences	Scientist
11	PhD	Professor, Immunobiology	Scientist
12	PhD	Associate Professor, Cellular & Molecular Medicine	Alternate, Scientist
13	DVM, MS	Associate Veterinary Specialist, University Animal Care	Veterinarian
14	PhD	Associate Staff Scientist, Arizona Research Labs	Scientist
15	PhD	Associate Professor, Physiology	Scientist
16	PhD	Assistant Professor, Pharmacology	Alternate, Scientist
17	PhD	Assistant Professor, Medicine	Scientist
18	BA	IACUC Officer, Research, Discovery & Innovation	Member
19	PhD	Professor, School of Natural Resources and the Environment	Scientist
20	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
21	BSBAM	Program Coordinator, Campus Health Service – Occupational Health	Alternate, Nonscientist
22	VMD, MS, DACLAM	Associate Veterinary Specialist, University Animal Care	Alternate, Veterinarian
23	PhD	Assistant Professor, School of Animal Comparative and Biomedical Sciences	Alternate, Scientist
24	PhD	Assistant Professor, Immunobiology	Alternate, Scientist
25	DVM	Associate Research Professor, Valley Fever Center for Excellence	Alternate, Scientist

26	PhD	Assistant Research Scientist, Surgery	Alternate, Scientist
27	PhD	Self-employed Anthropologist	Nonaffiliated
28	PhD	Assistant Professor, Medicine	Scientist
29	PhD	Assistant Professor, Cellular & Molecular Medicine	Alternate, scientist
30	PhD	Associate Professor, Medical Imaging	Scientist
31	PhD	Assistant Professor, Surgery	Alternate, Scientist
32	BSN	Retired Nurse	Nonaffiliated

IX: OTHER KEY CONTACTS

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

Name: David G. Besselsen,
Title: UAC Director and Attending Veterinarian
Phone: [REDACTED]
E-mail: besselsd@email.arizona.edu

X: FACILITY AND SPECIES INVENTORY

Date: 03/4/2019

Name of Institution: The University of Arizona

Assurance number: D16-00159 (A3248-01)

Laboratory, Unit, or Building	Gross Square Feet	Species Housed	Approximate Average Daily Inventory
[REDACTED]	47,000	Mouse	13,200
		Rat	1,000
		Guinea pig	5
		Rabbit	10
		Pig	15
		Frog	15
		Rhesus macaque	12
		Zebrafish	100
[REDACTED]	23,040	Mouse	14,100
	40,254	Mouse	2,400
[REDACTED]		Rat	120
		Hamster	12
		Calf	3
		Zebrafinch	200
		Mouse	4,200
[REDACTED]		Rat	250
		Bonnet macaque	4
[REDACTED]	5,166	Rat	10
	28,300	Sheep	18
	352	Mouse	18 (when in use)
	760	Rat	12 (when in use)
	200	Bird	120
	400	Fish	600

From: [ORCR iacuc](#)
To: pknapp@nih.gov
Cc: [REDACTED] [Besselsen, David G](#)
- (besselsd)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Thursday, July 25, 2019 9:52:00 AM
Attachments: [2019 PHS Assurance D16-00159 \(A-3248-01\) revised 7.25.2019.docx](#)
[D16-00159UniversityofArizonaClarificationLetter07.PDF](#)

Hello Ms. Knapp,

Please find our updated draft assurance attached. I believe these revisions have addressed each of the clarifications requested in your letter. Please let me know if you have any questions about these revisions, or if additional clarifications are needed.

Thank you,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

The University of Arizona
D16-00159 (A-3248-01)

ANIMAL WELFARE ASSURANCE

I, [REDACTED] as named Institutional Official for animal care and use at The University of Arizona, 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 and/or the National Science Foundation (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:**
University of Arizona [REDACTED] facilities, [REDACTED] facilities, Main Campus facilities, and [REDACTED] Center [REDACTED] facilities that house PHS- or NSF-funded animals and animal research.
- B. **The following are other institution(s), or branches and components of another institution:**
Not applicable

II. INSTITUTIONAL COMMITMENT

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*.
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with 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 (sub-award) 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:
1. The President of the University of Arizona is the Chief Executive Officer (CEO).
 2. The Vice President for Research (VPR) serves as the Institutional Official (IO).

3. The IACUC oversees the Animal Care and Use Program (ACUP). The IACUC is appointed by the IO, as per written authority from the CEO. The IACUC Chair reports to the IO. In addition, there are open lines of communication between the IACUC and the IO.
 4. The Attending Veterinarian (AV) reports directly to the IO. The AV has been given the authority and responsibilities outlined by the Animal Welfare Act, PHS Policy, and the *Guide* to ensure the welfare of all animals at the Institution. The current AV is the Director of University Animal Care (UAC).
 5. UAC is responsible for overseeing all veterinary care and husbandry functions for the Institution. The Director of UAC reports to the VPR.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: David G. Besselsen

Degrees: DVM, PhD, DACLAM, DACVP

Training and/or experience in laboratory animal medicine: Dr. Besselsen completed his DVM (1988), laboratory animal medicine residency program (1994), and PhD in Pathobiology (1995) at the University of Missouri. He joined UAC in 1995. He obtained board certification in Laboratory Animal Medicine in 1995 and Veterinary Pathology in 2004. His specialties are rodent medicine, pathology, quality assurance, and facility design. He is experienced with all traditional laboratory animal species.

Authority: Dr. Besselsen has direct program authority and responsibility for the Institution's ACUP, including access to all animals, as AV.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from the University of [REDACTED]. [REDACTED] joined UAC in 2012, and obtained ACLAM board-certification in 2013. [REDACTED] specialties are clinical medicine, non-human primate medicine, large animal surgical models, anesthesia, and analgesia. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from [REDACTED]. [REDACTED] became a researcher at the University of Arizona, completed an MS in Animal Science (1992), and joined UAC in 1996. [REDACTED] obtained [REDACTED] CPIA credentials in 2018. [REDACTED] specialties are regulatory affairs, rodent and large animal experimental surgery, analgesia, and public outreach. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] VMD from The University of [REDACTED] and completed [REDACTED] MS and laboratory animal medicine residency at the University of [REDACTED]. [REDACTED] joined UAC in 2015 and obtained ACLAM certification in 2016. [REDACTED] specialties are rodent medicine, surgery, biometrics, and gnotobiology. [REDACTED] is experienced with all traditional laboratory animals.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: MS, DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] MS in Pathobiology from the UA [REDACTED] and [REDACTED] DVM from [REDACTED]. He practiced mixed, large and companion animal medicine and surgery in [REDACTED]. [REDACTED] joined UAC in 2016. He specializes in clinical farm animal medicine and management, with an emphasis on production agriculture and large animal surgical models.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] DVM at [REDACTED] and a laboratory animal medicine residency program at [REDACTED]. [REDACTED] joined UAC in 2018. [REDACTED] specializes in general laboratory animal medicine and management, with an emphasis on rodent medicine, surgery, and biometrics, non-traditional laboratory animal species and environmental enrichment.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

- 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 ACUP 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:
 - a. Review of the ACUP occurs at six month intervals (currently May and November), generally 2-3 weeks after the semi-annual inspection of PI locations, at a convened IACUC meeting with a quorum present. At the meeting, the IACUC reviews the UAC Program Description, which is updated every six months to reflect any programmatic or procedural changes. The IACUC is also apprised of major changes to UAC SOPs. The IACUC reviews the semi-annual inspection findings, departures from the *Guide*, adverse events and any IACUC programmatic changes for the preceding six months. A representative from the Institution's Occupational Health Program provides the IACUC with an overview of the Animal Hazards Program, including emergent issues requiring IACUC input. The IACUC documents its review of the Institution's ACUP using the *OLAW Semi-Annual Program Review Checklist*.
 2. Inspect at least once every 6 months all of the Institution's animal facilities, including satellite animal housing facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - a. Inspections are performed at six month intervals, with 4 inspection cycles per year. PI use location inspections are performed during the spring and fall inspection cycles (currently April and October). UAC location inspections are performed in summer and winter inspection cycles (currently January and July). Due to the size and complexity of the ACUP, different inspection teams inspect locations within a 2-4 week period. Any IACUC member may take part in any inspection. Generally, an inspection team consists of two or more IACUC members. Occasionally, inspections involving non-

USDA regulated species may be performed by a single inspector. Inspection teams visit locations where animals are maintained for ≥ 12 hours (USDA-regulated) or ≥ 24 hours (non-USDA-regulated) and all areas where survival or non-survival surgery is performed. The inspection team uses a checklist, based on the *Guide*, to ensure consistency. Any deficiencies are noted, and those that have the potential to significantly impact the welfare of animals are reported to the AV for immediate resolution.

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:
 - a. Following the IACUC meeting at which the ACUP is reviewed, a draft report is written using the NIH-OLAW Sample *Semi-Annual Program and Facility Review Report*, and this is circulated to all members for comment. At a convened IACUC meeting with a quorum present, the draft is reviewed, approved and signed by a majority of IACUC members. This meeting is generally held the month after the ACUP review meeting (currently December and June). The written report is sent to IO, generally less than a week after approval, and the IACUC Chair and AV review the report with the IO.
 - b. PIs may request a departure from PHS Policy or the *Guide* during protocol submission or by amendment to the protocol (note that we currently do not have any departures from PHS Policy). Using the review procedures outlined below (III.D.6), the IACUC determines whether there is a scientific justification for the departure and may approve it as part of the protocol. A summary of all the departures from the *Guide* are discussed at the ACUP review meeting and included in the *Semi-Annual Program and Facility Review Report*, along with the reasons for the departures.
 - c. The IACUC discusses all deficiencies identified during the semi-annual inspection at the corresponding ACUP review and categorizes them as minor or significant. For deficiencies already corrected by the PI, the IACUC makes a determination as to whether the corrective action is sufficient or additional actions are needed. For uncorrected deficiencies, the IACUC approves a plan and schedule for correction. Minor deficiencies are generally handled by email correspondence. Re-inspections are required for significant deficiencies. The re-inspection may be by an IACUC member, a UAC veterinarian, or designee. The IACUC is responsible for ensuring all deficiencies are corrected according to the plan and schedule. All deficiencies are reported to the IO in the *Semi-Annual Program and Facility Review Report*. If follow-up is required, the IACUC Chair and/or AV will work with the IO to resolve any issues. The IO reports serious, uncorrected deficiencies to the appropriate regulatory agencies. For significant UAC facility issues, the UAC Director works with the IO to obtain funds for renovation, construction and/or equipment.
 - d. The *Semi-Annual Report of the Program Review and Facility Inspection* contains a discussion of the ACUP's adherence to PHS Policy and the Guide, and the reason for any departures, identification of deficiencies and designation as either minor or significant, a schedule and plan for correcting deficiencies and minority views (if any).
4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
 - a. The Institution has mechanisms in place for members of the public, faculty, staff and students to report concerns involving animal care and use. Individuals may contact the IACUC or UAC, verbally or in writing; the IACUC maintains a webpage for anonymous reporting of concerns; the Institution offers a hot line maintained by a third party. This information is widely disseminated and is posted in all locations where animals are used. The Institution has a whistleblower policy to protect employees or students from retribution for expressing concerns.
 - b. All concerns are forwarded to the IACUC Chair and AV, usually via IACUC Office staff. Depending on the nature of the concern, the IACUC Chair assigns an IACUC member, UAC veterinarian, or IACUC Office staff to further research the concern. If the concern is validated by the research, the IACUC prepares a report that documents the issue and includes a corrective action plan and schedule.
 - c. The IO is notified in writing of all validated concerns, the corrective action plan and schedule.

Corrective actions are overseen by the IACUC and the IO, in consultation with other institutional units, as appropriate. The IO reports any issues identified to the appropriate regulatory agencies, as applicable.

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:
 - a. As part of the *Semi-Annual Report of the Program Review and Facility Inspection*, the IACUC makes recommendations to the IO related the ACUP. The IACUC Chair and/or AV will provide additional information and/or meet with the IO, if assistance is needed in the decision making process.
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:
 - a. Protocols and supporting documentation are submitted to the IACUC Office staff.
 - b. The IACUC Office staff perform an administrative pre-review.
 - c. IACUC members are notified of incoming protocols by email. The notification includes a summary of the protocol. IACUC members have 2 business days to review the notification, request additional information and/or call for Full Committee Review (FCR). If there is no call for FCR, incoming protocols are sent to the IACUC Chair for assignment of at least one Designated Member Reviewer (DMR). The DMR process has been agreed to by all IACUC members in writing.
 - d. Protocols and supporting documentation are available on request to all IACUC members, either by email or access through an electronic system.
 - e. IACUC meetings are routinely held once a month. A quorum of the full committee is required prior to conducting official business. The IACUC Chair and AV set the agenda, in consultation with IACUC Office staff. The agenda generally consists of approval of minutes, announcements, member training, old business, new business (e.g., review and approval of SOPs, discussion of adverse events), review of protocols and/or amendments, and membership training. Minutes are circulated to the IACUC members for comment prior to the next meeting.
 - f. If a protocol undergoes FCR, the IACUC Chair appoints one or more IACUC members to review the protocol. The primary reviewer and consulting veterinarian may work with the PI, through the IACUC Office staff, to address any issues prior to FCR. The primary reviewer presents the protocol at an IACUC meeting. The UAC veterinarian that consulted on the protocol also provides their opinion. The Committee discusses the protocol and votes to 1) approve, 2) require modifications to secure approval or 3) withhold approval. If the IACUC votes to send a protocol to DMR following FCR, the convened quorum of the IACUC appoints one or more IACUC members as DMR, by a simple majority. If more than one DMR is appointed, the DMRs review identical copies of the protocol and all DMRs must be unanimous in their decision to 1) approve or 2) require modifications to secure approval. In the event that the DMRs do not agree, or at least one DMR calls for FCR, the protocol is returned to FCR.
 - g. The IACUC Office staff identify conflicts between an IACUC member and a protocol submission. Conflicts include an IACUC member being a spouse or close family member of a protocol participant or a protocol participant themselves. The IACUC Chair is apprised of these conflicts and does not assign a DMR or primary review to a conflicted member. If the DMR or primary reviewer has an unidentified or perceived conflict of interest, they are instructed to notify the IACUC Chair so that the review can be reassigned. The IACUC Chair also instructs IACUC members to recuse themselves from participation in the IACUC review or approval of a protocol in which the member has a conflicting interest, except to provide information requested by the IACUC.
 - h. Following discussion of a protocol at FCR, IACUC members record a written vote to 1) approve, 2) require modifications to secure approval by DMR or 3) withhold approval. A decision to approve (1) or withhold approval (3) is based on a simple majority of the convened quorum of IACUC members. If the majority of IACUC members vote for modifications to secure approval by DMR (2), a DMR is nominated by an IACUC member and the IACUC members present vote unanimously for this

individual by a show of hands/voice vote. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting of the IACUC may decide by unanimous vote to use DMR subsequent to FCR when modifications are needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- i. If there is a recognized need, a quorum of the full IACUC will convene to discuss and vote on a protocol in the absence of prior written notification of the IACUC members. At the convened meeting, IACUC members are notified of the protocol(s) to be reviewed and are provided with written documentation relating to the protocol(s). Time is allocated at the meeting for review of the documents prior to any discussion. Protocols are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above).
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:
 - a. Significant changes are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above). In addition, the IACUC has voted to use an SOP process for veterinary verification and consultation (VVC) of significant changes, as outlined in NOT-OD-14-126. VVC can be used for significant changes to anesthesia, analgesia, sedation, experimental substances, or euthanasia method or in the duration, frequency, type or number of procedures and/or changes in animal numbers. Any UAC veterinarian can consult and verify these changes. Verification of all changes made through this process are documented on the request form and become part of the electronic protocol record. The SOP describes specific evaluation criteria for each type of change and the IACUC reviews and approves the SOP no less than once every three years.
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:
 - a. The IACUC Office staff notifies investigators in writing of the IACUC's decision to approve or withhold approval of those activities relating to the care and use of animals, or of modifications required in the document to secure IACUC approval. The written notification includes the reason for the IACUC's decision to withhold approval and provides information on how the PI may respond to the IACUC's decision. The AV and IO are regularly notified of the IACUC's decisions to approve or withhold approval for animal activities.
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:
 - a. Protocols are reviewed by the IACUC each time an amendment is submitted. Protocols with USDA regulated species, or USDA, DoD, or VA funding undergo continuing review (CR) at years 1 and 2, with De Novo review at year 3. The IACUC membership is notified when the protocol is within 30 days of the annual approval date and is given the opportunity to call for FCR. The IACUC Chair assigns a member to perform DMR in the absence of a call for FCR. The CR process consists of a full review of the protocol and subsequent requirement for protocol modification via amendment or veterinary verification and consultation if deemed necessary (i.e.: to address changes in IACUC standards since the last review). Additional post-approval monitoring occurs on an *ad hoc* basis and consists of protocol review and/or in person visits by IACUC members, UAC veterinarians and/or IACUC Office staff. At these visits, records and drugs may be inspected, personnel interviewed and/or procedures observed. Satellite facilities undergo additional oversight by a UAC veterinarian or designee and are inspected biannually while animals are housed within these facilities.
 - b. The IACUC requires submission of a new protocol and supporting documentation every three years. The protocol renewal is reviewed as described for a new submission in Part III.D.6, with the addition that progress on the current protocol must be included in the protocol renewal.
 - c. The annual review process for USDA-regulated species is described in Part III.9.a (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:
- a. If the IACUC determines that an approved activity is not being conducted in accordance with federal regulations, the *Guide*, institutional policies and/or approved protocol, the IACUC may decide that the activity should be suspended. In this case, the IACUC reviews the issues at a convened meeting with a quorum present and votes whether or not to suspend the activity. A simple majority vote passes. In the event that the IACUC votes to suspend the activity, the PI and the IO are notified of this decision.
 - b. Once the IACUC has notified the IO of suspension of an activity, the IO in consultation with the IACUC will review the reasons for suspension and take the appropriate corrective action. A report is sent to OLAW detailing the reason for the suspension and the corrective action taken to address the issue and prevent a reoccurrence.
- 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. The Animal Hazards Program (AHP) is the occupational health program for personnel caring for, or using animals in research or teaching. The AHP includes hazard identification and risk assessment, personnel training, personal hygiene, facilities, procedures, and monitoring, personal protection and medical evaluation and preventive medicine. Participation in the AHP is required for individuals caring for or using live animals in research or teaching, and for those who perform necropsy. The following personnel may be required to also participate in the AHP, depending upon the assessment of risk: those working with unfixed animal tissues, cells, fluids or wastes or having environmental contact with live or dead animals; those who perform their duties in laboratory animal facilities, such as maintenance, police and safety, security and custodians; and non-affiliated students, consultants, volunteers or visiting scholars who will be performing animal activities as defined above. Oversight for the AHP is as follows:
 - i. The UA Committee on Occupational Health and the IACUC provide oversight of the AHP, which is managed by Research Laboratory Safety Services (RLSS). Programmatic decisions are based on current occupational health best practices, as recommended by Occupational Health and a working group consisting of the Senior Director of RLSS, Occupational Health medical providers and staff, stakeholders and subject matter experts. Each unit maintains policies, guidance documents, and standard operating procedures specific to their areas of expertise and responsibility. The Basic Occupational Health Care (BOHC) requirements are based on current occupational health recommendations and best practices identified from a number of sources and are used to reduce the health risks associated with specific animal activities. The BOHC requirements include clinic visits, immunizations, diagnostic tests and or counselling, as appropriate for the species used, the types of activity and the individual's medical history. The BOHC requirements are reviewed at least every six months by the Occupational Health working group. Changes are reviewed and approved by the IACUC prior to implementation.
 - ii. UAC provides expertise in animal hazards (zoonoses, bites, physical injuries), as well as current animal husbandry engineering standards that reduce exposure to allergens and prevent personnel exposure to pathogens and chemicals used in experimental studies.
 - iii. Occupational Health currently conducts medical surveillance for the AHP. Occupational Health providers use the Risk Assessment Questionnaire (RAQ) as the primary instrument for obtaining information to determine the risk associated with a participant's animal activities.
 - iv. Research Laboratory Safety Services (RLSS) administers three specific laboratory compliance programs; radiological, chemical and biohazard safety. Each compliance program is led by a responsible officer and appointed committees (several Radiation Safety Committees and the Institutional Biosafety Committee) that grant approval/authorization to those PIs requesting to use regulated hazardous materials under the Institution's licensure, registration, permit, or possession. RLSS provides all-inclusive services that include publishing required program rules,

plans and specific procedures, conducting hazard assessments, performing exposure monitoring, routine on-site inspections, incident investigation, spill response assistance, hazard communication signs and labels, and emergency response and training. RLSS reviews and approves all hazard use listed in IACUC protocols and amendments before work with hazardous materials commences. Locations are routinely inspected by RLSS personnel to evaluate and ensure continued compliance.

- v. Risk Management Services (RMS) administers the Institution's overall risk management effort by providing occupational health and safety services/programs and insurance coverage for property, liability, and workers' compensation. Those enrolled in the AHP receive support from RMS in the event of occupational illness or injury as a result of bites, scratches, needle sticks and exposures to infectious agents, including blood borne pathogens. RMS also provides support related to disposal of hazardous waste, facility air quality, fire safety, emergency response, respiratory protective equipment fit testing and training, and ergonomics.
- b. Individuals participate in the AHP by submission of the RAQ, which includes the individual's medical history, pregnancy status, current and prior illnesses and immunocompetence. After reviewing the RAQ, and in accordance with the BOHC requirements, the Occupational Health provider may require a clinic visit. The clinic visit is used to further determine the need for immunizations, diagnostic tests, personal protective equipment and/or counseling related to the individual's medical history, including pregnancy, current and prior illness and immunocompetence. As part of the counselling, individuals are provided with the specific precautions to reduce the risk associated with working in laboratory animal facilities, depending on their medical history and/or pregnancy status. Participants may be periodically recalled for medical follow-up, depending on the type of animal exposure and the BOHC requirements. Participation in the AHP is required (submission of the RAQ), but medical surveillance can be declined. Note that when working with certain species, immunizations, diagnostic tests and/or personal protective equipment are required and cannot be declined. Personnel choosing to decline any or all medical surveillance must sign a Medical Surveillance Program Declination form documenting an understanding of the risks associated with their declination.
- c. The BOHC (Part III.E.a.i) and the RAQ are used as the basis for medical evaluation and preventive medicine for individuals participating in the AHP. The specific BOHC requirements depends on the species used, the types of activity and the individual's medical history. For a typical rodent user, the individual's tetanus immunization status is assessed and the individual may be counselled on PPE to reduce exposure to allergens. For individuals working with sheep, the individual will also be counselled on Q Fever. All individuals have their tetanus immunization status evaluated and are offered immunization, as appropriate.
- d. Individuals working with or caring for *Macaca* spp. must undergo specialized training with a UAC veterinarian, or designee, to understand the special risks and procedures associated with these animals. The training includes a description of the PPE that must be worn when in animal rooms (fluid resistant gown or coveralls, mask, face shield, 2 pairs of gloves, 2 pairs of shoe covers) and procedures to prevent bites and scratches, including bite proof gloves and use of chemical restraint. Individuals are counselled on the risk of Macacine herpesvirus 1 by a UAC veterinarian, or designee and an Occupational Health provider, including the procedure for cleaning wounds, immediate prophylaxis and medical attention and reporting. All non-human primate areas have a Monkey Exposure Kit which contains detailed instructions, an anti-viral agent for prophylaxis and a thumb drive with information for the medical provider. Exposures must be reported to the individual's supervisor, Occupational Health, the facility coordinator and the UAC Director. All individuals must have an annual test for tuberculosis and may not work with these animals if suffering from an active case of measles.
- e. UAC is responsible for training employees that care for animals. All UAC employees receive training regarding zoonoses, allergens, injuries, personal hygiene and personal protective equipment (PPE) as

part of their new employee orientation. The IACUC is responsible for animal hazards training of individuals using animals in research or teaching. The CITI species specific modules taken by individuals using animals provide information on the risks associated with that species, including zoonoses, allergens and physical injuries. For higher risk activities (e.g., primate care and use), individuals meet with an Occupational Health provider and a UAC veterinarian for one-on-one counselling. RLSS and RMS have the responsibility for training of personnel related to non-animal hazards, such as blood borne pathogens, other biohazards, radiation and chemicals. The PI and RMS are responsible for training on reporting of occupational illness or injury as a result of physical injuries (e.g., bites, scratches, needle sticks, a fall, muscle strain, etc...) and/or exposures to infectious agents, including blood borne pathogens. Any individual with an occupational illness or injury is directed to contact Occupational Health for evaluation. After hours, individuals are directed to their personal physician, an Urgent Care Clinic, Corval, or the emergency room at Banner - University Medical Center Tucson.

- f. Any animal activity involving a hazard is routed to RLSS for review. RLSS works directly with researchers and UAC personnel to ensure that animal activities are conducted in a safe manner and in accordance with all applicable local, state and federal regulations. In addition, UAC facility coordinators provide one-on-one training for use of a particular hazard within UAC facilities. Hazardous material is collected and disposed of by RMS, in accordance with all applicable local, state and federal regulations.
 - g. UAC employees working in central animal facilities wear surgical scrubs provided by UAC. A combination of gloves, gowns, coveralls, N95 respirators, masks, face shields, goggles, safety glasses, ear protection, bonnets, rubber boots and/or shoe covers must be worn depending upon the species, housing requirements and activities being performed. These items are provided by UAC for use by their staff or researchers when in UAC facilities. RLSS oversees the requirements for personal protective equipment (PPE) such as gloves, safety glasses and lab coats for individuals performing animal activities outside of UAC.
 - h. All clothing provided by UAC is laundered in-house, by UAC employees. A commercial laundering service may be used for certain items such as lab coats. Shower facilities are available in all UAC facilities. The ARC has in-house laundry and shower facilities. RLSS is responsible for the procedures for laundering lab coats or other work clothing for individuals performing animal activities outside of UAC. A commercial laundering service is used for researcher lab coats or scrubs.
- 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:
- a. Prior to the start of animal activities, faculty, staff, students and volunteers who care for or use animals in research or teaching are required to complete all applicable certification and training. The Institution uses the Collaborative Institutional Training Institute (CITI) for training related to 1) humane animal care and use, including the applicable laws and regulations and the 3R's 2) species specific information, including animal care and handling and occupational health issues (e.g., zoonoses, allergens) and 3) activity specific information, including aseptic surgery. UAC provides facility orientation and hands-on training for safe animal handling, routine husbandry procedures, and hazard use within the animal facility. Individuals working with non-human primates have additional hands-on training requirements, including the risk of occupational hazards. A UAC veterinarian or designee provides hands-on training and certification for individuals performing physical euthanasia without pre-anesthesia. Completion of training and certification is confirmed by the IACUC Office staff.
 - b. All individuals working with animals in research or teaching must pass the CITI *Working with the*

IACUC: *Investigators, Staff and Students* course with a score of $\geq 80\%$. This course specifically addressed methods that minimize the number of animals used to obtain significant data. The course also addresses the need to minimize pain and distress. Each species-specific module describes the need to search for alternatives to animal use, humane standards and detecting pain and distress in that species. In addition, all laboratory rodent users must complete the CITI *Reducing Pain and Distress in Laboratory Mice and Rats* course which describes the responsibilities for minimizing animal pain and distress, the signs of pain and distress and methods for controlling pain and distress. Similarly, individuals listed on a protocol where survival or non-survival surgery is approved must pass the CITI *Aseptic Surgery* course, which includes information on surgical pain and distress, as well as analgesia and anesthesia. Individuals performing pre-operative procedures, survival or non-survival surgery and/or post-operative care must complete the *General Rodent Surgical Training* which is taught by a UAC veterinarian or designee. This class covers all aspects of rodent pain and distress, including signs and methods for alleviation with analgesia or other palliative care. UAC also provides optional hands-on training for rodent biometrics and advanced rodent surgery.

- c. Training for new IACUC members includes the CITI module for IACUC members and a one-on-one orientation with the IACUC Officer or designee. As part of the orientation, IACUC members receive written documentation, which includes links to online copies of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the OLAW/ARENA IACUC Guidebook and the Animal Welfare Act/Regulations. IACUC members are also provided the opportunity for mentoring and/or training with an experienced IACUC member. The Institution's IACUC website also provides extensive institutional and regulatory information, which the members can access at any time. IACUC members receive regular training at monthly Committee meetings and are encouraged to attend local training opportunities.

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.

The 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 semi-annual 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 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 IO, [REDACTED].
 - 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 IO, [REDACTED]
 - 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: [REDACTED]
Title: Interim Vice President for Research
Institution: University of Arizona
Address: PO Box 210066
Tucson, AZ 85721
Phone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

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: [REDACTED]

Date:

3/11/19

B. PHS Approving Official

Name/Title:
Address: Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
Phone: 301-496-7163
Fax: 301-915-9465

Signature: _____

Date: _____

Assurance Number:

Effective Date:

Expiration Date:

VIII: MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Name of Institution: The University of Arizona			
Assurance Number: D16-00159 (A3248-01)		Date: 3/4/2019	
Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson	
Name: [REDACTED] Title: Professor Degree/Credential: PhD		School of [REDACTED] University of Arizona P.O. Box 210090 Tucson, AZ 85721 Phone: [REDACTED] Fax: [REDACTED] Email: [REDACTED]	
Name of Member/Code	Degree/Credentials	Position Title	PHS Policy Membership Requirements
David G. Besselsen	DVM, PhD, DACLAM, DACVP	Director of University Animal Care, Attending Veterinarian	Veterinarian
3	PhD	Associate Professor, English	Nonscientist
4	DVM, PhD	Research Assistant Professor, Medicine	Alternate, Scientist
5	PhD	Research Assistant Professor, Pharmacology	Scientist
6	DVM, DACLAM	Associate Director, University Animal Care	Veterinarian
7	BS	Research Specialist Senior, Research, Discovery & Innovation	Alternate, Member
8	PhD	Professor, Psychology	Scientist
9	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
10	PhD	Professor, Basic Medical Sciences	Scientist
11	PhD	Professor, Immunobiology	Scientist
12	PhD	Associate Professor, Cellular & Molecular Medicine	Alternate, Scientist
13	DVM, MS	Associate Veterinary Specialist, University Animal Care	Veterinarian
14	PhD	Associate Staff Scientist, Arizona Research Labs	Scientist
15	PhD	Associate Professor, Physiology	Scientist
16	PhD	Assistant Professor, Pharmacology	Alternate, Scientist
17	PhD	Assistant Professor, Medicine	Scientist
18	BA	IACUC Officer, Research, Discovery & Innovation	Member
19	PhD	Professor, School of Natural Resources and the Environment	Scientist
20	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
21	BSBAM	Program Coordinator, Campus Health Service – Occupational Health	Alternate, Nonscientist
22	VMD, MS, DACLAM	Associate Veterinary Specialist, University Animal Care	Alternate, Veterinarian
23	PhD	Assistant Professor, School of Animal Comparative and Biomedical Sciences	Alternate, Scientist
24	PhD	Assistant Professor, Immunobiology	Alternate, Scientist
25	DVM	Associate Research Professor, Valley Fever Center for Excellence	Alternate, Scientist

26	PhD	Assistant Research Scientist, Surgery	Alternate, Scientist
27	PhD	Self-employed Anthropologist	Nonaffiliated
28	PhD	Assistant Professor, Medicine	Scientist
29	PhD	Assistant Professor, Cellular & Molecular Medicine	Alternate, scientist
30	PhD	Associate Professor, Medical Imaging	Scientist
31	PhD	Assistant Professor, Surgery	Alternate, Scientist
32	BSN	Retired Nurse	Nonaffiliated

IX: OTHER KEY CONTACTS

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

Name: David G. Besselsen,
Title: UAC Director and Attending Veterinarian
Phone: [REDACTED]
E-mail: besselsd@email.arizona.edu

X: FACILITY AND SPECIES INVENTORY

Date: 03/4/2019

Name of Institution: The University of Arizona

Assurance number: D16-00159 (A3248-01)

Laboratory, Unit, or Building	Gross Square Feet	Species Housed	Approximate Average Daily Inventory
[REDACTED]	47,000	Mouse	13,200
		Rat	1,000
		Guinea pig	5
		Rabbit	10
		Pig	15
		Frog	15
		Rhesus macaque	12
		Zebrafish	100
[REDACTED]	23,040	Mouse	14,100
	40,254	Mouse	2,400
[REDACTED]		Rat	120
		Hamster	12
		Calf	3
		Zebrafinch	200
[REDACTED]	19,603	Mouse	4,200
		Rat	250
[REDACTED]	5,166	Bonnet macaque	4
		Rat	10
[REDACTED]	28,300	Sheep	18
	352	Mouse	18 (when in use)
	760	Rat	12 (when in use)
	200	Bird	120
	400	Fish	600



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://olaw.nih.gov>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: 301-496-7133
Fax: 301-451-5672

July 24, 2019

RE: Assurance Clarification Letter
D16-00159 (A3248-01)
The University of Arizona

[REDACTED]
Interim Vice President for Research
University of Arizona
PO Box 210066
Tucson, AZ 85721

Dear [REDACTED]

Thank you for your Animal Welfare Assurance renewal application. The Office of Laboratory Animal Welfare has completed an initial review and requests the following clarifications. Please return your revised Assurance document to me via email at pknapp@nih.gov with revisions highlighted or in a different color font for efficiency of review. There is no need to include the IO signature until a final version is established.

Part I. The language in the Applicability section of the Assurance has changed since your last renewal to include HHS and/or NSF. Please update the Applicability section to the following 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, **HHS, and/or NSF**. This Assurance covers only those facilities and components listed below.

Part I.A.

- The Assurance lists Phoenix Biomedical Campus facilities as a covered component of The University of Arizona. As such, the program components described in the Assurance apply to the covered component listed in the Assurance. Please clarify that all the programs in the Assurance, including veterinary care, occupational health and safety, and training are applicable to the Phoenix Biomedical Campus facilities. Please describe the differences, if any exist.

- Arizona Cancer Center is listed as a covered component in the current Animal Welfare Assurance but not included in this renewal. Please verify the removal of Arizona Cancer Center as a covered component of The University of Arizona.

Part III.D.6.

- Paragraph f. includes the following statement, “If the IACUC votes to send a protocol to DMR following FCR, the convened quorum of the IACUC appoints one or more IACUC members as DMR, by a simple majority.” Additionally, paragraph h. includes the following statement, “...a DMR is nominated by an IACUC member and the IACUC members present vote unanimously for the individual by a show of hands/voice vote.” The PHS Policy states that the **IACUC Chairperson** is responsible for designating the committee member who would conduct the Designated Member Review. Please clarify this in your description. See reference below from PHS Policy IV.C.2. regarding protocol review.
- Paragraph g., regarding conflict of interest, includes that no member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest, except to provide information as requested by the IACUC. Please also include in the Assurance that a member who has a conflicting interest **may not contribute to the constitution of a quorum**.
- Paragraph i., describing expedited review, states, “If there is a recognized need, a quorum of the full IACUC will convene to discuss and vote on a protocol in the absence of prior written notification of the IACUC members. At the convened meeting, IACUC members are notified of the protocols(s) to be reviewed and are provided with written documentation relating to the protocols(s). Time is allocated at the meeting for review of the documents prior to any discussion. Protocols are reviewed and approved by FCR or DMR, as indicated in Part III.D.6. above.” This review method, as described, is not consistent with PHS Policy. Please see the reference to PHS Policy IV.C.2. below and address the following:
 - PHS Policy requires each IACUC member to be provided a list of protocols to be reviewed prior to the review. Please clarify in the Assurance if all IACUC members, not just a quorum of members present, are notified and provided with written documentation of the protocols to be reviewed prior to the expedited review.
 - Please also include the possible outcomes of protocol review in your expedited review process.
 - Please clarify to what the reference to “III.D.6. above” is referring.

[PHS Policy IV.C.2.](#)

Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval), or request full committee review of those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally

involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

Part VII.

- Please note that OLAW has a new mailing address. Please update the address in the PHS Approving Official block before submitting a final version with signature.

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910
(301) 496-7163

I look forward to hearing from you regarding the items listed above for continued review of your Animal Welfare Assurance document. If you have any questions or wish to discuss in more detail, I can be contacted directly at pknapp@nih.gov and [REDACTED] Thank you for your attention to these matters.

Animal Welfare Policy Scientist
Office of Laboratory Animal Welfare, NIH

cc. IACUC contact
Eileen Morgan, Director of Division of Assurances, OLAW

From: [Knapp, Paula \(NIH/OD\) \[E\]](#)
To: [ORCR iacuc](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Thursday, August 8, 2019 6:04:36 PM
Attachments: [image001.png](#)

Hi [REDACTED]

Thank you for the reminder and I apologize for not getting to this earlier in the week. I did upload a countersigned Assurance document as well as an approval letter into our system, so please let me know if you do not receive it.

Best,

Paula

Paula Knapp

Animal Welfare Policy Scientist

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Drive, Suite 2500 MSC 6910

Bethesda, MD 20892

301.451.4206



Disclaimer: Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Sent: Thursday, August 08, 2019 5:10 PM
To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>
Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Subject: RE: Assurance Renewal Clarification Letter - D16-00159

Hi Paula,

I just wanted to check in as suggested, as it does not appear that we have received a copy of our formal approval letter.

Thank you,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

We want your feedback! Please complete the [IACUC Customer Service Survey](#) to let us know how we are doing.

From: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Sent: Thursday, August 1, 2019 11:03 AM
To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>
Cc: [REDACTED]

[REDACTED]
Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>; ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

Hi Paula,

Please find a signed .pdf copy of the final version attached. Thank you very much for all of your help, I will keep an eye out for the official approval letter.

Best regards,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

We want your feedback! Please complete the [IACUC Customer Service Survey](#) to let us know how we are doing.

From: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Sent: Wednesday, July 31, 2019 11:40 AM

To: ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Cc: [REDACTED]

[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

Hi [REDACTED]

Again, thank you for the revisions. Your Assurance is ready for approval. At your convenience, please return a clean pdf (without markups) with the IO signature. I will countersign and send back along with an official OLAW approval letter via our automated system. Please let me know if you do not receive it in the next day or so. It has been a pleasure working with you and your colleagues to renew your institution's Animal Welfare Assurance. Please feel free to reach out anytime with questions or comments about your animal program or Assurance document.

Best Regards,

Paula

Paula Knapp

Animal Welfare Policy Scientist

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Drive, Suite 2500 MSC 6910

Bethesda, MD 20892

301.451.4206



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From: ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Sent: Thursday, July 25, 2019 12:52 PM

To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Cc: [REDACTED]
[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

Hello Ms. Knapp,

Please find our updated draft assurance attached. I believe these revisions have addressed each of the clarifications requested in your letter. Please let me know if you have any questions about these revisions, or if additional clarifications are needed.

Thank you,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

From: [ORCR iacuc](#)
To: [Knapp, Paula \(NIH/OD\) \[E\]](#)
Cc: [ORCR iacuc](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Thursday, August 8, 2019 2:10:00 PM
Attachments: [image001.png](#)

Hi Paula,

I just wanted to check in as suggested, as it does not appear that we have received a copy of our formal approval letter.

Thank you,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

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Sent: Thursday, August 1, 2019 11:03 AM

To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Cc: [REDACTED]

[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>; ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

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Best regards,

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[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

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From: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Sent: Wednesday, July 31, 2019 11:40 AM

To: ORCR iacuc <[ORCR-IACUC@email.arizona.edu](#)>

Cc: [REDACTED]

[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

Hi [REDACTED]

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Best Regards,

Paula

Paula Knapp

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Sent: Thursday, July 25, 2019 12:52 PM

To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Cc: [REDACTED]
[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

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Thank you,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

From: [Knapp, Paula \(NIH/OD\) \[E\]](#)
To: [ORCR iacuc](#)
Cc: [REDACTED] [Besselsen, David G - \(besselsd\)](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Wednesday, July 31, 2019 11:40:03 AM
Attachments: [image001.png](#)

Hi [REDACTED]

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Sent: Thursday, July 25, 2019 12:52 PM

To: Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

Cc: [REDACTED]
[REDACTED]

Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>

Subject: RE: Assurance Renewal Clarification Letter - D16-00159

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Thank you,

[REDACTED]
[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona



<https://rgw.arizona.edu/compliance/IACUC>

From: [Knapp, Paula \(NIH/OD\) \[E\]](#)
To: [ORCR iacuc](#)
Cc: [REDACTED] [Besselsen, David G - \(besselsd\)](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Wednesday, July 31, 2019 6:14:15 AM
Attachments: [image001.png](#)

Hi [REDACTED]

Thank you for the revisions. I will review and get back to you soon.

Best,

Paula

Paula Knapp

Animal Welfare Policy Scientist

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Drive, Suite 2500 MSC 6910

Bethesda, MD 20892

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Cc: [REDACTED]
[REDACTED]

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Subject: RE: Assurance Renewal Clarification Letter - D16-00159

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[REDACTED]
[REDACTED]
Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona
[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

From: [ORCR iacuc](#)
To: [Knapp, Paula \(NIH/OD\) \[E\]](#)
Cc: [REDACTED] [Besselsen, David G](#)
- (besselsd); [ORCR iacuc](#)
Subject: RE: Assurance Renewal Clarification Letter - D16-00159
Date: Thursday, August 1, 2019 11:03:09 AM
Attachments: [2019 PHS Assurance D16-00159 \(A-3248-01\) Final.pdf](#)
[image001.png](#)

Hi Paula,

Please find a signed .pdf copy of the final version attached. Thank you very much for all of your help, I will keep an eye out for the official approval letter.

Best regards,

[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

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Cc: [REDACTED]

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Subject: RE: Assurance Renewal Clarification Letter - D16-00159

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[REDACTED]

[REDACTED]

Officer

Institutional Animal Care and Use Committee Program

Research, Discovery & Innovation

The University of Arizona

[REDACTED]

<https://rgw.arizona.edu/compliance/IACUC>

The University of Arizona
D16-00159 (A-3248-01)

ANIMAL WELFARE ASSURANCE

I, [REDACTED] as named Institutional Official for animal care and use at The University of Arizona, 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 and/or the National Science Foundation (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:

University of Arizona Health Sciences Center facilities, Phoenix Biomedical Campus facilities, Main Campus facilities, and Agricultural Research Center (ARC) facilities that house PHS- or NSF-funded animals and animal research.

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

Not applicable

II. INSTITUTIONAL COMMITMENT

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*.
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with 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 (sub-award) 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:
 - 1. The President of the University of Arizona is the Chief Executive Officer (CEO).
 - 2. The Vice President for Research (VPR) serves as the Institutional Official (IO).

3. The IACUC oversees the Animal Care and Use Program (ACUP). The IACUC is appointed by the IO, as per written authority from the CEO. The IACUC Chair reports to the IO. In addition, there are open lines of communication between the IACUC and the IO.
 4. The Attending Veterinarian (AV) reports directly to the IO. The AV has been given the authority and responsibilities outlined by the Animal Welfare Act, PHS Policy, and the *Guide* to ensure the welfare of all animals at the Institution. The current AV is the Director of University Animal Care (UAC).
 5. UAC is responsible for overseeing all veterinary care and husbandry functions for the Institution. The Director of UAC reports to the VPR.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: David G. Besselsen

Degrees: DVM, PhD, DACLAM, DACVP

Training and/or experience in laboratory animal medicine: Dr. Besselsen completed his DVM (1988), laboratory animal medicine residency program (1994), and PhD in Pathobiology (1995) at the University of Missouri. He joined UAC in 1995. He obtained board-certification in Laboratory Animal Medicine in 1995 and Veterinary Pathology in 2004. His specialties are rodent medicine, pathology, quality assurance, and facility design. He is experienced with all traditional laboratory animal species.

Authority: Dr. Besselsen has direct program authority and responsibility for the Institution's ACUP, including access to all animals, as AV.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from the University of [REDACTED] joined UAC in 2012, and obtained ACLAM board-certification in 2013. [REDACTED] specialties are clinical medicine, non-human primate medicine, large animal surgical models, anesthesia, and analgesia. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] DVM from [REDACTED] became a researcher at the University of Arizona, completed an MS in Animal Science (1992), and joined UAC in 1996. [REDACTED] obtained [REDACTED] CPIA credentials in 2018. [REDACTED] specialties are regulatory affairs, rodent and large animal experimental surgery, analgesia, and public outreach. [REDACTED] is experienced with all traditional laboratory animal species.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: [REDACTED]

Training and/or experience in laboratory animal medicine: [REDACTED] received [REDACTED] VMD from The University of [REDACTED] and completed [REDACTED] MS and laboratory animal medicine residency at the University of [REDACTED] joined UAC in 2015 and obtained ACLAM certification in 2016. [REDACTED] specialties are rodent medicine, surgery, biometrics, and gnotobiology. [REDACTED] is experienced with all traditional laboratory animals.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: MS, DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] MS in Pathobiology from the UA [REDACTED] and [REDACTED] DVM from [REDACTED]. He practiced mixed, large and companion animal medicine and surgery in [REDACTED]. [REDACTED] joined UAC in 2016. He specializes in clinical farm animal medicine and management, with an emphasis on production agriculture and large animal surgical models.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

Name: [REDACTED]

Degrees: DVM

Training and/or experience in laboratory animal medicine: [REDACTED] completed [REDACTED] DVM at [REDACTED] and a laboratory animal medicine residency program at [REDACTED]. [REDACTED] joined UAC in 2018. [REDACTED] specializes in general laboratory animal medicine and management, with an emphasis on rodent medicine, surgery, and biometrics, non-traditional laboratory animal species and environmental enrichment.

Authority: [REDACTED] has delegated program authority and responsibility for the Institution's ACUP, including access to all animals.

Time contributed to program: Full time employee; time commitment to UAC is 100%.

- 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 ACUP 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:
 - a. Review of the ACUP occurs at six month intervals (currently May and November), generally 2-3 weeks after the semi-annual inspection of PI locations, at a convened IACUC meeting with a quorum present. At the meeting, the IACUC reviews the UAC Program Description, which is updated every six months to reflect any programmatic or procedural changes. The IACUC is also apprised of major changes to UAC SOPs. The IACUC reviews the semi-annual inspection findings, departures from the *Guide*, adverse events and any IACUC programmatic changes for the preceding six months. A representative from the Institution's Occupational Health Program provides the IACUC with an overview of the Animal Hazards Program, including emergent issues requiring IACUC input. The IACUC documents its review of the Institution's ACUP using the *OLAW Semi-Annual Program Review Checklist*.
 2. Inspect at least once every 6 months all of the Institution's animal facilities, including satellite animal housing facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - a. Inspections are performed at six month intervals, with 4 inspection cycles per year. PI use location inspections are performed during the spring and fall inspection cycles (currently April and October). UAC location inspections are performed in summer and winter inspection cycles (currently January and July). Due to the size and complexity of the ACUP, different inspection teams inspect locations within a 2-4 week period. Any IACUC member may take part in any inspection. Generally, an inspection team consists of two or more IACUC members. Occasionally, inspections involving non-

USDA regulated species may be performed by a single inspector. Inspection teams visit locations where animals are maintained for ≥ 12 hours (USDA-regulated) or ≥ 24 hours (non-USDA-regulated) and all areas where survival or non-survival surgery is performed. The inspection team uses a checklist, based on the *Guide*, to ensure consistency. Any deficiencies are noted, and those that have the potential to significantly impact the welfare of animals are reported to the AV for immediate resolution.

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:
 - a. Following the IACUC meeting at which the ACUP is reviewed, a draft report is written using the NIH-OLAW Sample *Semi-Annual Program and Facility Review Report*, and this is circulated to all members for comment. At a convened IACUC meeting with a quorum present, the draft is reviewed, approved and signed by a majority of IACUC members. This meeting is generally held the month after the ACUP review meeting (currently December and June). The written report is sent to IO, generally less than a week after approval, and the IACUC Chair and AV review the report with the IO.
 - b. PIs may request a departure from PHS Policy or the *Guide* during protocol submission or by amendment to the protocol (note that we currently do not have any departures from PHS Policy). Using the review procedures outlined below (III.D.6), the IACUC determines whether there is a scientific justification for the departure and may approve it as part of the protocol. A summary of all the departures from the *Guide* are discussed at the ACUP review meeting and included in the *Semi-Annual Program and Facility Review Report*, along with the reasons for the departures.
 - c. The IACUC discusses all deficiencies identified during the semi-annual inspection at the corresponding ACUP review and categorizes them as minor or significant. For deficiencies already corrected by the PI, the IACUC makes a determination as to whether the corrective action is sufficient or additional actions are needed. For uncorrected deficiencies, the IACUC approves a plan and schedule for correction. Minor deficiencies are generally handled by email correspondence. Re-inspections are required for significant deficiencies. The re-inspection may be by an IACUC member, a UAC veterinarian, or designee. The IACUC is responsible for ensuring all deficiencies are corrected according to the plan and schedule. All deficiencies are reported to the IO in the *Semi-Annual Program and Facility Review Report*. If follow-up is required, the IACUC Chair and/or AV will work with the IO to resolve any issues. The IO reports serious, uncorrected deficiencies to the appropriate regulatory agencies. For significant UAC facility issues, the UAC Director works with the IO to obtain funds for renovation, construction and/or equipment.
 - d. The *Semi-Annual Report of the Program Review and Facility Inspection* contains a discussion of the ACUP's adherence to PHS Policy and the Guide, and the reason for any departures, identification of deficiencies and designation as either minor or significant, a schedule and plan for correcting deficiencies and minority views (if any).
4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
 - a. The Institution has mechanisms in place for members of the public, faculty, staff and students to report concerns involving animal care and use. Individuals may contact the IACUC or UAC, verbally or in writing; the IACUC maintains a webpage for anonymous reporting of concerns; the Institution offers a hot line maintained by a third party. This information is widely disseminated and is posted in all locations where animals are used. The Institution has a whistleblower policy to protect employees or students from retribution for expressing concerns.
 - b. All concerns are forwarded to the IACUC Chair and AV, usually via IACUC Office staff. Depending on the nature of the concern, the IACUC Chair assigns an IACUC member, UAC veterinarian, or IACUC Office staff to further research the concern. If the concern is validated by the research, the IACUC prepares a report that documents the issue and includes a corrective action plan and schedule.
 - c. The IO is notified in writing of all validated concerns, the corrective action plan and schedule.

Corrective actions are overseen by the IACUC and the IO, in consultation with other institutional units, as appropriate. The IO reports any issues identified to the appropriate regulatory agencies, as applicable.

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:
 - a. As part of the *Semi-Annual Report of the Program Review and Facility Inspection*, the IACUC makes recommendations to the IO related the ACUP. The IACUC Chair and/or AV will provide additional information and/or meet with the IO, if assistance is needed in the decision making process.
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:
 - a. Protocols and supporting documentation are submitted to the IACUC Office staff.
 - b. The IACUC Office staff perform an administrative pre-review.
 - c. IACUC members are notified of incoming protocols by email. The notification includes a summary of the protocol. IACUC members have 2 business days to review the notification, request additional information and/or call for Full Committee Review (FCR). If there is no call for FCR, incoming protocols are sent to the IACUC Chair for assignment of at least one Designated Member Reviewer (DMR). The DMR process has been agreed to by all IACUC members in writing.
 - d. Protocols and supporting documentation are available on request to all IACUC members, either by email or access through an electronic system.
 - e. IACUC meetings are routinely held once a month. A quorum of the full committee is required prior to conducting official business. The IACUC Chair and AV set the agenda, in consultation with IACUC Office staff. The agenda generally consists of approval of minutes, announcements, member training, old business, new business (e.g., review and approval of SOPs, discussion of adverse events), review of protocols and/or amendments, and membership training. Minutes are circulated to the IACUC members for comment prior to the next meeting.
 - f. If a protocol undergoes FCR, the IACUC Chair appoints one or more IACUC members to review the protocol. The primary reviewer and consulting veterinarian may work with the PI, through the IACUC Office staff, to address any issues prior to FCR. The primary reviewer presents the protocol at an IACUC meeting. The UAC veterinarian that consulted on the protocol also provides their opinion. The Committee discusses the protocol and votes to 1) approve, 2) require modifications to secure approval or 3) withhold approval. If the IACUC votes to send a protocol to DMR following FCR, the convened quorum of the IACUC appoints one or more IACUC members as DMR, by a simple majority. If more than one DMR is appointed, the DMRs review identical copies of the protocol and all DMRs must be unanimous in their decision to 1) approve or 2) require modifications to secure approval. In the event that the DMRs do not agree, or at least one DMR calls for FCR, the protocol is returned to FCR.
 - g. The IACUC Office staff identify conflicts between an IACUC member and a protocol submission. Conflicts include an IACUC member being a spouse or close family member of a protocol participant or a protocol participant themselves. The IACUC Chair is apprised of these conflicts and does not assign a DMR or primary review to a conflicted member. If the DMR or primary reviewer has an unidentified or perceived conflict of interest, they are instructed to notify the IACUC Chair so that the review can be reassigned. The IACUC Chair also instructs IACUC members to recuse themselves from participation in the IACUC review or approval of a protocol in which the member has a conflicting interest, except to provide information requested by the IACUC.
 - h. Following discussion of a protocol at FCR, IACUC members record a written vote to 1) approve, 2) require modifications to secure approval by DMR or 3) withhold approval. A decision to approve (1) or withhold approval (3) is based on a simple majority of the convened quorum of IACUC members. If the majority of IACUC members vote for modifications to secure approval by DMR (2), a DMR is nominated by an IACUC member and the IACUC members present vote unanimously for this

individual by a show of hands/voice vote. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting of the IACUC may decide by unanimous vote to use DMR subsequent to FCR when modifications are needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

- i. If there is a recognized need, a quorum of the full IACUC will convene to discuss and vote on a protocol in the absence of prior written notification of the IACUC members. At the convened meeting, IACUC members are notified of the protocol(s) to be reviewed and are provided with written documentation relating to the protocol(s). Time is allocated at the meeting for review of the documents prior to any discussion. Protocols are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above).
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:
 - a. Significant changes are reviewed and approved by FCR or DMR, as indicated in Part III.D.6 (above). In addition, the IACUC has voted to use an SOP process for veterinary verification and consultation (VVC) of significant changes, as outlined in NOT-OD-14-126. VVC can be used for significant changes to anesthesia, analgesia, sedation, experimental substances, or euthanasia method or in the duration, frequency, type or number of procedures and/or changes in animal numbers. Any UAC veterinarian can consult and verify these changes. Verification of all changes made through this process are documented on the request form and become part of the electronic protocol record. The SOP describes specific evaluation criteria for each type of change and the IACUC reviews and approves the SOP no less than once every three years.
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:
 - a. The IACUC Office staff notifies investigators in writing of the IACUC's decision to approve or withhold approval of those activities relating to the care and use of animals, or of modifications required in the document to secure IACUC approval. The written notification includes the reason for the IACUC's decision to withhold approval and provides information on how the PI may respond to the IACUC's decision. The AV and IO are regularly notified of the IACUC's decisions to approve or withhold approval for animal activities.
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:
 - a. Protocols are reviewed by the IACUC each time an amendment is submitted. Protocols with USDA regulated species, or USDA, DoD, or VA funding undergo continuing review (CR) at years 1 and 2, with De Novo review at year 3. The IACUC membership is notified when the protocol is within 30 days of the annual approval date and is given the opportunity to call for FCR. The IACUC Chair assigns a member to perform DMR in the absence of a call for FCR. The CR process consists of a full review of the protocol and subsequent requirement for protocol modification via amendment or veterinary verification and consultation if deemed necessary (i.e.: to address changes in IACUC standards since the last review). Additional post-approval monitoring occurs on an *ad hoc* basis and consists of protocol review and/or in person visits by IACUC members, UAC veterinarians and/or IACUC Office staff. At these visits, records and drugs may be inspected, personnel interviewed and/or procedures observed. Satellite facilities undergo additional oversight by a UAC veterinarian or designee and are inspected biannually while animals are housed within these facilities.
 - b. The IACUC requires submission of a new protocol and supporting documentation every three years. The protocol renewal is reviewed as described for a new submission in Part III.D.6, with the addition that progress on the current protocol must be included in the protocol renewal.
 - c. The annual review process for USDA-regulated species is described in Part III.9.a (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:
- a. If the IACUC determines that an approved activity is not being conducted in accordance with federal regulations, the *Guide*, institutional policies and/or approved protocol, the IACUC may decide that the activity should be suspended. In this case, the IACUC reviews the issues at a convened meeting with a quorum present and votes whether or not to suspend the activity. A simple majority vote passes. In the event that the IACUC votes to suspend the activity, the PI and the IO are notified of this decision.
 - b. Once the IACUC has notified the IO of suspension of an activity, the IO in consultation with the IACUC will review the reasons for suspension and take the appropriate corrective action. A report is sent to OLAW detailing the reason for the suspension and the corrective action taken to address the issue and prevent a reoccurrence.
- 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. The Animal Hazards Program (AHP) is the occupational health program for personnel caring for, or using animals in research or teaching. The AHP includes hazard identification and risk assessment, personnel training, personal hygiene, facilities, procedures, and monitoring, personal protection and medical evaluation and preventive medicine. Participation in the AHP is required for individuals caring for or using live animals in research or teaching, and for those who perform necropsy. The following personnel may be required to also participate in the AHP, depending upon the assessment of risk: those working with unfixed animal tissues, cells, fluids or wastes or having environmental contact with live or dead animals; those who perform their duties in laboratory animal facilities, such as maintenance, police and safety, security and custodians; and non-affiliated students, consultants, volunteers or visiting scholars who will be performing animal activities as defined above. Oversight for the AHP is as follows:
 - i. The UA Committee on Occupational Health and the IACUC provide oversight of the AHP, which is managed by Research Laboratory Safety Services (RLSS). Programmatic decisions are based on current occupational health best practices, as recommended by Occupational Health and a working group consisting of the Senior Director of RLSS, Occupational Health medical providers and staff, stakeholders and subject matter experts. Each unit maintains policies, guidance documents, and standard operating procedures specific to their areas of expertise and responsibility. The Basic Occupational Health Care (BOHC) requirements are based on current occupational health recommendations and best practices identified from a number of sources and are used to reduce the health risks associated with specific animal activities. The BOHC requirements include clinic visits, immunizations, diagnostic tests and or counselling, as appropriate for the species used, the types of activity and the individual's medical history. The BOHC requirements are reviewed at least every six months by the Occupational Health working group. Changes are reviewed and approved by the IACUC prior to implementation.
 - ii. UAC provides expertise in animal hazards (zoonoses, bites, physical injuries), as well as current animal husbandry engineering standards that reduce exposure to allergens and prevent personnel exposure to pathogens and chemicals used in experimental studies.
 - iii. Occupational Health currently conducts medical surveillance for the AHP. Occupational Health providers use the Risk Assessment Questionnaire (RAQ) as the primary instrument for obtaining information to determine the risk associated with a participant's animal activities.
 - iv. Research Laboratory Safety Services (RLSS) administers three specific laboratory compliance programs; radiological, chemical and biohazard safety. Each compliance program is led by a responsible officer and appointed committees (several Radiation Safety Committees and the Institutional Biosafety Committee) that grant approval/authorization to those PIs requesting to use regulated hazardous materials under the Institution's licensure, registration, permit, or possession. RLSS provides all-inclusive services that include publishing required program rules,

plans and specific procedures, conducting hazard assessments, performing exposure monitoring, routine on-site inspections, incident investigation, spill response assistance, hazard communication signs and labels, and emergency response and training. RLSS reviews and approves all hazard use listed in IACUC protocols and amendments before work with hazardous materials commences. Locations are routinely inspected by RLSS personnel to evaluate and ensure continued compliance.

- v. Risk Management Services (RMS) administers the Institution's overall risk management effort by providing occupational health and safety services/programs and insurance coverage for property, liability, and workers' compensation. Those enrolled in the AHP receive support from RMS in the event of occupational illness or injury as a result of bites, scratches, needle sticks and exposures to infectious agents, including blood borne pathogens. RMS also provides support related to disposal of hazardous waste, facility air quality, fire safety, emergency response, respiratory protective equipment fit testing and training, and ergonomics.
- b. Individuals participate in the AHP by submission of the RAQ, which includes the individual's medical history, pregnancy status, current and prior illnesses and immunocompetence. After reviewing the RAQ, and in accordance with the BOHC requirements, the Occupational Health provider may require a clinic visit. The clinic visit is used to further determine the need for immunizations, diagnostic tests, personal protective equipment and/or counseling related to the individual's medical history, including pregnancy, current and prior illness and immunocompetence. As part of the counselling, individuals are provided with the specific precautions to reduce the risk associated with working in laboratory animal facilities, depending on their medical history and/or pregnancy status. Participants may be periodically recalled for medical follow-up, depending on the type of animal exposure and the BOHC requirements. Participation in the AHP is required (submission of the RAQ), but medical surveillance can be declined. Note that when working with certain species, immunizations, diagnostic tests and/or personal protective equipment are required and cannot be declined. Personnel choosing to decline any or all medical surveillance must sign a Medical Surveillance Program Declination form documenting an understanding of the risks associated with their declination.
- c. The BOHC (Part III.E.a.i) and the RAQ are used as the basis for medical evaluation and preventive medicine for individuals participating in the AHP. The specific BOHC requirements depends on the species used, the types of activity and the individual's medical history. For a typical rodent user, the individual's tetanus immunization status is assessed and the individual may be counselled on PPE to reduce exposure to allergens. For individuals working with sheep, the individual will also be counselled on Q Fever. All individuals have their tetanus immunization status evaluated and are offered immunization, as appropriate.
- d. Individuals working with or caring for *Macaca* spp. must undergo specialized training with a UAC veterinarian, or designee, to understand the special risks and procedures associated with these animals. The training includes a description of the PPE that must be worn when in animal rooms (fluid resistant gown or coveralls, mask, face shield, 2 pairs of gloves, 2 pairs of shoe covers) and procedures to prevent bites and scratches, including bite proof gloves and use of chemical restraint. Individuals are counselled on the risk of Macacine herpesvirus 1 by a UAC veterinarian, or designee and an Occupational Health provider, including the procedure for cleaning wounds, immediate prophylaxis and medical attention and reporting. All non-human primate areas have a Monkey Exposure Kit which contains detailed instructions, an anti-viral agent for prophylaxis and a thumb drive with information for the medical provider. Exposures must be reported to the individual's supervisor, Occupational Health, the facility coordinator and the UAC Director. All individuals must have an annual test for tuberculosis and may not work with these animals if suffering from an active case of measles.
- e. UAC is responsible for training employees that care for animals. All UAC employees receive training regarding zoonoses, allergens, injuries, personal hygiene and personal protective equipment (PPE) as

part of their new employee orientation. The IACUC is responsible for animal hazards training of individuals using animals in research or teaching. The CITI species specific modules taken by individuals using animals provide information on the risks associated with that species, including zoonoses, allergens and physical injuries. For higher risk activities (e.g., primate care and use), individuals meet with an Occupational Health provider and a UAC veterinarian for one-on-one counselling. RLSS and RMS have the responsibility for training of personnel related to non-animal hazards, such as blood borne pathogens, other biohazards, radiation and chemicals. The PI and RMS are responsible for training on reporting of occupational illness or injury as a result of physical injuries (e.g., bites, scratches, needle sticks, a fall, muscle strain, etc...) and/or exposures to infectious agents, including blood borne pathogens. Any individual with an occupational illness or injury is directed to contact Occupational Health for evaluation. After hours, individuals are directed to their personal physician, an Urgent Care Clinic, Corval, or the emergency room at Banner - University Medical Center Tucson.

- f. Any animal activity involving a hazard is routed to RLSS for review. RLSS works directly with researchers and UAC personnel to ensure that animal activities are conducted in a safe manner and in accordance with all applicable local, state and federal regulations. In addition, UAC facility coordinators provide one-on-one training for use of a particular hazard within UAC facilities. Hazardous material is collected and disposed of by RMS, in accordance with all applicable local, state and federal regulations.
 - g. UAC employees working in central animal facilities wear surgical scrubs provided by UAC. A combination of gloves, gowns, coveralls, N95 respirators, masks, face shields, goggles, safety glasses, ear protection, bonnets, rubber boots and/or shoe covers must be worn depending upon the species, housing requirements and activities being performed. These items are provided by UAC for use by their staff or researchers when in UAC facilities. RLSS oversees the requirements for personal protective equipment (PPE) such as gloves, safety glasses and lab coats for individuals performing animal activities outside of UAC.
 - h. All clothing provided by UAC is laundered in-house, by UAC employees. A commercial laundering service may be used for certain items such as lab coats. Shower facilities are available in all UAC facilities. The ARC has in-house laundry and shower facilities. RLSS is responsible for the procedures for laundering lab coats or other work clothing for individuals performing animal activities outside of UAC. A commercial laundering service is used for researcher lab coats or scrubs.
- 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:
- a. Prior to the start of animal activities, faculty, staff, students and volunteers who care for or use animals in research or teaching are required to complete all applicable certification and training. The Institution uses the Collaborative Institutional Training Institute (CITI) for training related to 1) humane animal care and use, including the applicable laws and regulations and the 3R's 2) species specific information, including animal care and handling and occupational health issues (e.g., zoonoses, allergens) and 3) activity specific information, including aseptic surgery. UAC provides facility orientation and hands-on training for safe animal handling, routine husbandry procedures, and hazard use within the animal facility. Individuals working with non-human primates have additional hands-on training requirements, including the risk of occupational hazards. A UAC veterinarian or designee provides hands-on training and certification for individuals performing physical euthanasia without pre-anesthesia. Completion of training and certification is confirmed by the IACUC Office staff.
 - b. All individuals working with animals in research or teaching must pass the CITI *Working with the*

IACUC: *Investigators, Staff and Students* course with a score of $\geq 80\%$. This course specifically addressed methods that minimize the number of animals used to obtain significant data. The course also addresses the need to minimize pain and distress. Each species-specific module describes the need to search for alternatives to animal use, humane standards and detecting pain and distress in that species. In addition, all laboratory rodent users must complete the CITI *Reducing Pain and Distress in Laboratory Mice and Rats* course which describes the responsibilities for minimizing animal pain and distress, the signs of pain and distress and methods for controlling pain and distress. Similarly, individuals listed on a protocol where survival or non-survival surgery is approved must pass the CITI *Aseptic Surgery* course, which includes information on surgical pain and distress, as well as analgesia and anesthesia. Individuals performing pre-operative procedures, survival or non-survival surgery and/or post-operative care must complete the *General Rodent Surgical Training* which is taught by a UAC veterinarian or designee. This class covers all aspects of rodent pain and distress, including signs and methods for alleviation with analgesia or other palliative care. UAC also provides optional hands-on training for rodent biometrics and advanced rodent surgery.

- c. Training for new IACUC members includes the CITI module for IACUC members and a one-on-one orientation with the IACUC Officer or designee. As part of the orientation, IACUC members receive written documentation, which includes links to online copies of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the OLAW/ARENA IACUC Guidebook and the Animal Welfare Act/Regulations. IACUC members are also provided the opportunity for mentoring and/or training with an experienced IACUC member. The Institution's IACUC website also provides extensive institutional and regulatory information, which the members can access at any time. IACUC members receive regular training at monthly Committee meetings and are encouraged to attend local training opportunities.

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.

The 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 semi-annual 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 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 IO [REDACTED]
 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 IO, [REDACTED]
 - 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: [REDACTED]
Title: Interim Vice President for Research
Institution: University of Arizona
Address: PO Box 210066
Tucson, AZ 85721
Phone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

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: [REDACTED]

Date: 3/11/19

B. PHS Approving Official

Name/Title:
Address: Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
Phone: 301-496-7163
Fax: 301-915-9465

Signature: _____

Date: _____

Assurance Number:

Effective Date:

Expiration Date:

VIII: MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Name of Institution: The University of Arizona			
Assurance Number: D16-00159 (A3248-01)		Date: 3/4/2019	
Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson	
Name: [REDACTED] Title: Professor Degree/Credential: PhD		School of [REDACTED] University of Arizona P.O. Box 210090 Tucson, AZ 85721 Phone: [REDACTED] Fax: [REDACTED] Email: [REDACTED]	
Name of Member/Code	Degree/Credentials	Position Title	PHS Policy Membership Requirements
David G. Besselsen	DVM, PhD, DACLAM, DACVP	Director of University Animal Care, Attending Veterinarian	Veterinarian
3	PhD	Associate Professor, English	Nonscientist
4	DVM, PhD	Research Assistant Professor, Medicine	Alternate, Scientist
5	PhD	Research Assistant Professor, Pharmacology	Scientist
6	DVM, DACLAM	Associate Director, University Animal Care	Veterinarian
7	BS	Research Specialist Senior, Research, Discovery & Innovation	Alternate, Member
8	PhD	Professor, Psychology	Scientist
9	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
10	PhD	Professor, Basic Medical Sciences	Scientist
11	PhD	Professor, Immunobiology	Scientist
12	PhD	Associate Professor, Cellular & Molecular Medicine	Alternate, Scientist
13	DVM, MS	Associate Veterinary Specialist, University Animal Care	Veterinarian
14	PhD	Associate Staff Scientist, Arizona Research Labs	Scientist
15	PhD	Associate Professor, Physiology	Scientist
16	PhD	Assistant Professor, Pharmacology	Alternate, Scientist
17	PhD	Assistant Professor, Medicine	Scientist
18	BA	IACUC Officer, Research, Discovery & Innovation	Member
19	PhD	Professor, School of Natural Resources and the Environment	Scientist
20	DVM, MS	Assistant Veterinary Specialist, University Animal Care	Alternate, Veterinarian
21	BSBAM	Program Coordinator, Campus Health Service – Occupational Health	Alternate, Nonscientist
22	VMD, MS, DACLAM	Associate Veterinary Specialist, University Animal Care	Alternate, Veterinarian
23	PhD	Assistant Professor, School of Animal Comparative and Biomedical Sciences	Alternate, Scientist
24	PhD	Assistant Professor, Immunobiology	Alternate, Scientist
25	DVM	Associate Research Professor, Valley Fever Center for Excellence	Alternate, Scientist

26	PhD	Assistant Research Scientist, Surgery	Alternate, Scientist
27	PhD	Self-employed Anthropologist	Nonaffiliated
28	PhD	Assistant Professor, Medicine	Scientist
29	PhD	Assistant Professor, Cellular & Molecular Medicine	Alternate, scientist
30	PhD	Associate Professor, Medical Imaging	Scientist
31	PhD	Assistant Professor, Surgery	Alternate, Scientist
32	BSN	Retired Nurse	Nonaffiliated

IX: OTHER KEY CONTACTS

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

Name: David G. Besselsen,
Title: UAC Director and Attending Veterinarian
Phone: [REDACTED]
E-mail: besselsd@email.arizona.edu

X: FACILITY AND SPECIES INVENTORY

Date: 03/4/2019

Name of Institution: The University of Arizona

Assurance number: D16-00159 (A3248-01)

Laboratory, Unit, or Building	Gross Square Feet	Species Housed	Approximate Average Daily Inventory
[REDACTED]	47,000	Mouse	13,200
		Rat	1,000
		Guinea pig	5
		Rabbit	10
		Pig	15
		Frog	15
		Rhesus macaque	12
		Zebrafish	100
[REDACTED]	23,040	Mouse	14,100
	40,254	Mouse	2,400
[REDACTED]		Rat	120
		Hamster	12
		Calf	3
		Zebrafinch	200
[REDACTED]	19,603	Mouse	4,200
		Rat	250
[REDACTED]	5,166	Bonnet macaque	4
		Rat	10
[REDACTED]	28,300	Sheep	18
[REDACTED]	352	Mouse	18 (when in use)
	760	Rat	12 (when in use)
	200	Bird	120
	400	Fish	600

From: [OLAW Division of Assurances \(NIH/OD\)](#)
To: [REDACTED]
Cc: [Besselsen, David G - \(besselsd\)](#); [ORCR iacuc](#); [OLAW Division of Assurances \(NIH/OD\)](#); [REDACTED]
Subject: RE: Domestic Assurance Renewal Acknowledgement : PHS Assurance Renewal for D16-00159 (A3248-01)
University of Arizona
Date: Tuesday, March 12, 2019 10:22:31 AM
Attachments: [D16-00159\(#A3248-01\)RenewalAck.doc](#)

Dear [REDACTED]

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has received your Animal Welfare Assurance (Assurance) renewal.

Best Wishes,

Kiara A. James

Program Analyst (Contractor)

Office of Laboratory Animal Welfare, NIH

6700B Rockledge Drive, Suite 2500

Bethesda, Maryland 20892

Phone: (301) 594-2289

Email: kiara.james@nih.gov

Division of Assurances

E-Fax (301) 451-5672

Email: olawdoa@mail.nih.gov

Disclaimer: Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: [REDACTED]

Sent: Tuesday, March 12, 2019 12:39 PM

To: OLAW Division of Assurances (NIH/OD) <assurances.olaw@od.nih.gov>

Cc: Besselsen, David G - (besselsd) <besselsd@email.arizona.edu>; ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Subject: PHS Assurance Renewal for D16-00159 (A3248-01) University of Arizona

Good Morning,

The University of Arizona's PHS Animal Welfare Assurance renewal document is attached.

Best regards,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

University of Arizona

Tucson, AZ 85721



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700B 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
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Fax: (301) 451-5672

October 20, 2020

RE: Receipt of Animal Welfare Assurance
D16-00159 (#A3248-01)

[REDACTED]
Interim Vice President for Research
University of Arizona
P.O. Box 210066
Tucson, AZ 85721

Dear [REDACTED]

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has received your Animal Welfare Assurance (Assurance) renewal.

Mrs. Doreen H. Bartlett, Senior Assurance Officer for the Division of Assurances will be reviewing your Assurance. If you have questions regarding the status of your Assurance, please feel free to contact Mrs. Bartlett at (301) 402-4325.

If there are delays in the review process, please be assured that your current Assurance will remain in effect during the review period.

Sincerely,

X

Kiara A. James

Program Analyst, Division of Assurances
Office of Laboratory Animal Welfare