

## Animal Welfare Assurance for Domestic Institutions

I, Scott Whittenburg, as named Institutional Official for animal care and use at the University of Montana, 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, HHS, and/or NSF. This Assurance covers only those facilities and components listed below.

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

*The University of Montana: All departments associated with the main campus of the University of Montana in Missoula, MT, and all satellite facilities such as the Field Research Station at Fort Missoula. The facility at Flathead Lake Biological Station is primarily the headquarters for aquatic field studies and animals are not currently housed there. Montana Tech-UM at Butte, MT and UM Western at Dillon, MT are other UM campuses where field studies may be conducted. This is the expected usage for the next 5 years.*

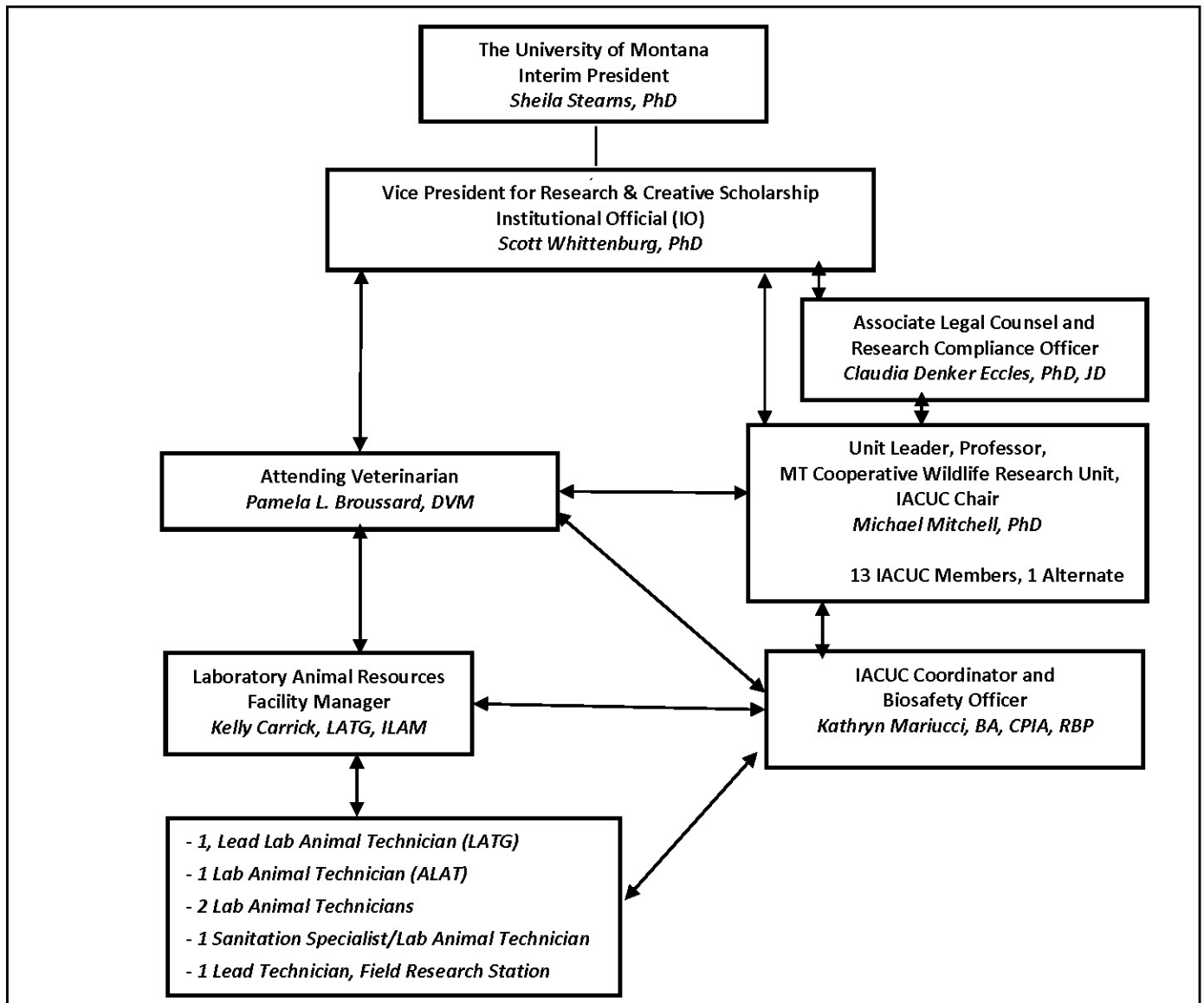
- B. The following are other institution(s), or branches and components of another institution:  
*Not applicable*

### II. Institutional Commitment

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

### III. Institutional Program for Animal Care and Use

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



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

1) Name: *Pamela L. Broussard*

Qualifications

- Degrees:

- *BS, Wildlife Studies, University of Montana*
- *DVM, Colorado State University, 1993*
- *Certifications*
  - *American College of Veterinary Internal Medicine Cardiac Ultrasonography Training Certification (2009)*
  - *Surgical Research Specialist Certification (2010)*
  - *Montana Trichomoniasis Testing Certification (2011)*
  - *National Animal Health Emergency Response Corps (NAHERC), Veterinary Medical Officer Certification (2011)*
  - *Good Laboratory Practice Certification from West Coast Quality Training Institute (2011)*

- *USDA-APHIS National Veterinary Accreditation Program recertification (2014)*
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 

*Dr. Pam Broussard has 23 years of experience in clinical veterinary practice in emergency and critical care medicine (11 years), wildlife veterinary rehabilitation and medicine (5 years), pre-clinical cardiovascular research and laboratory animal medicine (8 years). Her experience in clinical veterinary care and research includes the following species; dogs, cats, reptiles, exotic species (sugargliders, hedgehogs), rabbits, sheep, mice, rats, guinea pigs, hamsters, pot-belly pigs, whitetail deer, upland game birds, marine and freshwater waterfowl, marine mammals, grizzly bears, and wolves.*

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

Time contributed to program:

*Dr. Broussard works half-time and devotes 4 hours each weekday to the animal care and use program at UM. She is available 24/7 for emergencies. If Dr. Broussard is unavailable, there are 2 local, back-up veterinarians on call.*

- 2) Name: *Mark Kleitz, back-up veterinarian on call*
  - *DVM, 1987, University of Illinois, College of Veterinary Medicine*
  - *Private practitioner whose scope of practice includes birds, reptiles, rodents, dogs and cats*
  - *Member of the AVMA, Montana VMA, Association of Exotic Mammal Veterinarians, Association of Sugar Glider Veterinarians*
  - *Authority: when standing in for the Attending Veterinarian, Dr. Kleitz has responsibility for the Institution's animal care and use program including access to all animals.*
- 3) Name: *Shoni Card, back-up veterinarian on call*
  - *DVM, 1988, Colorado State University, College of Veterinary Medicine*
  - *Private practitioner whose scope of practice includes birds, reptiles, rodents, dogs and cats*
  - *Certified Canine Rehabilitation Practitioner, CCRP from the University of Tennessee, College of Veterinary Medicine*
  - *Authority: when standing in for the Attending Veterinarian, Dr. Card has responsibility for the Institution's animal care and use program including access to all animals.*
  - *Previous member of the University of Montana IACUC*

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

*see Part VIII Non-scientist, Claudia Denker-Eccles, has a PhD in Business Administration and a JD. She does not have a scientific background nor has she had any scientific training. As the University of Montana Compliance Officer, Dr. Denker-Eccles facilitates quarterly meetings of the different compliance committee chairmen on campus and then directs any issues to the Institutional Official.*

- 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:

*Semiannual program reviews are conducted in January and July and involve a minimum of 2 IACUC members, although any committee member who wishes may participate. A checklist is used to review the major components of the program, including veterinary care, occupational health program, IACUC procedures, and training programs. Any departures from the Guide or PHS policy are discussed and evaluated during the semiannual program review. Current and future directions of the animal care program are also discussed. Typically, program review occurs in the office of the IACUC Coordinator in order to easily access policies and training records.*

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

*Semiannual facility inspections are conducted in March and September and involve at least 2 IACUC members although any committee member who wishes may participate. The off-site facility, the Field Research Station at Fort Missoula, is inspected on the same day. Main campus facilities, including the SPF mouse locations and the multi-species location, are usually inspected on the same day or within the same week as the off-site location. Laboratories are also inspected on the same day or during the same week. Different IACUC members may be involved in inspections at different locations. An extensive checklist modified from the OLAW sample is used to facilitate thorough inspections. Informal personal interviews with researchers and animal care staff are included in the inspections.*

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

*The IACUC Coordinator maintains master checklists and reports of findings of the committee members conducting the reviews. The findings of the facility and program evaluations are presented and discussed at the next scheduled IACUC meeting. Deficiencies are categorized as minor or significant (potential danger to the health and well-being of animals), the anticipated plan for correction of the deficiency and assignment of corrections date deadlines. The IACUC Coordinator also presents to the IACUC a draft report to the IO based on the OLAW sample document template which includes a description of the nature and extent of UMs adherence to the Guide. Departures from the Guide are identified specifically and reasons for each departure are stated as well as deficiencies, reasonable correction dates and plans, and minority views. The IACUC meeting consists of a quorum of members, a majority of whom then modify, approve, and sign the report to the IO, noting any minority views or the lack thereof, and the report is delivered to the IO within several days of the IACUC meeting. As follow-up to the evaluation reports, the IACUC Coordinator reports at each monthly IACUC meeting thereafter any deficiencies remaining to be corrected, progress on these items, and correction deadlines.*

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

*The IACUC has an extensive policy and procedure in place for handling concerns about animal care and use. The document is available on the IACUC website, in hard copy displayed in the entryways of all animal facilities, and the IACUC Coordinator includes information concerning these procedures in required annual didactic training for animal care staff, animal users, and principal investigators. Concerns or complaints may be submitted by e-mail, written note, or verbal communication to any IACUC member or animal care staff member.*



*A complainant may remain anonymous. Typically, the AV puts the complaint in writing and conducts the initial investigation unless the complaint is directed against the AV or the Chair. In these cases, the IO designates an investigator. After collection of facts and review with the IACUC Chair, a remedy is either applied in minor cases and reported to the IACUC or the matter is brought to the IACUC for discussion, further investigation, and recommendation of remedy to the IO. The IO is informed of all complaints and their resolutions. No one reporting a violation of LAR and/or IACUC standards, procedures, rules and protocols shall be subjected to any retaliation. Likewise, no person who is the subject of, or related to a complaint shall undertake reprisals. Retaliations or reprisals in the context of IACUC procedures for handling complaints represent violations of IACUC standards that could result in loss of privileges and/or access to the facilities for animal care and use under the oversight of the UM IACUC.*

*Federal animal welfare regulations (under the Animal Welfare Act) state that all employees or concerned parties must have the means to report deficiencies in animal care and treatment. Federal animal welfare regulations state that no facility employee, committee member or laboratory personnel shall be discriminated against or be subjected to any reprisal for reporting violations of any regulation or standards under the Animal Welfare Act. Such persons are further protected under the University of Montana's Whistleblower Policy which protects the reporting person from discrimination and reprisals.*

- 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:

*Items of concern to the IACUC on which the committee wishes to make a recommendation to the IO are usually handled first by committee discussion which is followed by recommendation by the full IACUC. Any official recommendation to the IO is voted on at a full committee meeting. Recommendations by the IACUC are made with full knowledge of the institution's financial ability to act on recommendations. Therefore, the IO takes recommendations under advisement and communicates with the committee about potential resolutions.*

- 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:

#### Animal Use Protocol (AUP) Application

*The AUP application is an official document sanctioned by the IACUC. Modifications of the form must be reviewed and approved by the IACUC to ensure compliance with regulatory requirements. AUP forms are available on the IACUC website [www.umt.edu/research/compliance/IACUC](http://www.umt.edu/research/compliance/IACUC). There are 3 different Animal Use Protocols to choose from depending upon the type of animal research to be conducted:*

- *Laboratory Animal Use Protocol: use for any laboratory-related species such as mice, rats, rabbits, guinea pigs, etc.*
- *Wildlife Laboratory Animal Use Protocol: use for wildlife field studies.*
- *Wildlife Observational Animal Use Protocol: use for wildlife field studies that are observational only and do not require any handling of animals*

#### Review of New Protocols and Triennial Resubmissions

- *Electronic Submission by Investigator to IACUC Coordinator*
  - *Preliminary number assigned*
  - *AUP reviewed for completeness*
  - *AUP formatted for conciseness*
  - *AUP emailed to AV for review*
  - *Animal users listed on AUP added to animal user list and notified of training and occupational health and safety requirements for animal use*

- *Veterinary review*
  - *Principal investigator (PI) asked for clarifications or revisions*
  - *Drug dosages reviewed*
  - *AUP sent back to IACUC Coordinator for distribution to the IACUC with a brief explanation of the proposed work and any potential animal welfare issues for consideration*
- *AUP made available to all IACUC members for recommendation of type of review*
  - *The AUP is sent electronically to all IACUC members for initial review. Members have 5 business days to ask questions and electronically respond to the IACUC Coordinator and recommend either DMR or FCR. If a quorum of the IACUC has not responded with a recommendation after 5 days, the IACUC Coordinator will remind those who have not responded.*
  - *Any committee member may request a full IACUC review*
  - *A quorum of the IACUC must recommend the protocol for Designated Member review (DMR) before the IACUC Coordinator can forward to DMR*
  - *IACUC Coordinator maintains a list of committee members responding to each protocol and their response*
- *Designated member review*
  - *5 business days for designated member review (DMR); the IACUC Coordinator moves the AUP from the IACUC pending folder to DMR folder on the password-protected website.*
  - *The Chair assigns a member of the IACUC as the reviewer. If the Chair is out of town or unavailable, the Vice-Chair assigns the reviewer.*
  - *IACUC Coordinator maintains a list of designated reviewers used for all AUPs. Such a list is useful to make certain that all members are sharing the responsibilities of review.*
  - *Designated reviewers may approve, recommend revisions, or request a full committee review of the protocol.*
  - *If there is more than 1 designated reviewer appointed, and additional modifications are required to secure approval, each reviewer receives identical copies of the protocol via email. All reviewer responses are received and compiled by the IACUC Coordinator, and mutual agreement must be met by all assigned reviewers.*
  - *Approved protocols receive a final approval number from IACUC Coordinator*
  - *An approval letter from the IACUC Coordinator and the approved AUP are sent to the PI and posted in their folder on the password-protected website.*
- *Full committee review*
  - *Submission to the IACUC Coordinator and veterinary review as described above.*
  - *The AV, any IACUC member, or the Designated reviewer may request a full committee meeting at any step during the DMR process above.*
  - *All E category protocols will receive full committee review.*
  - *All protocols involving major survival surgery in UDSA-regulated animals will receive full committee review.*
    - *Major survival surgery is defined in the Guide as a surgery which "penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions."*
  - *At the request of a full committee review, the AUP is added to the agenda for the next full committee meeting, provided the meeting is scheduled for not less than 1 week from the date of request.*
  - *AUP PIs may be requested to attend the meeting or to be available by phone to address questions from the IACUC related to animal care and use. The IACUC may offer suggestions to revise the AUP prior to approval.*
  - *A quorum of the committee must be present at the convened meeting, and a majority vote of the quorum present is required for protocol approval, to require modifications to secure approval, to withhold approval or to defer or table review.*
  - *Minority opinions are recorded in the meeting minutes and acknowledged in regulatory reports where required.*
  - *Categories of IACUC actions include: approval, modifications required to secure approval, withhold approval or defer or table review.*



- *Approved protocols receive final approval number from the IACUC Coordinator*
- *An approval letter from the IACUC Coordinator and the approved AUP are e-mailed to PI and posted in their folder on the password-protected website.*
- *DMR to review an AUP subsequent to FCR when modifications are needed to secure approval*
  - *If all members are not present at the FCR, the committee has the option to vote to return the AUP for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.*

*IACUC members with direct or perceived conflicts of interest must recuse themselves from voting, and a quorum must be maintained following exclusion of member(s) with a conflict of interest.*

- *The recused member(s) may provide information requested by other members of the IACUC about the AUP.*
- *The recused member(s) cannot participate in voting and are temporarily dismissed from the meeting for the final discussion of the AUP.*
- *If a quorum is not maintained, the AUP could not be voted on and would have to either go to DMR as described in Part III.D.6 of the Assurance or come back to FCR at the next convened IACUC meeting.*

*Modifications or amendments (minor changes)*

*The IACUC encourages the use of an amendment form to be used by PIs. The PI sends the completed amendment form to the IACUC Coordinator. The AV and IACUC Coordinator determine if the modification(s) is minor or significant. Minor amendments may include, but are not limited to:*

- *Change in strain of mice or rats used in the same experiment(s)*
- *Change in support personnel (not PI) who do not train others*
- *Increase in animal numbers of less than 10%*

*Minor amendments are administratively approved by the IACUC Coordinator or AV. The IACUC Coordinator adds the amendment to the protocol with the approval date. An amendment approval letter and the amended protocol are sent to the PI by the IACUC Coordinator. The IACUC Coordinator provides a brief report at the next IACUC meeting of protocols that were amended with minor changes since the last meeting.*

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

*Review of significant changes to a previously approved animal use protocol*

*Significant changes are handled by the IACUC using DMR or FCR as described above and include:*

- *Changes in duration, frequency, type of number of procedures performed on an animal*
- *Change from nonsurvival to survival surgery*
- *Changes resulting in greater pain, distress, or degree of invasiveness*
- *Changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC*
- *Changes in species*
- *Changes in study objectives*
- *Changes in Principal Investigator*
- *Changes that impact personnel safety*

*After the IACUC has approved a significant change, an amendment approval letter and a copy of the amended AUP are sent to the PI by the IACUC Coordinator who then provides*



*a brief report of the number of protocols with significant changes at the next scheduled IACUC meeting.*

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

*The IACUC Coordinator e-mails an approval letter and the approved version of the animal use protocol to the principal investigator. In circumstances of required modifications when using designated member review, the IACUC coordinator e-mails the investigator with an anonymous list of questions and/or requested modifications from the designated member reviewer. Responses to these questions/modifications are relayed back to the reviewer, and when satisfactory, the protocol is approved by DMR. If the response remains unsatisfactory, the protocol undergoes FCR. In circumstances of required modifications when using full committee review, the investigator responds to all IACUC concerns in person at the IACUC meeting and the IACUC Coordinator incorporates the changes into the AUP. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol is reviewed using either FCR or DMR as described in Part III.D.6.*

*The Institutional Official (IO) stays updated about IACUC activities and approved protocols in order that he may make informed decisions on any animal activity. The IACUC Coordinator emails monthly IACUC meeting minutes to the IO. The IO meets individually and together as needed with the IACUC Chair, Vice Chair (IACUC Coordinator), and AV to discuss IACUC matters, and on a quarterly basis the Compliance Officer facilitates a meeting between the IO and all compliance committee Chairs and Vice Chairs to discuss compliance-related issues. The IACUC Coordinator contacts the IO in person with semi-annual facility inspection and program review reports, and via email or in person following IACUC discussion of a suspension or violation at a convened IACUC meeting.*

*As a matter of convenience, the IO and the IACUC Coordinator use the same IACUC shared drive (BOX) that specifically supports IACUC business including annual reports and inspections, AUPs, AUP annual renewals/reviews, amendments, approval letters, etc. from most current documents to 7 years prior. This shared drive is updated by the IACUC Coordinator in real time and on a daily basis and provides the IO with immediate and accurate access to IACUC information.*

*If protocol approval is withheld by the IACUC, the investigator receives written notification from the IACUC Coordinator stating the reasons protocol approval was denied and suggestions for revision. The notification letter also includes a reminder that the AV and IACUC Coordinator are always available for consultation. Future notifications will include a statement that PIs are welcome to respond to the IACUC in person at a convened meeting or in writing.*

- 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:

*Annual Renewals*

*The IACUC Coordinator sends electronic reminders of protocol renewal dates to PIs 90 days in advance. If necessary, additional reminders are sent at 60 and 30 days. PIs are informed in reminders that submission of renewal requests should be submitted 60 days before the AUP expiration date to allow sufficient time for AUP review if amendments are included. Upon PI review, any changes needed to the protocol (minor or significant amendments) will be submitted as an amendment by the PI and reviewed by the IACUC*

as previously described (minor changes approved by the IACUC Coordinator and major amendments approved by DMR or FCR). The PI may also renew the protocol without modification. Once the renewal is completed, the IACUC Coordinator e-mails an annual renewal approval letter to the PI, and reports the approved renewal at the next IACUC meeting.

#### Annual Review Process for USDA-regulated species.

An Animal Use Protocol (AUP) annual review reminder letter is e-mailed to the PI and IACUC members 90-days prior to the 1-year and 2-year anniversary date of the original approval. The IACUC members have 72 hours to examine the documents and inform the IACUC Coordinator if they have any suggested revisions to the AUP which are then forwarded to the PI by the IACUC Coordinator for incorporation into the revised AUP. Outcomes of an annual review are (1) no changes, (2) major revisions, or (3) minor revisions. Major revisions (amendments) are reviewed and approved by DMR or FCR as described in Part III.D.6.

Minor revisions (amendments) as described in Part III.D.6 are approved administratively by the IACUC Coordinator. A letter detailing the outcome of the annual review is e-mailed to the PI, and the outcome of the review is reported at the next IACUC meeting. The IACUC reviews and decisions are documented in writing and available for inspection within each AUP folder.

If the PI does not respond to the 90-day reminder, a reminder is sent at 60-days, followed by a final reminder 30-days prior to the AUP anniversary date. If an AUP is not reviewed and approved annually before the anniversary date, the AUP will not be renewed (this has never happened) and the PI is notified in writing that the AUP is no longer valid.

#### Triennial de novo submissions

Protocols permanently expire 3 years after they are first approved (unless a shorter time is indicated in the protocol). A brand new protocol must be submitted to the IACUC and approved by DMR or FCR every 3 years if the work is to continue.

#### Post approval monitoring (PAM)

- PAM is a continuous process at UM and includes
  - semiannual IACUC facility inspections,
  - annual AUP review/renewal and 3-year complete resubmission for all animal use protocols,
  - daily monitoring of animals by LAR staff,
  - monitoring of animals and procedures by the AV, and
  - comprehensive review of an AUP and supporting techniques (i.e., surgery, post-procedure care, diet restrictions) by the LAR lead animal technician (post-approval reviewer) in conjunction with the PI and his/her research staff.
- LAR lead technician performs post-approval review of AUPs
  - Post-approval review involves review of animal use protocols and observation of animal manipulations by animal users on a regular basis.
  - Post-approval review involves periodic table-top discussions with PIs and lab personnel
  - Protocols are chosen for post-approval review based on their potential for pain and distress and random selections to provide a cross-section of the animal care program.
  - Post-approval review reports are presented in person or in writing at convened IACUC meetings
- If urgent action is required, the employee conducting PAM will report immediately to the AV, facility manager or IACUC Coordinator.

#### USDA-covered species

The University of Montana Laboratory Animal Resources maintains registration with the USDA-APHIS. Animals and facilities are inspected annually by a Veterinary Medical Officer.

- 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:

Suspension of AUP Activity

*The IACUC may suspend the activity of an approved AUP when necessary to ensure animal welfare. Suspension of an AUP may occur at a convened meeting of a quorum with a majority vote of the quorum present. A recommended corrective action will be outlined by the IACUC for recommendation to the IO.*

- *Immediately after IACUC suspension of AUP activity, the IACUC Chair or his/her designee will inform the IO of the suspension and recommended corrective actions.*
- *The IO, in consultation with the IACUC, will review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to OLAW, and to other appropriate regulatory, accrediting and funding agencies.*
- *The IO does not have the authority to overturn an IACUC suspension of AUP activity.*

External Reporting Policies

*The designee of the IACUC Chair (currently the IACUC Coordinator) must report promptly (telephone call or written report) to the Director of Compliance and Oversight at OLAW, through the IO, stating the circumstances and corrective actions taken and any minority views filed in the following instances:*

- *suspension of any activity by the IACUC*
- *serious or continuing non-compliance with the PHS Policy*
- *significant deviation from the provisions of the Guide for the Care and Use of Laboratory Animals*

*The contents of the PHS Suspension/Noncompliance Report will include:*

- *a full explanation of circumstances*
- *description of corrective action taken*
- *minority views filed by IACUC*

- 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:

Participation

*All students, researchers, and visitors who work with or near laboratory or wild animals in the course of their association with the University of Montana are offered the opportunity to participate. The extent and level of participation by students, researchers and visitors in the OH&S program is based on risk assessment by a qualified OH&S physician.*

*All new Laboratory Animal Resources (LAR) staff members are required to have a pre-employment medical surveillance evaluation by a qualified OH&S physician. All LAR staff members, including existing staff, are included as part of the occupational health program. All LAR staff members are required to have a follow-up medical surveillance evaluation annually or more often as health changes warrant.*

*Participation in the OH&S program at UM is in full compliance with the Federal and State Health Insurance Portability and Accountability Act (HIPAA).*

- *Participant capture and training*
  - *Visitors*
    - ✓ *Right-to-know hazard information posted in facility*
    - ✓ *LAR main entrances*
      - *OH&S informational letters*
      - *Risk assessment forms/postage-paid envelopes*
      - *Sign-in sheet verifying availability of information*



- Declination to participate in OH&S program
- Employees and Animal Users
  - ✓ All information available to visitors as listed above and additional items listed below
  - ✓ Annual training by IACUC and LAR - includes reminders of updating risk assessment with changes in medical conditions or animal exposure intensity
    - LAR facility users and principal investigators (PI)
    - Wildlife researchers
    - Maintenance personnel
    - Security personnel
  - ✓ Identification through experimental hazards assessment
    - Institutional Biosafety Committee (IBC)
    - Radiation Safety Committee (RSC)
    - Animal Use Protocol (AUP) evaluated by IACUC
- Annual policy reminder to department chairs and PIs with active AUPs
  - ✓ IACUC Coordinator distributes OH&S policy and instructions for risk assessment
  - ✓ Encourages PI identification of visiting scientists, new students, research personnel

#### Risk Assessment

- AUPs - assess experimental hazards
  - Approval number required, when applicable, from
    - ✓ IBC
    - ✓ RSC
  - Descriptions of safety procedures, personal protective equipment, and knowledge of zoonotic risks required in AUP
- Work Environment (non-experimental hazards) - LAR facilities evaluated annually by on-site visits by
  - Occupational Health Program
  - Environmental Health & Risk Management (EHRM) Office
- Personnel - medical history and animal exposure intensity evaluated by OH&S provider
  - Risk assessment questionnaire initially and when any changes in medical conditions or animal exposure intensity occur
  - Medical surveillance questionnaire annually for personnel assessed as high risk by the OH&S physician
- Risk assessment or medical surveillance required for Griz (proximity) card access to LAR animal facilities and before beginning wildlife field work

#### Occupational Health & Safety program

- A team of trained health professionals consisting of 1 MD, 1 RN (a member of the IACUC and IBC) and 1 Health Clinic coordinator, leads our Occupational Health Program and is contracted by the University of Montana
- Primary responsibilities include:
  - Review of individual medical questionnaires
    - ✓ Risk assessment
    - ✓ Medical surveillance
  - Provision of physical examinations, consultations, and post-exposure counseling on a case-by-case basis
  - Conducting periodic hazard assessment of LAR facilities via walk-throughs and/or meetings with AV and LAR staff
  - Assessment of hazards of novel projects at the request of the IACUC
  - Providing feedback to IACUC of identified trends in occupation-related diseases of participants and recommends preventive intervention

#### Training

Animal care staff members participate in the national certification program for laboratory animal technicians through the American Association for Laboratory Animal Science and receive additional occupational health training through this program. Currently, there are 2

*LAR staff members with LATG certifications and 1 with ALAT certification. The AV also provides the LAR staff with continuing education and occupational health information at regular staff meetings.*

*Our institution implements universal precautions for laboratory and animal areas including hand washing, use of hand sanitizers as appropriate, no eating or drinking in animal or laboratory areas, no use of tobacco products, no application of cosmetics, wearing appropriate personal protective equipment, and proper disposal of sharps. During annual didactic sessions and LAR hands-on training, faculty, staff and students associated with the animal care and use program receive instruction in the use of personal protective equipment, the mechanisms, recognition, and prevention of allergies, and waste and carcass disposal.*

*If an employee or animal user alerts an LAR staff member that a change has occurred in their medical condition (pregnancy, decreased immunocompetence or illness), additional precautions and training will be provided by the LAR facility manager (after assessment and release by an OH&S physician) in the use of additional PPE or safety devices which may include but are not limited to:*

- Safety goggles*
- Double gloving*
- Respirator*
- Biosafety cabinet*

*The occupational health provider and PIs may offer discussion and additional information for precautions taken during pregnancy or illness. They may also recommend other specific health guards depending upon the outcome of the risk assessment by the OH&S physician and the nature of any hazardous agent involved. Tetanus immunizations are mandated for LAR staff and recommended for all other personnel involved with the animal care and use program.*

#### *Zoonoses*

*Zoonoses are more likely to be encountered in wildlife field studies. The PI is responsible for training his/her personnel in awareness and recognition of zoonotic diseases which may be encountered while working with the wildlife species of interest. All persons included on wildlife protocols are required to take an on-line training course and subsequent quiz (passing with 81% or better) developed by the UM IACUC which covers field safety, hazards, prevention strategies, major zoonoses and environmental awareness.*

*Laboratory zoonotic diseases, symptoms and preventative measures are briefly discussed at annual didactic training sessions, and facility hands-on training conducted by LAR senior staff members.*

#### *Hazards*

*Chemical hazard training is the responsibility of the PI. The PI must provide details about the chemical hazard in the AUP which is then evaluated by Environmental Health and Risk Management before review and approval by the IACUC.*

*Biological hazard training is the responsibility of the PI. The PI must provide details about the biological hazard in the AUP which is then evaluated by the Biosafety Officer and/or IBC before review and approval by the IACUC.*

*Radiation hazard training is the responsibility of the PI. The PI must provide details about the radiation hazard in the AUP which is then evaluated by the Radiation Safety Committee before review and approval by the IACUC.*

*Fact sheets detailing chemical, biological, radiation and physical hazards are available in all animal facility entry areas.*

#### *Reporting Injuries*

*Worker's Compensation Program information is posted in each animal facility and is also covered in the mandatory Wildlife Training presentation. When someone is injured while working with research animals the steps are:*

- Initial wound or injury treatment is provided utilizing a first aid kit (located in the central hallway of each animal facility, and located with each field supervisor)*
- Alert supervisor*
- Seek medical attention if the wound or injury is beyond the capabilities of the first aid kit. Call 911, or transport the injured party to a local Emergency Room, or transport to Curry Health Center if on campus during regular business hours.*
- Fill out First Report of Injury online and submit to Environmental Health & Risk Management*

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

*See Part X.*

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

*Laboratory Animal Researchers*

*The IACUC Coordinator maintains individual training files and a training spreadsheet of all PIs and all persons currently listed in a protocol who are involved with laboratory animal care, treatment or use and who are required to participate in training that encompasses the proper and humane care of animals. This spreadsheet is updated daily as needed and includes:*

- (1) complete and pass user-specific training module(s) on the CITI training web site ([www.citiprogram.org](http://www.citiprogram.org)) determined by the animal species included on the protocol under which they are working and procedures being performed (update online training every 3 years);*
- (2) participate in OH&S Risk Assessment (update every 3 years or more often if health status changes);*
- (3) attend one-on-one training with an LAR staff member for safe and proper use and exit of LAR facilities and for any relevant work-related OH&S training (one-time training or as needed);*
- (4) attend didactic laboratory animal user training at earliest possible opportunity (attend once each year); and (5) participate in individualized training, such as bi methodology techniques involving research species used at UM, provided by AV, LAR employees, or invited specialists.*

*Training which covers the principles of the 3Rs, limiting pain and distress in animals, and minimizing the number of animals required to obtain valid results is presented in:*

- (1) required CITI animal-specific on-line training modules,*
- (2) required annual didactic training classes offered several times a year at UM, and*
- (3) required one-on-one training with an LAR staff member before work with animals may begin.*

*In addition, the animal use protocol is designed to prompt responses from the PI regarding the proper and humane care and use of animals, following the 3Rs, using the minimum number of animals to obtain the maximum experimental results, and limiting pain and distress.*

*Wildlife Researchers*

*The IACUC Coordinator maintains individual training files and a training spreadsheet of all PIs and all persons listed in a protocol who are involved with wildlife care, and humane use and treatment of animals. This spreadsheet is updated daily as needed and includes:*

- (1) review the online Wildlife Training Presentation and complete and pass the Wildlife Handlers Quiz on the UM IACUC web site ([www.umt.edu/research/compliance/IACUC/default.php](http://www.umt.edu/research/compliance/IACUC/default.php));*



- (2) participate in OH&S Risk Assessment (update every 3 years or more often if health status changes);
- (3) complete and pass the wildlife research training module and as applicable the amphibian or fish training module on the CITI training web site at [www.citiprogram.org/](http://www.citiprogram.org/) (update online training every 3 years); and
- (4) participate in individualized training provided by the PI, AV, LAR employees, or invited specialists on the proper and humane use of animals.

*Training for wildlife researches which covers the principles of the 3Rs, limiting pain and distress in animals, and minimizing the number of animals required to obtain valid results is presented in the required CITI animal-specific on-line training modules.*

*In addition, the wildlife animal use protocol is designed to prompt responses from the PI regarding the proper and humane care and use of animals and responses relevant to following the 3Rs and using the minimum number of animals to obtain the maximum experimental results.*

#### Laboratory Animal Resources Staff

*The IACUC Coordinator maintains individual training files and a training spreadsheet of all Laboratory Animal Resources Staff who are required to participate in training that encompasses the proper and humane care, use and treatment of animals. This spreadsheet is updated daily as needed and includes:*

- (1) complete and pass all relevant animal training module(s) and "Working with the IACUC" on the CITI training web site (<http://www.citiprogram.org>) (update online training every 3 years);
- (2) participate in OH&S Risk Assessment and Medical Surveillance (update every 3 years or more often if health status changes);
- (3) review the Guide;
- (4) review all animal SOPs; and
- (5) participate in on-going training by the AV or invited specialists.

*Training which covers the principles of the 3Rs, limiting pain and distress in animals, and minimizing the number of animals required to obtain valid results is presented in:*

- (1) required CITI animal-specific on-line training modules,
- (2) required annual didactic training classes offered several times a year at UM, and
- (3) required one-on-one training with the facility manager before work with animals may begin.

#### IACUC Members

*The IACUC Coordinator maintains individual training files and a training spreadsheet of IACUC members. Each new IACUC member is provided with "The Guide for the Care and Use of Laboratory Animals", the "Institutional Animal Care and Use Committee Guidebook", the "Animal Welfare Act" updated 2013, and the "PHS Policy on Humane Care and Use of Laboratory Animals". Training the IACUC members includes:*

- (1) an initial tour of the animal facilities;
- (2) review the IACUC web site;
- (3) complete and pass "Essentials for IACUC Members" on the CITI training web site (<http://www.citiprogram.org>) (updated every 3 years); The IACUC unaffiliated member also takes the CITI course "IACUC Community Member;"
- (4) participate in OH&S Risk Assessment (updated every 3 years or more often if health status changes);
- (5) 10 minute training modules on specific topics at most IACUC meetings;
- (6) annual in-service training by the IACUC Coordinator;
- (7) the opportunity to attend one IACUC 101 meeting; and
- (8) IACUC policies and forms, OLAW Assurance, AAALAC Program Description, SOPs, etc. are available for downloading and/or reading on the IACUC web site ([www.umd.edu/research/compliance/IACUC/default.php](http://www.umd.edu/research/compliance/IACUC/default.php)).

*Training which covers the principles of the 3Rs, limiting pain and distress in animals, and minimizing the number of animals required to obtain valid results is presented in:*

- (1) the Guide,*
- (2) required CITI on-line training module,*
- (3) UM IACUC web site,*
- (4) training modules during IACUC meetings,*
- (5) IACUC 101/201*

#### **IV. Institutional Program Evaluation and Accreditation**

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

#### **V. Recordkeeping Requirements**

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


#### **VI. Reporting Requirements**

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
  3. Any change in the IACUC membership

4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, *Dr. Scott Whittenburg*.
  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

<b>A. Authorized Institutional Official</b>	
Name: Scott L. Whittenburg	
Title: Vice President for Research and Creative Scholarship	
Name of Institution: University of Montana	
Address: <i>(street, city, state, country, postal code)</i> 32 Campus Drive, UH116 Missoula, MT 59812	
Phone: 406-243-6670	Fax: 406-2436330
E-mail: scott.whittenburg@mso.umt.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 4-12-17

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
<p>Name/Title: Eileen Morgan, Director, Division of Assurances Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465</p>	
<p>Eileen M. Morgan - S</p> <p>Digitally signed by Eileen M. Morgan -S DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010142050, cn=Eileen M. Morgan -S Date: 2017.04.12 16:27:25 -04'00'</p>	
Signature:	Date: 4/12/2017
Assurance Number: D16-00210 (A3327-01)	
Effective Date: 4/12/2017	Expiration Date: 4/30/2021

## VIII. Membership of the IACUC

Date:	January 1, 2017		
Name of Institution:	University of Montana		
Assurance Number:	D16-00210 (A3327-01)		
<b>IACUC Chairperson</b>			
Name*: Michael Mitchell			
Title*: Unit Leader, Professor, MT Cooperative Wildlife Research Unit			Degree/Credentials*: PhD
Address*: ( <i>street, city, state, zip code</i> ) 32 Campus Drive, NS205 Missoula, MT 59812			
E-mail*: <a href="mailto:mike.mitchell@umontana.edu">mike.mitchell@umontana.edu</a>			
Phone*: 406-243-4390		Fax*: 406-243-6064	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Pamela Broussard	DVM	Attending Veterinarian	Veterinarian
Kathryn Mariucci	BS, CPIA, RBP	IACUC Coordinator & Vice Chair; Biosafety Officer	Member
Sherrill Brown	DVM, PharmD	Director, Drug Information Services	Member
Claudia Denker-Eccles	PhD, JD	Associate Legal Counsel; Research Compliance Officer	Non-scientist
Kay Altenhofen	BA	Director, Environmental Health Risk Management	Member
Mike Parnell	PhD, DVM	Veterinarian	Member
Dionne Peterson	BS, RN	Occupational Health representative; nurse	Member
Bret Tobalske	PhD	Director, Field Research Station Ft. Missoula, Professor	Scientist
Scott Wetzel	PhD	Professor	Scientist
Celine Beamer	PhD	Research Associate Professor	Scientist
Christopher Migliaccio	PhD, PharmD	Research Assistant Professor	Scientist
Creagh Breuner	PhD	Professor	Scientist (alternate)
Kimberly Dredger	BA	Middle School Teacher, retired	Nonaffiliated member

## IX. Other Key Contacts (optional)

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

<b>Contact #1</b>	
Name:	
Title:	
Phone:	E-mail:
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:



## X. Facility and Species Inventory

[illegible]

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