Rocky Mountain Regional VA Medical Center – VA Station 554
(formerly Eastern Colorado Health Care System – Denver VA Medical Center)
#A4493-01 – D16-00748

Animal Welfare Assurance for Domestic Institutions

I, Sallie A. Houser-Hanfelder as named Institutional Official for animal care and use at Rocky Mountain Regional VA Medical Center, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, DHHS and/or NSF (if applicable). 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:
Rocky Mountain Regional VA Medical Center – Research Service

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

II. Institutional Commitment

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* (*Guide*).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows: The animal care and use program, at the lowest level, is run and administered by the Veterinary Medical Unit Supervisor/IACUC Director (b)(6) She has a staff of (up to) five animal care technicians. The veterinarians (b)(6) and

(b)(6) and the Institutional Animal Care and Use Committee (IACUC) oversee the program and are ultimately responsible for the entire animal care and use program. The IACUC (known in the VA as the Animal Studies Subcommittee) is a subcommittee of the Research and Development Committee (R&DC). The R&DC is ultimately responsible for the research program at this facility. For any animal or program related issues, the IACUC and the veterinarian report directly to the MCD/IO/CEO. The Institutional Official (IO) and Chief Executive Officer (CEO) are one and the same, the Medical Center Director (MCD) (Sallie A. Houser-Hanfelder). See **attached organizational chart**.

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

1) Name: (b)(6)

Qualifications

- Degrees, certifications, licensure: BS Biology, Eastern Kentucky University, 2000; DVM, Auburn University College of Veterinary Medicine, 2004; Post-doctoral training in Comparative Medicine, Centers for Disease Control and Prevention, Atlanta, GA, 2009-2013; DACLAM certification 2013. Licensed in State of Colorado, VET 0010067 (expires 10/2018).

- Training or experience in laboratory animal medicine or in the use of the species at the institution: 5+ years of small and large animal general medicine and surgery practice, 2004-2009. Comparative Medicine Residency Training Program at the CDC-Atlanta 2009-2012. Associate clinical veterinarian in laboratory animal medicine with species including rodents, rabbits, ferrets, and non-human primates, CDC 2012-2013. Currently, Associate Director of Laboratory Animal Resources and Associate Attending Veterinarian with clinical responsibility for rodents, rabbits, dogs, cats, swine, sheep, goats, cattle, and other non-traditional species, Colorado State University 2013-current.

Authority: Dr. (b)(6) has direct program authority and responsibility for the institution's animal care and use program, including access to all animals in the animal care and use program.

Time contributed to program: .02 FTE: Approximately 1 hour per month on site or 3 hours quarterly and one hour per week in consultation with resident or facility manager via email or phone. Dr. (b)(6) participates in major inspections and semi-annual review process.

(b)(6) is the on-site supervisor providing daily animal care and use oversight and facility management. (b)(6) oversees a staff of three to five and provides daily animal care as required by OLAW, AAALAC, and USDA.

2) Name: (b)(6)

Qualifications

- Degrees: BS Animal Science, University of California, Davis, 2012. DVM, Kansas State University College of Veterinary Medicine, 2016.

- Training or experience in laboratory animal medicine or in the use of the species at the institution: Second year comparative medicine resident at Colorado State University.

Responsibilities: Provides primary veterinary care and IACUC responsibilities under the supervision of Dr. (b)(6). Dr. (b)(6) provides pre-review veterinary consults for all ACORP's, Protocol Review and post-approval monitoring, trouble-shooting, veterinary care, and training.

Time contributed to program: Approximately 2-5 hours per month at the institution and 10-15 hours per month contributing to the program off-site.

Dr. (b)(6) advises the lab animal residency program at CSU. A resident from this program will be assigned the task of a consulting veterinarian for a one to two-year term. Under the guidance of Dr (b)(6) this resident will have full responsibility as consulting veterinarian within the VA guidelines. If at any time both Dr. (b)(6) and Dr. (b)(6) are unavailable, another resident from the program provides back-up veterinary services under the direction of Dr. (b)(6)

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

D. The IACUC will:

1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

VA Station 554 utilizes the VA IACUC Semi-Annual Self-Review Forms packet that has been instituted by the Office of Research Development (ORD), VA Central Office. This packet includes four forms and they follow the *"GUIDE"*. **Part 1 – Checklist, Section A. Review of the Program**: This form itemizes the animal care and use program as a guide. Items are designated as *Not Applicable, Acceptable, Approved Departure, Minor Deficiency* and *Significant Deficiency*. **Part 1 – Checklist, Section B. Inspection of the Facilities** is utilized for the inspection of the vivarium and all areas within the facility along with any area an animal will be utilized. Items on this form are designated as listed above for section a, with an added designation of *Could Not Evaluate*. **Part 2 – Table of Deficiencies and Departures** is utilized to summarize all concerns noted on forms Part 1 A and B. **Part 3 – Post-Review Documentation** is utilized to document the review team that did the facility inspection and all members who participated in the program review. This form also documents any minority opinions. The form is signed off by all IACUC members in attendance and accompanies all documents for final approval by the Medical Center Director (MCD). The Resident (consulting) Veterinarian, Administrative Officer for Research & Development, and the Chief, Facilities Management Service are all invited and encouraged to meet and discuss this evaluation with the Medical Center Director. The Supervising (attending) Veterinarian, The IACUC Chair and the VMU Supervisor/IACUC Director are required to attend this meeting either in person or via conference call. Once the process is completed with the MCD signature, the packet is forwarded to the Chief Veterinary Officer.

The process for the inspection and review are as follows:

- A subcommittee consisting of the VMU Supervisor/IACUC Director, consulting veterinarian and at minimum one scientist (3 voting members) conduct the facility and laboratory inspection (all members of the IACUC are invited to attend the inspection). The results of the inspection are documented on Part 1, Section B.
- A subcommittee consisted of the VMU Supervisor/IACUC Director and at least two other committee members (3 voting members) conduct the program review utilizing Part 1, Section A.
- Part 1, Section A and B are presented to the full IACUC. The IACUC reviews the documents and determine if the designations provided by the committee are adequate. The committee then determines a timeline for corrections. This is documented on Part 2. Part 3 will then be signed by the committee. The VMU Supervisor/IACUC Director will complete forms 2 and 3 and send to committee for concurrence prior to the meeting with the MCD. After full concurrence and MCD signature the packet is forwarded to ORD.

2) Inspect at least once every 6 months all 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: See above
3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: Reports are initiated and developed by the IACUC staff in conjunction with the IACUC Chair and the veterinarian in many cases. The required meeting with the IO mentioned in D1 is held and the report is then forwarded to VACO. If there are any departures from PHS Policy and the "GUIDE", they are identified and noted on the forms within the Semi-Annual Program Review and Facility Inspection packet. The semi-annual facilities and program review is an agenda item at each IACUC meeting until all deficiencies are corrected and closed out. This institution adheres to the PHS Policy and the "GUIDE" along with guidance from ORO. Items that are departures from the "GUIDE" are discussed at length at a convened IACUC meeting and a majority vote is required to approve a departure. Departures are monitored and noted within the semi-annual program review. During the IACUC approval process of the semi-annual program review, deficiencies are designated as either minor or significant and a schedule for correction is documented on Part 2 of the report. All minority opinions are documented in Part 3 of the report.

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

   The VA IACUC acts as the reviewing body for all expressed concerns, public or private, involving the care and use of animals at the institution. The IACUC utilizes the Veterinarians, VMU/Supervisor-IACUC Director, and the IACUC chair to do the initial investigation and report to the committee for the most part. There are signs throughout the vivarium with instructions on reporting animal welfare concerns and who to report them too. This includes names, phone numbers and emails of all individuals that can be contacted. At https://www.diversity.va.gov/whistleblower.aspx on the facilities web page, Whistleblower Rights and Protections can be found.

   In accordance with the Animal Welfare Act, no facility employee, committee member or laboratory personnel shall be discriminated against or subject to any type of reprisal for reporting violations.

   Any concern over the possible inappropriate care of animals, or charges of animal abuse at this institution can be reported to the Chair or any member of the IACUC, any research administrative staff or any VMU personnel. Anything reported outside of these people, should be forwarded to the IACUC Chair and/or staff for investigation and reporting. The report should include a factual description with date, time, location, animal species, numbers and identifications of animals and personnel involved, as well as any other relevant details.

   An immediate telephonic or email report is sent to the VA Veterinarian and to the VMU Supervisor, to correct or terminate the inappropriate care/condition immediately, and a written report of the alleged violation is submitted to the Chair of the IACUC either by hard copy mail or email. The complainant's identity will be kept confidential when requested and anonymous reports are acceptable if sufficient detail is provided to allow for an adequate investigation of the charges. The IACHC Chair will consult with the VMU Supervisor and the Consulting Veterinarian, and they will provide an initial review of the problem. After the initial review, the above mentioned sub-committee will provide the IACUC with all available information (apart from the name of the complainant if asked to be anonymous) about the complaint and the alleged violation. The IACUC will investigate further (if required), and determine the proper action needed to resolve the problem. If the initial investigation reveals that misuse of animals may be occurring, the IACUC will provide written notification to the investigator/instructor involved of the concerns of the IACUC and provide him/her with an opportunity to respond to the complaint. In cases where significant problems are identified which are not satisfactorily resolved by communications between the IACUC and the investigator, the IACUC may make recommendations to the MCD for further action. The

IACC is responsible for maintaining a file documenting complaints, committee review, and actions taken or recommended to rectify the problems identified. The MCD is notified of any significant issue by email, phone conversation or an electronic/sit-down meeting with the veterinarian, VMU supervisor and IACUC Chair.

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: The VA IACUC forwards recommendations directly to the MCD by means of the Semi-annual Program Review Report, unless the urgency of the issue necessitates earlier communication. The veterinarians, the IACUC Chair and the VMU Supervisor/IACUC Director are all present at these meetings.

6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

The IACUC office initiates new protocols for PI's at their request. The PI will submit a veterinary consultation form which includes a list of the employees that will be working on the animal study and a brief description of the animal study. The PI is asked if they would like an in person, email or telephone consultation with the PI. Once the consultation is completed a full Animal Component of Research Proposal (ACORP) is prepared and sent to the PI for completion. During this time, the qualifications for the employees are reviewed and all required training is submitted to them for completion. The IACUC staff also ensures that all employees are enrolled in an approved occupational health program and cleared to work with the animals in the protocol. The full ACORP is returned to the IACUC office, and it is reviewed for completeness. The ACORP is then forwarded to the veterinarian, non-affiliated member and non-scientist for review. The veterinarian will review the entire proposal. The non-affiliated and non-scientist members review sections **B. Description of Relevance and harm/Benefit Analysis** and section **C. 1. Lay Summary** to ensure that it is easily understood. Once the protocol is given preliminary approval by the veterinarian it is forwarded to a scientific reviewer. The scientific reviewer will review the protocol, may request changes of the ACORP and prepare a presentation of the protocol to the IACUC.

At least one week prior to the IACUC meeting, all IACUC members are sent a copy of the agenda along with all supporting documents. This will include full ACORP's, annual reviews and protocol revisions along with written reviews. IACUC members are given a review form to submit any questions or concerns prior to the meeting.

Full Committee Review (FCR) – As discussed above, the protocol is sent out to the full IACUC at least one week in advance for their review. At the convened IACUC meeting, the ACORP is presented to the full IACUC by the scientific reviewer. Each study is discussed in detail. After discussion of the protocol, a vote is taken. Full committee review may result in approval, a requirement for modifications (to secure approval) or withholding of approval. All minority opinions are documented in the meeting minutes and available to the R&DC and the PI.

If the protocol requires modifications prior to approval, the committee may vote to use the DMR process for final review, as approved in IACUC Policy 2017-014. The Chair designates at least two DMR members, which usually consist of the scientific reviewer and the veterinarian and/or the IACUC Manager. DMR will result in approval (unanimous by all reviewers), request for further modifications (which would then be returned to all DMR members for review), or referral back to full committee review; protocols cannot have approval withheld via the DMR process.

All ACORP's are reviewed by the stations Subcommittee on Research Safety (SRS) along with their safety forms prior to approval by the IACUC. Prior to beginning work on a new animal study or submitting the protocol to a funding agency, the ACORP must have SRS and IACUC approval and the R&DC committee must concur.

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. The following modifications can be made administratively:
      i. Personnel additions and deletions are handled administratively. The PI will initiate the addition/deletion by submitting a Personnel Addition/Deletion Form. The IACUC office will insure the added personnel have enrolled in the stations OHP, completed all the required education and have the proper qualifications to perform their duties on the protocol. If the employee has no previous experience performing the duties of the protocol, a training plan will be required.
      ii. Updated contact information
      iii. Change in housing location within an IACUC approved facility
      iv. Increase in animal numbers of non-USDA covered species, not to exceed 20% of the original approved protocol number

   b. The following modifications can be made via VVC by the Attending Veterinarian or their alternate, as outlined in the VVC document and supporting guidelines developed and approved by the IACUC. Changes made to a protocol via this process are documented via the protocol amendment form:
      i. Anesthesia, analgesia, or sedation, protocols that use referenced dosages for the species. Reference material may include textbooks (such as Harkness and Wagner's Biology and Medicine of Rabbits and Rodents; Flecknell's Laboratory Animal Anesthesia; Plumb's Veterinary Drug Handbook; Hawk and Leary's Formulary for Laboratory Animals; Fowler's Zoo and Wildlife Medicine; Lumb and Jones Veterinary Anesthesia and Analgesia; Quesenberry and Carpenter's Ferrets, Rabbits and Rodents Clinical Medicine and Surgery; Fish and Danneman Anesthesia and Analgesia of Laboratory Animals); journal publications (peer reviewed from PubMed and CAB database), personal communications with veterinary anesthesiologist. *(any new drugs that are not in the original protocol must be added to an SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*
      ii. Experimental substances administration that does not exceed guidelines published by Diehl et al. A good practice guide to the administration of substances and removal of blood, including routes and volumes. *J App Tox*. 2001; 21:15-23. *(any new drug, chemical, substance, etc. that is not in the original protocol must be added to an SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*
      iii. Changes in experimental substances within a similar class of substances to the original protocol approval. For example, chemotherapeutic, antibiotic, hormone, vehicle, etc. This would also include changes in instrumentation that do not alter the objectives of the original proposal. Administration of over-the-counter (OTC) products used to facilitate research may be used with veterinary approval. *(any new drug, chemical, substance, etc. that is not in the original protocol must be added to an SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*
      iv. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals. *(if chemical or gas euthanasia is added and the agent is not mentioned in the original ACORP, the change will must be added to a SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*
      v. Change in final disposition of animal, including change from euthanasia to adoption, or transfer to another protocol. Transfer to more invasive protocols such as survival surgery or infectious disease studies require IACUC review.
      vi. Duration, frequency, type (e.g. blood collection site or volumes, route of administration, volumes, and dosages) of previously approved procedures contingent upon them not exceeding IACUC guidelines.
      vii. Blood collection site or volume
      viii. Route of administration, volumes, and dosages

ix. Increasing food/fluid restriction prior to a procedure to more than 12 hours with adequate justification
x. Change in timing of collections, if there are no additional welfare concerns and other guidelines are followed.
xi. Number of procedures performed on an animal, excluding surgical procedures contingent upon them not exceeding IACUC guidelines.
xii. Additional strains or sources of animals *(any new genetically modified animal that has not already been approved on the protocol must be added to a SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*
xiii. Changes to space requirements if restriction is justified and not excessive based on veterinary consultation.
xiv. Change in diet or water composition if the remainder of diet maintains the proper nutritional needs of the animals. Alternative feeding strategies may also be reviewed such as placing feed on the floor of the cage. *(any new diet containing a new experimental agent that has not already been approved on the protocol must be added to a SRS update form and sent to the VA Subcommittee on Research Safety Committee prior to the final change/approval)*

c. All other changes to the protocol require submission on a protocol amendment form for and review and approval by the committee. The review process for the amendment is the same as for a new ACORP. The amendment is sent out to a scientific reviewer, community members and the veterinarian for review and presentation to the committee. Major changes require a complete new protocol.

d. All changes to the ACORP must be submitted to the SRS. That committee will determine if they are exempt from safety review. If they are not exempt from safety review, they must be approved by the SRS prior to IACUC approval.

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 office initiates a form that lists all IACUC meeting approvals. This form is forwarded to the Research and Development committee (R&DC) member for presentation to the R&DC for final approval. The form indicates dates of all committee approvals (SRS & IACUC). The ACOS for R&D will send an "official" approval letter to the PI. A copy of the letter is included in the IACUC file.

If the ACORP or revision was not approved, the IACUC office initiates written notification to the PI which contains the reasons for its decision. The notification states that either minor modifications are required before the project is approved or the protocol/revision must be tabled until some added information is submitted. The PI is notified that no work can begin on this project/amendment until all concerns are addressed and the protocol/revision is approved. This notification is emailed to the PI and a copy kept in the official IACUC file. The PI is allowed the opportunity to respond to all IACUC concerns in person, however, the concerns must be addressed in writing before the protocol/revision is approved.

The IACUC procedures for approving protocols reviewed at full committee that require modifications are in accordance with OLAW guidance and utilize a designated member review process subsequent to full committee approval. All members are advised at the time of required modification and may request the opportunity to review the modification and/or request full committee review.

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:

The committee reviews all protocols annually after submission of a Protocol – Annual Review Form. Protocols are approved for a maximum of three years and a complete, new protocol is required at that time. Lack of responses by investigators to committee set deadlines for annual or third year re-submission result in study suspension. Studies may not be reinitiated until the full committee reviews and approvals from all committees have been obtained (IACUC, SRS & R&D)

The process for this review is as follows: The IACUC Offices sends out an IACUC and SRS annual review form to the PI. The PI will fill out these forms and return to the IACUC office. The IACUC office insures that all personnel are currently enrolled in the stations OHP and current in all education requirements. The office then forwards the SRS annual review form to the SRS and forwards the IACUC annual review form, a copy of the full ACORP and all revisions to the veterinarians and to a designated scientist who will present this annual review to the full IACUC. The approval process is the same as for a full ACORP or protocol revision. All annual reviews are sent out to the full IACUC at least one week prior to the IACUC meeting for their review.

The IACUC's post approval monitoring is satisfied with annual review, any submitted revision and the semi-annual program review/facility inspection. No animals are taken out of the vivarium and all areas of animal manipulations are visited during the semi-annual facility inspection and the work involved with each protocol is discussed with the PI. Employee's compliance for OHP enrollment, education requirements and qualifications statements are monitored during each annual review and revision.

10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends a previously approved activity, the Institutional Official (IO) in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and report that the action with a full explanation to OLAW.

Issues are discussed at an IACUC meeting where there is a quorum. A vote is required, and then the protocol may be suspended. The IACUC has the authority to suspend a protocol for animal mistreatment (a special meeting would be called immediately), not following submitted protocol, expiration of protocol, yearly annual reviews not submitted in time, personnel on the protocol not current in all requirements (OHP enrollment/clearance, education, etc.) or any other consideration that may come up. After the suspension is voted on; a phone call, email or letter is sent immediately to the responsible PI. Any of the previously mentioned IACUC suspensions of an ongoing protocol will immediately be discussed with the IO with a follow-up letter sent directly to OLAW and ORO. Animal work may also be suspended for non-payment of animal related charges.

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

All employees who work with or around animals or their tissue are required to participate in the VA's Occupational Health Program (OHP) or an approved affiliates OHP. The VA's OHP is described in detail in ECHSC Research and Development Memorandum 151-5, titled "Occupational Health Program for Employees Who Work with Animals). The OHP defines two classes of personnel: 1) employees of the animal research facility and 2) employees who have direct contact with animals, their viable tissues, body fluids, wastes or living quarters (including all principal investigators, research technicians, pre-and post-doctoral fellows and residents, etc.) Also defined are three levels of animals: 1) small vendor supplied or derived animals including rodents and rabbits, 2) large animals including cats, dogs and livestock but excluding primates

and 3) primates. PI's who do not perform animal work, but have a staff that does animal work, employees of the research department that do not work directly with animals but may encounter a lab that utilizes animals may opt out of the program. Employees with direct contact may not opt out. A supplement to the OHP – Research and Development Memorandum 151-5 is the Occupational Health and Safety Program for Limited Exposure to Research Animals. This program is intended for contractors, FMS & EMS employees, office staff and any other employee that may come into brief contact with animals or into an area where animals may be or have been. All employees given access to any research area where animals may be are required to be enrolled in the OHP or sign a statement of training associated with the limited exposure program.

Responsibility for oversight of the program is designated to the VMU supervisor/IACUC Director, individual PI's and Employee Health. The program is coordinated through the station's OHP Nurse Practitioner in the division of Employee Health. All VA employees with affiliate appointments have the option of enrollment in either the VA program or the affiliates OHP. (there must be an MOU with the affiliate).

The primary procedures for all personnel in the VA program includes: 1) pre-employment physical which includes risk assessment and medical history including allergies and immunizations, general physical examination, CBC, TB skin test and/or chest x-ray, tetanus immunization or booster, and Hepatitis 2 titer and immunization. This program includes annual physicals as needed, TB tests and tetanus booster.

Employees sustaining work-related injury or illness (including allergic reactions) report such to Employee Health or the ER. Employees enrolled in this OHP are subject to mandatory surveillance recall annually. The recall begins with a questionnaire. After the questionnaire is submitted to the EH department, it is evaluated and employees needing a full physical or just general questions answered will be called back to EH for further evaluation. Failure to respond to the recall by the annual anniversary date will result in the employees' supervisor being notified of employees' non-compliance and the employee will not be allowed to work with research animals until the recall is completed.

F. The vivarium occupies the service level of Building B (aka Research Building) The service level has a total 15,228 square feet. This includes electrical room, telcom room, biohazardous/radioactive/recycle storage room, gas cylinder storage room, dock warehouse and corridors. There is approximately 888 square feet for large animals and 2253 square feet for small animals/rodents (14 rooms). Remaining square footage is support rooms that include procedure areas, cage wash and storage, locker rooms, laundry, offices, etc. See attached Facility and Species Inventory table.

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

The Veterinarians, VMU Supervisor/IACUC Director, Animal Care Staff and the IACUC provide guidance to research staff on the appropriate and humane procedures and treatments of animals. Research technicians are also instructed by the PI's. Required training for PI's and their research staff is protocol specific. Training is determined by the employees' experience and qualifications.

The VA utilizes the AALAS Learning Library (AALAS LL), on-line training courses. All personnel who work with animals, animal care staff, and the IACUC members are required to take specific AALAS LL training on a tri-annual basis. The veterinarians provide instruction on research testing methods that minimize the number of animals required to obtain valid results and limit animal pain and distress. There are also courses utilized from the AALAS LL that provide guidance with these issues. The veterinarians also provide protocol specific surgical and anesthetic training if necessary.

IACUC members utilize the AALAS LL, are given copies of the stations AAALAC Program Description, a copy of this PHS Assurance, "The Guide", The Animal Welfare Act, Public Health Service Policy on Humane Care and Use of Laboratory Animals, and OLAW's Institutional Animal

care and Use Committee Guidebook. The committee also receives on-the-job training at each monthly IACUC meeting. VA Central Office provides monthly training scenarios for IACUC members which we also utilize.

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, [Sallie A. Houser-Hanfelder].
   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, [Sallie A. Houser-Hanfelder].

5. Any minority views filed by members of the IACUC

[*Note: if there are no changes to report, provide written notification that there are no changes.*]

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: Sallie A. Houser-Hanfelder, FACHE

Title: Medical Center Director

Name of Institution: Rocky Mountain Regional VA Medical Center

Address: *(street, city, state, country, postal code)*
13611 East Colfax
Aurora, Colorado 80045

Phone: (b)(6) Fax: (b)(6)

E-mail: (b)(6) @va.gov

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: (b)(6) Date: 01-18-2018

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

Dr. Venita B. Thornton - Senior Assurance Officer
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Signature (b)(6) Date: Jan. 26, 2018

Assurance Number: D16-00748 (A4493-01)

Effective Date: Jan. 26, 2018 Expiration Date: Dec. 31, 2021

VIII. Membership of the IACUC

Date:	
Name of Institution: Rocky Mountain Regional VA Medical Center *(Eastern Colorado Healthcare System)*	
Assurance Number: A4493-01 (D16-00748)	

IACUC Chairperson

Name*: (b)(6)	
Title*: Associate Professor of Medicine	Degree/Credentials*: PhD
Address*: *(street, city, state, zip code)* Rocky Mountain Regional VAMC Research Laboratory Building B, Room B3-112 13611 E. Colfax Aurora, CO 80045	
E-mail*: (b)(6) @va.gov	
Phone* (b)(6)	Fax*: none

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
S005	PhD, DVM	Research Associate	Scientist
S010	PhD, DVM		Scientist
S007	PhD		Scientist
S009	MS	Sr. Professional Research Assistant	Scientist
NS001	AA	Research Safety Officer	Member
NS003		Animal Technician	Member
NS002		VMU Supv/IACUC Dir	Member
NA004	BS, MS	Homemaker	Non-Affiliated
NS005		Supply Technician	Non-Scientist
(b)(6)	DVM	Attending Veterinarian	Veterinarian
	DVM	Consulting Veterinarian	Veterinarian

* This information is mandatory.

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

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

**** PHS Policy Membership Requirements:

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

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

IX. Other Key Contacts (optional)

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

Contact #1	
Name: (b)(6)	
Title: VMU Supervisor – IACUC Director	
Phone: (b)(6)	E-mail: (b)(6) @va.gov
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date:			
Name of Institution: Rocky Mountain Regional Medical Center			
Assurance Number: A4493-01 (D16-00748)			
Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
BS-114	98 SF	Mouse – smoke study/holding	TBD
BS-117	201 SF	Mouse Breeding Mice	TBD Moving ~10 cages from Clermont
BS-122	214 SF	Mouse Breeding/holding protocol	TBD Moving ~ 90 cages from Clermont into this room
BS-123	199 SF	Mouse Weaning room	TBD Moving ~20 cages from Clermont
BS-125	202 SF	Mouse MR1506M	TBD Moving ~10 cages from Clermont
BS-126	214 SF	Mouse	TBD
BS-128	214 SF	Mouse	TBD
BS-129	202 SF	Mouse 2MR1705M	TBD Moving ~50 cages from Clermont
BS-130	214 SF	Rat CD1704R	TBD ~30 – study to begin late November
BS-131	201 SF	Mouse 2MR1604M	TBD Moving ~50 cages from Clermont
BS-134	213 SF	Mouse	TBD
BS-135	199 SF	Rat	TBD
BS-137	195 SF	Rat	TBD
BS-145	115 SF	Rodent – incoming quarantine	TBD

This is a new research facility and we are gradually moving our animals in and determining our numbers. An updated chart will be submitted at a later time to detail our census.

*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.

APPENDIX I

Organizational Chart