CENTRAL ARKANSAS VETERANS HEALTHCARE SYSTEM
D16-00315 (A3509-01)

Animal Welfare Assurance for Domestic Institutions

I, (b)(6), as named Institutional Official for animal care and use at Central Arkansas Veterans Healthcare System (CAVHS), 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, NSF, and/or NASA. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution, CAVHS, has legal authority, included are those that operate under a different name: Medical Research Service and the Veterinary Medical Unit (VMU).

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

II. Institutional Commitment

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

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

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

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

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

III. Institutional Program for Animal Care and Use

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

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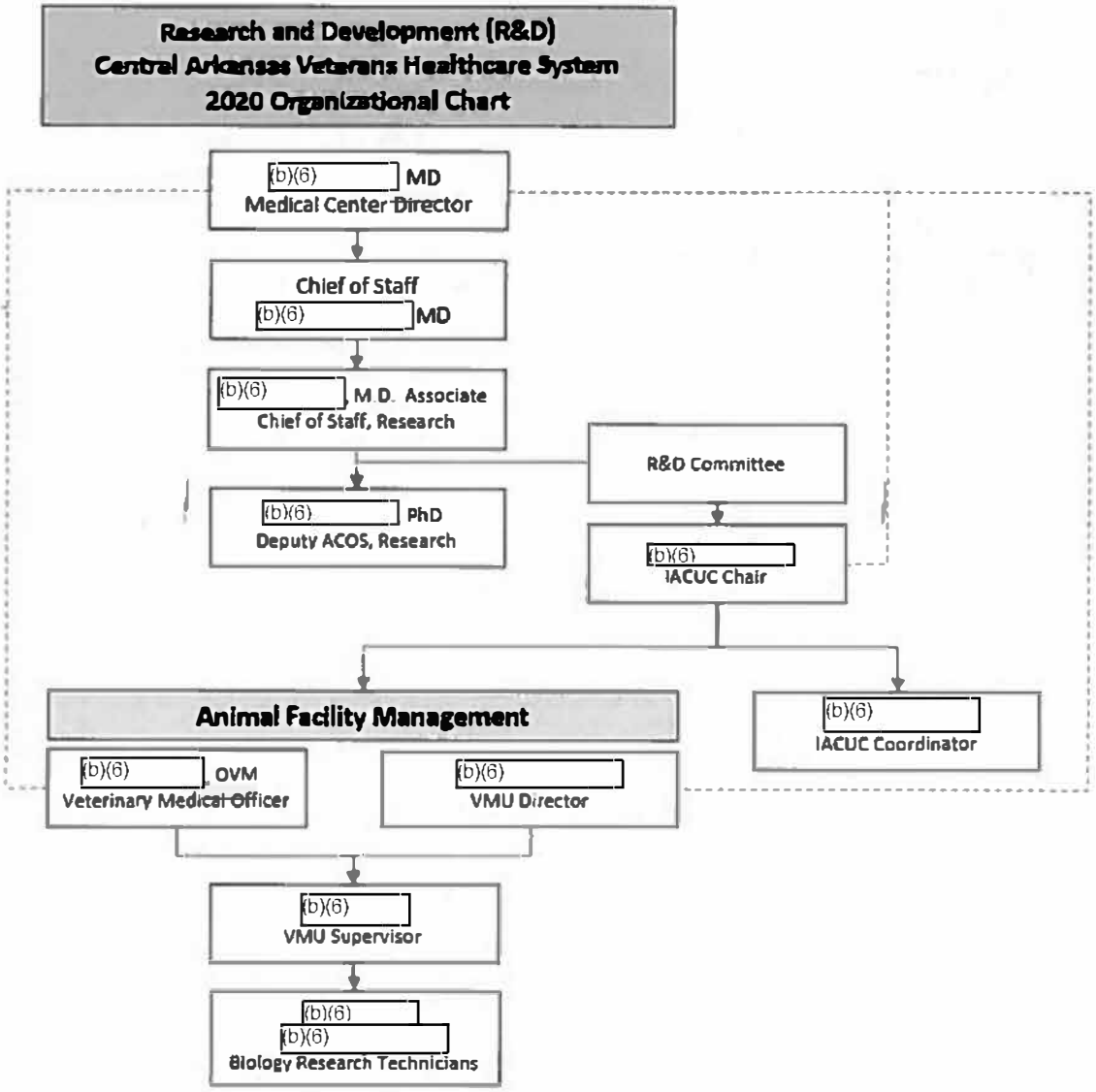

There is a direct line of communication for all members of the IACUC to the Institutional Official (IO) of the institution. This direct line of communication is used for cases of pressing IACUC business. All other routine communications, such as the IO signature on reports, is handled through the regular chain of command.

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

1) Name: Dr. (b)(6)

Qualifications

- Degrees:
  Doctor of Veterinary Medicine (DVM)
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  (b)(6) DVM received her degree in veterinary medicine from (b)(6) University, (b)(6) in (b)(6). She has been a small animal practitioner since graduation and now owns (b)(6) in (b)(6), AR. From (b)(6) to (b)(6) she was also the on-call veterinarian at the (b)(6) when their

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veterinarian was out of town. In 2017 she became the Veterinary Medical Officer for the CAVHS VMU. Dr. (b)(6) is a member of the American Veterinary Medical Association, the (b)(6) Veterinary Medical Association and the American Association of Laboratory Animal Science. She was (b)(6) of the (b)(6) Veterinary Medical Association in (b)(6).

Authority: Dr. (b)(6) 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. (b)(6) is responsible for veterinary care of all animals used at CAVHS. As the Veterinary Medical Officer (VMO), she makes routine inspections of animal wards twice a month for at least one (1) hour each time and responds to requests for assistance on all aspects of animal health and care made by the Supervisor of the VMU. She also provides emergency and weekend veterinary care if necessary. The VMO assists research personnel in meeting established standards and in the preparation of animal use protocols. The VMO implements and maintains institutional veterinary care policies and standards that meet or exceed the requirements of regulatory and accrediting agencies. The VMO serves on the IACUC and provides veterinary and professional consultation services on the design, construction and maintenance of the animal facility. Both the VMO and the VMU Supervisor are available for emergency consultation cellular or home phone. Phone numbers (home and cellular) are posted in the VMU and recorded with CAVHS Police. In the event that Dr. (b)(6) was not available, provisions have been made with Dr. (b)(6), DVM, (b)(6) in (b)(6), AR concerning animal health issues.

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

D. The IACUC will:

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

   a. The VMU Supervisor evaluates, reviews, and updates the institution's program for humane care and use of animals using USDA regulations, the Guide, institutional policies, VA policies, and other relevant material in May and November of each year. The Supervisor then consults with the VMO and IACUC Chair on the contents.

   b. The document is then distributed to each of the members of the IACUC at least two weeks prior to the monthly meeting. The document is then discussed at the monthly meeting and the document approved pending any relevant changes that are necessary.

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:

   a. The IACUC members conduct the semiannual facility inspection in May and November of each year. Representatives from the Medical Center Director's Office, the Chief of Staff's Office and the Engineering Service of the institution are encouraged to participate. All IACUC members are also encouraged to participate in the semiannual facility inspection. However, according to the Animal Welfare Act Regulations, at least two IACUC members, delegated by the IACUC, are required for the inspection. The inspection includes the animal facility and satellite laboratories, if applicable. Each area is inspected for cleanliness, proper record keeping and general condition. Freezers and refrigerators, cold

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rooms, the dirty and clean sides of the cage washing area, and the surgery and recovery rooms are also inspected.

b. The IACUC utilizes the following three (3) forms for conducting the semi-annual institution's program for humane care and use of animals and the institution's animal facilities:

1) VA IACUC Semi-Annual Self-Review Form
2) Table of Program and Facilities Deficiencies
3) Post-Review Documentation

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 prepared reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3 are submitted to Dr. (b)(6), ACOS for Research, Research and Development Committee of CAVHS, Dr. (b)(6), Medical Center Director, and (b)(6), DVM, PhD, Chief Veterinary Medical Officer, Department of Veterans Affairs. The reports are updated at least once every six months upon completion of the semiannual facility inspection and review of the institution's program for human care and use of animals. The reports are maintained on file by the institution.

- Within the VA IACUC Semi-Annual Self-Review Form, there is a description of the nature and extent of the institution's adherence to the Guide and PHS Policy and states any departures from the provisions of the Guide and PHS Policy and the resultant reasons for each departure.

- The Table of Program and Facilities Deficiencies distinguishes between significant and minor deficiencies, with a significant deficiency being one that is or maybe a threat to health or safety of the animals. Also, within this table are specific plans and reasonable time frames for correction of all deficiencies.

- The Post-Review Documentation lists the dates of the program evaluation and facilities inspection and those who participated. Any minority views are discussed within this document or, if there were no minority views, a statement reflecting this is included. The semiannual report is signed by a majority of all voting members of the IACUC, including members who reviewed the program and those who attended the facilities inspection, and sent to the Medical Center Director's (IO) office.

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

- CAVHS is in compliance with the Whistleblower Protection Act of 1989. No employee, principal investigator, project manager, research technician, animal care personnel, volunteer, or student shall be subject to coercion, reprisal, discrimination, or other adverse action as a result of reporting any concerns involving the care and use of animals at CAVHS.
- The email addresses for reporting concerns are posted in multiple locations throughout the animal facility, including the only entry door for research laboratory personnel.
- If personnel do not wish to email, also posted in the same location are the instructions for making reports anonymously. There is a comment card box on the wall before the entrance to the VMU so people can report their concerns anonymously. Reports that are made in writing should include a detailed description of the incident, the personnel involved, the date, the time, place, and animals involved.

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- All concerns will be reviewed with safeguards to protect the individual's identity, and, if warranted, the IACUC chairperson will appoint a subcommittee to perform an IACUC investigation.
- Any subcommittee findings are reviewed at the next convened meeting of the IACUC with appropriate action taken. This includes possible suspension of the protocol with notification of the Institutional Official and OLAW.
- In addition, any IACUC member can bring a concern involving animal care and use to the IACUC chairperson or to the full IACUC without fear of reprisal.
- If the concern cannot be resolved to the satisfaction of the individual bringing the concern, the IACUC chairperson must report the concern to the Associate Chief of Staff for Research. If the ACOS is not able to resolve the concern, it must be reported to the Medical Center Director. All serious animal care and use concerns are reported to the Office of Laboratory Animal Welfare (OLAW).

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 IACUC Coordinator distributes the report to each member of the IACUC committee for review prior to a discussion and a vote to accept or reject the report. Each member of the IACUC has the right to include a minority report. After any revisions have been made and the semiannual report has been accepted by the IACUC, each member present at the meeting signs the final report. The final semiannual report, which includes the VA IACUC Semi-Annual Self-Review Form and the Table of Program and Facilities Deficiencies, is then submitted to the Medical Center Director. After the Medical Center Director has reviewed the documents, the ACOS for Research, the Administrative Officer for Research, the VMO, the VMU Director, the Supervisor of the VMU, and the IACUC chairperson meet with the Medical Center Director, either face-to-face or by teleconference or videoconference, to discuss the program.

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

   a. The IACUC reviews all proposals involving animal use to ensure that the principal investigator incorporates the following principles into their research: scientific reliance on live animals should be minimized, and pain, distress and other harm to laboratory animals should be reduced to the minimum necessary to obtain valid scientific data.

   b. All protocols are first submitted to the Veterinary Medical Officer (VMO) for their review. The VMO submits their comments and suggestions in writing (e.g., email) to the Principal Investigator (PI) of the protocol. The VMO is specifically concerned with procedures which may result in pain, distress or ill effects that cannot be alleviated or prevented with drugs; procedures using prolonged restraint; procedures requiring the development of a serious natural or experimental disease, especially when that disease state would be maintained for an extended period of time; and methods of euthanasia differing from those recommended by the AVMA panel on euthanasia.

   c. The PI incorporates the changes suggested by the VMO and submits copies of the protocol along with the Budget Sheet, appropriate Safety Data Sheet/s (SDS), database search strategy and appropriate ACORP appendices to the IACUC Coordinator.

   d. The IACUC Coordinator notifies the IACUC Chairperson, and the Chairperson assigns the ACORP to two (2) IACUC members for pre review. All new and renewal ACORPS are subjected to full review. Protocol procedures that have the potential to cause pain or distress are reviewed by the full IACUC. The Principal Investigator must address personnel qualifications, pre and post operation procedures including intra operative

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monitoring if surgery is involved, analgesics, post-operative monitoring and support methods. The IACUC Coordinator forwards a packet containing all of the protocols to be discussed at the IACUC meeting to all IACUC members. If a quorum is not present at the monthly IACUC meeting, no votes are taken on protocols. However, if a quorum is present at the monthly IACUC meeting, the reviewers then present their comments and concerns to the committee members and the protocol is discussed by all committee members. If a member of the committee has submitted a protocol application to be discussed, that member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum, and will be excused from the meeting until the discussion and vote on the protocol has been completed. The IACUC then votes on the protocol. The vote must be at a convened meeting of a quorum of the IACUC and with a majority vote of that convened quorum. The vote may result in approval of the protocol, address modifications prior to approval of the protocol, or withholding of approval of the protocol (table the protocol). If the protocol is tabled, a list of concerns is forwarded to the Principal Investigator from the IACUC chairperson and the protocol is resubmitted to the IACUC for full review at the next monthly meeting.

e. Designated member review (DMR) is only available for modifications to an existing protocol or in the event of a FCR outcome of require modifications to secure approval. For modifications to an approved protocol, the changes must be described on the form "Application for Protocol Modification." This form can only be used in making a minor change to an approved protocol.

   If the FCR outcome is require modifications to secure approval, the IACUC committee can:

   1) Vote for DMR when all members of the IACUC are present.
   2) If all members are not present at the meeting, and all members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR, then a quorum of members at a convened meeting can vote for FCR.
   3) If all members are not present and the IACUC hasn't received, in writing, the agreement of all members that the committee may decide by unanimous vote to use DMR, the committee then has the option to vote to return the protocol for FCR at a future convened meeting or to use DMR. If electing to use DMR, all members, including the members not present at the meeting, will have the revised research protocol available to them on VAIRRS and will have the opportunity to call for FCR.

   A DMR will only be conducted if all members of the committee have had the opportunity to request FCR (within 3 business days) and none have done so.

   If changes to an approved protocol are substantial (i.e., change of/or additional animal species, survival surgery, change increases the potential for pain or distress in the animal, or involves a significant procedure not previously approved for these animals), a new ACORP must be submitted. A new experiment or a pilot study cannot be approved as a modification even if the same funding source is used.

   Changes considered minor by the IACUC are eligible for designated members review. Minor changes can include, but not limited to such things as a change in the strain of rodent, a small increase in the total number of animals used, a change in the experimental treatment regime of the animals that will not alter the health or pain level of the animals being used for the study, and a change in the choice or dose of anesthetic, analgesic, or antibiotic.

f. All proposed changes must be reviewed by the Veterinary Medical Officer before submission to the IACUC Coordinator. The IACUC Coordinator will forward this within the packet of all the materials to be discussed at the monthly IACUC meeting. Any member of the IACUC has the opportunity to request full committee review of a protocol modification within three business days. If this is the case, the IACUC Chairperson will

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follow the procedure for full committee review. If there are no objections to designated member review, the IACUC Chairperson appoints two members of the IACUC committee for designated review. The designated reviewers receive and review identical copies of the protocol and have authority to approve the ACORP or approve the protocol after appropriate corrections have been made. The designated reviewers must be unanimous in their decision. They cannot disapprove the protocol. If they cannot approve the protocol, it must come back for a full IACUC review. Therefore, DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review.

g. There is no form of expedited protocol review.

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. Any significant changes, such as a change in pain category, change from nonsurvival to survival surgery, resulting in greater distress or degree of invasiveness, in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC, In study objectives, a request for an increase in the number of animals (*generally exceeding 10% of the number originally approved), change in endpoint criteria that would increase the amount of time animals may experience pain or distress, addition of previously untested or unknown test articles or substances, change in species, change in PI and changes impacting personnel safety, in an approved protocol must be approved by the IACUC prior to their implementation.

Any increase in animal numbers must be addressed through a request for modification. Each request for modification begins as a full committee review; if there are no objections within three business days, it is entrusted to DMR.

All our deliberations regarding animal numbers—whether in a new protocol or a request for modification—are performed in a manner consistent with PHS Policy IV.A.1.g and IV.D.1.b. The rationale for the number of animals is not likely to change in a request for modification because it is always required that rationale be based on a power analysis or other rational, good-faith information that estimates the minimal number necessary for achieving the scientific objective(s).

We consider changes in study objectives analogously to changes in procedures or numbers: some are significant, and some are not. Study objectives are by their nature diverse, complex, and qualitative. It does not seem likely that study objectives could be measured by specific, universal criteria. In accordance with NOT-OD-14-126, we rely on the committee's discretion to define what it considers a significant change on a case-by-case basis.

Any request—whether for a new protocol or a request for modification—is subjected to the same rules and guidelines for promoting animal welfare. A negative impact on animal welfare would not necessarily lead to rejection of a request, though it typically results in requirement for FCR. Any negative impact, including increased numbers of animals, must be justified and should be examined for the potential application of replacement, reduction, or refinement.

b. The Principal Investigator must submit a modified ACORP with the changes identified to the VMO for their suggestions followed by a review of the IACUC. The IACUC may review the protocol or may elect to have the protocol reviewed by designated reviewers. However, if even one member of the IACUC requests full review for the modifications, the protocol will go for full review. Each IACUC member has three (3) business days to request a full committee review after receipt of the amended protocol.

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

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required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

a. Within seven working days after the protocol has been reviewed by the IACUC, the IACUC chairperson notifies the Principal Investigator of the committee's decision in writing. If the protocol was approved, a letter of approval is sent to the Principal Investigator. In addition, the approval letter is sent to sponsoring agencies and the Veterinary Medical Unit as required. If approval is withheld pending modifications, the changes necessary to secure approval are detailed in writing to the Principal Investigator. If the IACUC withheld approval or tabled a protocol, the principal investigator receives a detailed memorandum outlining all of the concerns and recommendations of the committee.

b. Principal Investigators have thirty (30) days to respond in writing to the IACUC committee's recommendations and concerns raised during the review. If the protocol was approved pending modifications, the investigator can submit a revised protocol any time during the 30 days to the IACUC chairperson. The chairperson, along with the two primary reviewers, will decide if the concerns of the IACUC have been properly addressed. If the IACUC's concerns are resolved, the protocol is then approved, and an approval letter provided as necessary. If the Principal Investigator fails to respond by the deadline or fails to adequately address the concerns of the IACUC, the protocol is administratively withdrawn from review. A protocol that has had approval withheld or has been tabled, can be resubmitted for full committee review at any time.

c. Protocols approved by the IACUC are forwarded to the Research and Development (R&D) Committee for their approval. Commencement of a protocol approved by the IACUC cannot begin until also approved by the R&D Committee. The R&D Committee can disapprove a protocol approved by the IACUC, but they cannot approve a protocol which has not been approved by the IACUC.

d. The R&D Committee meets once per month and the IACUC meeting minutes are presented and recorded. A copy of the R&D meeting minutes is forwarded to the Institutional Official, who is a non-voting, ex-officio member of the R&D Committee. Actions of the IACUC, including the disposition of each protocol reviewed during the monthly meeting are outlined in the IACUC committee minutes. If a protocol has approval withheld or is tabled, specific reasons are detailed within the minutes.

9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

a. The IACUC will conduct a yearly continuing review of each approved ongoing protocol where USDA animal species are used. This is primarily the responsibility of the VMO, the Supervisor of the VMU, and the IACUC chairperson. Protocols with non-USDA animal species will not undergo a yearly continuing review but will undergo de-novo review every three years in the form of a new ACORP submission.

b. All protocols are initially approved for a three (3) year period and must be resubmitted as a new ACORP to the VMO near the end of the three-year period. Normal procedures are then followed as for a new ACORP with suggested changes by the VMO incorporated into the ACORP and a full committee review is completed by the IACUC.

c. For USDA covered species, the Veterans Affairs Innovation and Research Review System (VAIRRS) sends investigators an email reminder at 90, 60, and 30 days before their ACORP expires requesting that the investigator submit a "Request for Continued Approval for Animal Use" form. This form is required annually during the anniversary month of the original IACUC approval. The Principal Investigator then completes and uploads all required forms into VAIRRS. Once it is reviewed by research administration, it is then forwarded to the IACUC Coordinator, who adds it to the agenda of the next convened IACUC meeting. If amendments are included, it will get assigned to two designated reviewers. The approvals are noted in the IACUC minutes.

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Post Approval Monitoring

1. PURPOSE

   The goal of post-approval monitoring is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner.

2. RESPONSIBLE PARTIES AND APPLICABILITY
   - The post-approval monitoring (PAM) reviews will be performed by the VMU Supervisor and the VMO. If either is not available a member of IACUC can be designated by the IACUC Chair to perform the review.
   - The reviewer will be familiar with IACUC policies and the Guide requirements and be knowledgeable about changes in regulations and standards that may affect the way in which research is conducted.
   - The reviewer will work in conjunction with Principal Investigators (PIs), Co-Investigators (Co-Is) and research personnel during the visit to facilitate observation of procedures and document compliance with approved protocols.
   - The reviewer will work with the PIs, Co-Is and research personnel to perform protocol reviews, prepare accurate reports, and if necessary, provide training of personnel and recommendations to the PIs for maintaining compliance.
   - The reviewer will coordinate visits, correspondence and documentation, maintain records, and communicate with the IACUC.
   - Designated Members (DMs) of the IACUC will perform PAM for procedures that require a particular level of expertise (surgical procedures, for example) and will report any finding's in the PAM reports and records.

3. TYPE OF REVIEW
   - Routine Review: Two active animal protocols will be selected each quarter for routine review.
   - Select or "For Cause" Review: "For cause" monitoring may be conducted at any time, with or without advance notice to the PI or research personnel. "For cause" reviews may be performed when requested by the VMU personnel, IACUC, or based on previous non-compliance.
   - Follow-up Review: These assessments will be performed for the purpose of confirming resolution on any concern found during a previous review. This will occur within 90 days of the previous review and will be unannounced.
   - New Project Review: Newly approved ACORPs will be reviewed within three to 6 months of approval.

4. PROCEDURE

   a. Advisement of a Routine Review:
      - The reviewer shall make an appointment for visits by e-mail. Initial correspondence with the PI should contain the information noted in the PAM visit memo.
      - The reviewer will arrange a visit according to the PI/Co-I/research personnel calendar and scheduled animal use procedures.

   b. Performing a Review:
      - The reviewer shall use the approved PAM Checklist for the review to compare procedures conducted in the laboratory with those listed in the approved ACORP.
      - Undocumented observed discrepancies will be documented by the reviewer. Discrepancies documented in the research records or by the reviewer between procedures performed and those listed in the ACORP will be brought to the attention of the PI. Issues that pose an immediate threat to animal welfare must be referred to the attending veterinarian and the IACUC for immediate resolution.

   c. Exit Briefing of a Routine Review:
      - At the conclusion of the review, the reviewer shall discuss the observations with the personnel who performed the work as well as the PI or designee.
      - The goal of this interaction is to confirm observations are accurate and the reviewer and laboratory staff agree on the observations. The laboratory may offer

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additional information, but the reviewer may not negotiate but can request a specific laboratory corrective action plan.

d. Post Review:
- If potential deviations/concerns exist: A final written report e-mail will be sent to the PI or designee describing the observed concern(s). The PI/laboratory staff shall have 10 business days from the receipt of the email to provide corrective action plan for any discrepancies reported.
- If no deviations/concerns exist: An e-mail shall be sent to the PI noting the fully compliant nature of the review.
- In cases where the PI desires to initiate corrective actions the reviewer may assist the laboratory if requested. Assistance may include coordinating/providing training and or assistance with protocol addendum process.

5. Reporting of Findings:
All findings will be reported to the IACUC. Animal misuse, mistreatment or neglect (welfare issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse or willful disregard for appropriate animal care) will be reported immediately to the IACUC Chair and VMO.

6. Process of Sharing Information Concerning the Review:
- The reviewer shall discuss monitoring results with the PI and/or other research personnel before leaving the laboratory. Issues that pose an immediate threat to animal welfare shall be referred to the VMO and IACUC Chair for immediate resolution.
- The reviewer shall send a final written report and a follow up letter of significant findings to the PI and the IACUC.

7. Process Follow Up:
- Any issues that require protocol modifications, orientation of new personnel, or training must be presented to the reviewer when complete.
- On occasion, additional monitoring sessions may be a part of the follow-up to assist with proper corrective actions.

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

a. The IACUC has the authority to suspend an ongoing protocol for a variety of reasons such as failure of the Principal Investigator to follow the protocol as outlined in the approved ACORP, performing procedures not defined or listed in the ACORP, or animal mistreatment.

b. If the infraction(s) is minor, the IACUC may notify the Principal Investigator and give him an appropriate time frame to correct the infractions and, if necessary, incorporate the revisions in a revised ACORP.

c. If the infractions(s) are of a more serious nature, the IACUC has the option of immediate suspension of the protocol.

d. Suspension of an ongoing approved protocol requires a majority vote of a quorum of the IACUC. The IACUC chairperson or any member of the IACUC may call an emergency meeting of the IACUC to consider suspension of a protocol. If a protocol is suspended, the IACUC, through the Institutional Official (Medical Center Director), will promptly provide the Office of Laboratory Animal Welfare (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 provision of the Guide
3) Any suspension of an activity by the 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:

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1. An occupational health program (OHP) is essential for personnel who work in laboratory animal facilities, or, through their work, come in contact with animals. These type of animal contacts potentially expose personnel to physical demands, allergens, and hazardous agents including infectious diseases, radioactive materials, and toxic substances. Infectious diseases may be experimental in origin or naturally occurring zoonotic diseases for a given animal species. Human allergies to animals are common and may become serious enough to constitute an important health consideration. The IACUC, in consultation with the Occupational Health and Safety Division within Engineering Service, is responsible for implementation of the occupational health program related to the use of animals in research. The Occupational Health and Safety Division in Engineering Service is responsible for the overall management and monitoring of the occupational health program at the Central Arkansas Veterans Healthcare System.

   All individuals that care for and use laboratory animals at the facility are required to participate in an occupational health program. Facility service individuals, including Engineering Service, Environmental Management Service and Police Service, must enroll in the occupational health program at CAVHS. If an employee is a WOC (e.g., summer student, visiting faculty) and they are not enrolled in the CAVHS occupational health program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training on zoonoses and allergies common in animal research, and if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health.

2. Medical Evaluation and Preventative Medicine for Personnel: The CAVHS employee health clinic consists of 2 APNs (advanced practical Nurse) and a physician consultant. The Occupational Health and Safety program for full, part-time, and Without Compensation (WOC) employees of the VMU includes the following procedures that each employee must observe and participate in:

   a. A pre employment physical examination that includes a complete blood count, a urinalysis, a varicella titer, and if the employee is above the age of 40, an electrocardiogram.

   b. Determination that tetanus immunization is current. The immunization is not required but offered if needed.

   c. Every twelve (12) months a PPD skin test is administered for tuberculosis monitoring usually on the Entered on Duty (EOD) date. PPD testing is performed as per Medical Center Policy.

   d. Blood pressure checks are offered by the Employee Heath Service.

   e. An annual flu inoculation is available. If not administered at CAVHS, proof of inoculation must be provided.

   f. Free screening and vaccine for Hepatitis B is provided by the Employee Health Service on a voluntary basis.

   g. A pre-exposure questionnaire is required by the is institution for all VMU employees exposed to carcinogens followed by an annual questionnaire specific to the hazard. A physical exam may be suggested based on the answers to the questionnaire. Personnel assigned to projects using cancer-causing agents (i.e., cispiatin) must follow all Standard Operating Procedures developed for that hazard.

   h. Preventative Medicine: Personnel must participate in the Preventative Medicine Program if they have to handle animals or handle unfixed animal tissues. Because CAVHS ensures that a safe workplace is provided, all employees involved in animal research that is conducted completely or partially at CAVHS must provide proof to the Institutional Animal Care and Use Committee (IACUC) that they have participated in the Preventative Medicine Program before they enter the Veterinary Medical Unit and before they begin work with the animals. If the employee is a WOC and they are not enrolled in the CAVHS Preventative Medicine Program, they must provide verification of participation in a comparable program which is confirmed by the IACUC coordinator. Employees are provided information and training on zoonoses and allergies common in animal research,

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and if necessary, on precautions to be taken in the event of pregnancy, illness, and decreased immunocompetence, by CAVHS employee health.

i. Medical Follow-up Questionnaire: An annual review in the form of an interview by a qualified medical professional can substitute for a physical exam in the Preventative Medicine Program. The following information will be obtained from the VMU personnel.

1. Name, last four digits of their social security number, date of birth, gender, pregnancy status, hospital service, job title, and contact information.
2. The species of laboratory animal(s) encountered
3. The amount of contact time per week including contact time with animal tissues, waste, body fluids, carcasses, and animal housing areas.
4. Whether human or animal pathogens are included in the employee's work.
5. History of tuberculosis testing (PPD Skin Test/Quantiferon Gold).
6. Whether the employee has received immunosuppressive therapy within the past year that could increase the risk of zoonotic disease.
7. How often does the employee wear the personal protective equipment (PPE) suggested for the assigned tasks; such as gloves, mask, and protective eyewear.
8. Whether the employee smokes, eats or drinks in the animal or procedure areas.
9. How often the employee washes hands, changes clothing (if soiled), or showers after handling animals during the day.
10. Is there any history of asthma, hay fever, allergic skin problems, eczema, sinusitis, chronic respiratory infections or disease.
11. Whether any allergic symptoms occur during or after contact with a laboratory animal species, and if so, which species is involved and how frequently each symptom occurs.
12. Whether the employee has any house pets that could be responsible for the allergic symptoms or that could represent a disease transmission hazard to the employee or to the animals in the research facility.
13. In the past year, has the employee ever suffered from an inguinal or similar hernia, from back pain, or from joint problems or arthritis. If so, the severity and corrective measures need to be described.
14. Whether the employee works with chemicals or hazardous materials in the workplace and does the employee have any symptoms associated with such exposure.
15. The immunization and testing history for the employee which includes date, side effect(s), or other relevant information for each of the following: tetanus, hepatitis B, and other immunizations or tests as would be appropriate for the employees work.
16. Include the printed name, signature, and date for both the employee and interviewer.

The Research Safety Officer, in conjunction with CAVHS's Industrial Hygienist, provides yearly training to all hospital personnel concerning hazardous agents. The Research Health Science Officer, along with experts in the specific relevant field (i.e. Radiation Safety Officer), does annual risk assessments for each laboratory with VA personnel. If the approved study has animals, the risk assessments include working with animals and the dangers posed by such.

The VMU provides information concerning the dangers associated with the use of hazardous biologic, chemical, or physical agents and safeguards with periodic SOP review. VMU personnel directly involved with animals exposed to hazardous agents are given special

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counsel and training appropriate to the hazardous biologic, chemical, or physical agent being used.

3. Personnel handling research animals, performing routine animal husbandry or other duties within the animal wards or working in areas where research animals are being housed or manipulated will wear appropriate Personnel Protective Equipment (PPE) such as a scrub suit, lab coat, or gown. Personnel will also wear shoe covers and gloves. Disposable gloves will be changed each time personnel leave an area of work (i.e. animal ward, necropsy, surgery, soiled cage room). Disposable face masks (N95) will be worn when manipulating dirty bedding outside of the dump stations. Protective clothing is provided to the employees at no cost. Uniforms and laboratory coats are laundered at the VMU facility so that clean, protective clothing is available whenever needed. Within the VMU, there are enough clean inventories for research staff and animal husbandry personnel to change into clean uniforms or coats multiple times daily. Soiled protective clothing is not taken away from the work site and soiled outer garments are not worn outside the animal research facility. Protective equipment and clothing for animal care personnel who are exposed to hazardous agents or hazardous situations are provided by the Veterinary Medical Unit. They include: gowns, face masks, face shield (plastic), goggles (plastic), exam gloves, surgeon's gloves, heavy rubber gloves, shoe covers, heavy rubber boots, rubber aprons, head covers, hearing protectors, scrub suits, steel toe shoes/boots, lab coats, jump suits, and lifting supports.

4. All individuals working with or having contact with animals must be enrolled in the CAVHS OHP or be enrolled in a similar program that meets CAVHS requirements prior to being permitted to enter the VMU and/or begin working with animals. Those individuals working with anesthetic gases on VA property are required to participate in the waste anesthetic gas (WAG) services offered by the OHP.

   The industrial hygienist will perform annual screenings for noise levels. If noise levels are equal to or higher than 85 dBA 8-hour TWA. VMU personnel working in the cage washing area must participate in the hearing conservation services offered by the CAVHS OHP.

   CAVHS PIs are required to list all individuals working with animals, their fresh, frozen, or non-fixed tissues, body fluids, or waste on both the SRS Form and the ACORP. Prior to IACUC review and approval, the CAVHS IACUC Coordinator verifies that all individuals identified via the SRS Form or ACORP are either enrolled in an appropriate preventive medicine program or have signed a declination form to participate. Those who have not provided proof are notified by the IACUC Coordinator that they must present for clinical evaluation at CAVHS Occupational Health or provide documentation of their declination to participate in the program.

   Those that initially enroll in the CAVHS OHP program (or another comparable program) must undergo a physical. If the evaluation is not completed, the name of the individual is provided to the IACUC to be considered for suspension of authorization to utilize laboratory animals and/or their viable tissues and body fluids. The R&D Office maintains a system to ensure that annual evaluations are completed for those enrolled in the CAVHS OHP or another comparable program. The date of the completion of annual review is forwarded to the IACUC Coordinator from Occupational Health. Employee Health will provide an enrollment completion form and that form must be given to the VMU Supervisor and uploaded to the participant's user profile in VAIRRS.

   All personnel working with hazardous drugs (e.g., cancer chemotherapeutic drugs, antineoplastic agents or cytotoxic drugs) are required to enroll in the CAHVS OHP program. Personnel must complete training and are monitored by completing:
   2) Baseline medical assessment.
   3) Annual medical evaluation by OHP.
   4) Medical evaluation in the case of exposure to the drug.

5. Personnel who receive animal bites or scratches, cuts from objects such as surgical blades and glass, puncture wounds from needles or other sharp objects, foreign objects or chemicals in the eye, back strains or other injuries will report to the Veterinary Medical Unit Supervisor who will then escort them to Employee Health for evaluation and/or treatment. If the injury requires emergency treatment, personnel will report directly to Employee Health.

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6. All situations requiring treatment at Employee Health Service will be reported to the Veterinary Medical Unit Supervisor on the day of evaluation and/or treatment or as soon as possible.

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:

1. This institution provides mandatory training in animal care and handling/methodology for all investigators and technicians with approved research protocols using laboratory animals. This training consists of lectures and hands on simulations. Investigators who have not received this training will not be allowed to order research animals. Investigative staff who have not received this training will not be allowed access to research animals. This training applies to all persons including visiting scientists and students who will be active with the protocol using the research animals. All technical and research staff working in the CAVHS VMU must also take a Web-Based training course and pass an examination. The Web-Based course has been modified for CAVHS VMU personnel from one developed by the Medical Research Service in the VA Office of Research and Development. CAVHS belongs to the Collaborative Institutional Training Initiative (CITI). The CITI Laboratory Animal Welfare Courses are required by the VMU for animal training. The site for this training is found at: http://www.citiprogram.org. Personnel must complete a course for each species of animal they will use. If the research protocol contains surgery, the course "Post-Procedural Care of Rodents" must also be completed. Personnel must score at least 80% on either of the web site exams before they are permitted to order or use experimental animals. Personnel who have not successfully completed all phases of this training are not allowed access to the research animal.

2. Lectures are provided to animal care personnel and research technicians for initial orientation to the Veterinary Medical Unit. Covered in these lectures are the policies and procedures of the VMU, security procedures, and correct usage of the animal ward logbook and cage cards, the AVMA Panel on Euthanasia report, and the Animal Component of Research Protocol (ACORP). Specialized training films are available for surgery techniques and experimental procedures.

3. The Animal Component of Research Protocol (ACORP) requires that all investigators requesting experimental animal use must perform a Power Analysis in order to minimize the number of animals required to obtain valid results. In addition, an extensive literature search is required to demonstrate that investigators must consider less painful or less stressful alternatives to procedures and provide assurance that the proposed research does not unnecessarily duplicate previous work. Moreover, it is the responsibility of the investigator to ensure that the proposed animal procedures could not be replaced by computer models or in vitro techniques. Training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress is provided to all personnel working with animals through the required CITI training "Working With the IACUC" and provided to all IACUC members in the CITI training "Essentials for IACUC Members." Additional training or consultation is available to all scientists, animal technicians, IACUC members and other personnel involved in animal care through the Research Administration Biostatistician by appointment. Training status for the required CITI training as well as minimization of animal number and pain and distress are confirmed during the IACUC's review of the ACORP.

4. All IACUC Members must take the CITI course titled "Essentials for IACUC Members." New members are provided background materials including the IACUC and VMU SOPs, VHA Handbook 1200.07 "Use of Animals in Research.". A brief orientation is given to new members by the IACUC Coordinator. All serving members are provided with links to the PHS

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Policy, the Guide for the Care and Use of Laboratory Animals, the current Program Description, and a printed copy of the approved PHS Animal Welfare Assurance.

5. The institution does not use any species covered under the Animal Welfare Act.

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, (b)(6), MD.
   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. (b)(6).
   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.]

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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.

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VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: (b)(6), MD

Title: Medical Center Director

Name of Institution: Central Arkansas Veterans Healthcare System

Address: *(street, city, state, country, postal code)*

4300 W. 7th Street
Little Rock, AR 72205

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

E-mail: (b)(6)

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: 5/14/2020

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

(b)(6)
Senior Assurance Officer, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive Suite 2500 MSC 6910
Bethesda, MD 20892
bartletd@od.nih.gov
301-496-7163

Signature: (b)(6) Date: May 20, 2020

Assurance Number: D16-00315 (A3509-01)

Effective Date: May 13, 2020 Expiration Date: April 30, 2024

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VIII. Membership of the IACUC

Date: 05/13/2020	
Name of Institution: Central Arkansas Veterans Healthcare System	
Assurance Number: D16-00315 (A3509-01)	
IACUC Chairperson	
Name*: (b)(6)	
Title*: Director, Transgenic Core	Degree/Credentials*: MS
Address*: *(street, city, state, zip code)* 4300 W. 7th Street Little Rock, AR 72205	
E-mail*: (b)(6)	
Phone*: (b)(6)	Fax*: (b)(6)

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b)(6)	MS	Director, Transgenic Core	Scientist
(b)(6)	PhD	Associate Professor	Scientist
(b)(6)	DVM	Veterinarian	Veterinarian
(b)(6)	ALAT	VMU Supervisor	Scientist
(b)(6)	PhD	Assistant Professor	Scientist
(b)(6)	PhD	Professor	Scientist
(b)(6)	DHSc.	VMU Director	Scientist
(b)(6)	BFA	Museum Program Assistant	Nonscientist, Nonaffiliated
(b)(6)	MEd	Educator	Non-Affiliated Member

* 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.

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*** 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:	IACUC Coordinator		
Phone:	(b)(6)	E-mail:	(b)(6)
Contact #2			
Name:	(b)(6)		
Title:	Director, Veterinary Medical Unit		
Phone:	(b)(6)	E-mail:	(b)(6)

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X. Facility and Species Inventory

Date: 05/13/2020			
Name of Institution: Central Arkansas Veterans Healthcare System			
Assurance Number: D16-00315 (A3509-01)			
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
John L. McClellan Hospital, Veterinary Medical Unit, Little Rock, AR	11,975 sq ft	Rats, mice	Rats-2 Mice-2563

*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.

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