

BOISE VA MEDICAL CENTER
A3256-01
ANIMAL WELFARE ASSURANCE

I, David Wood as named, Medical Center Director, as named Institutional Official for animal care and use at the Boise Veterans Affairs Medical Center (Boise VAMC), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or NSF. This Assurance covers only those facilities and components listed below.

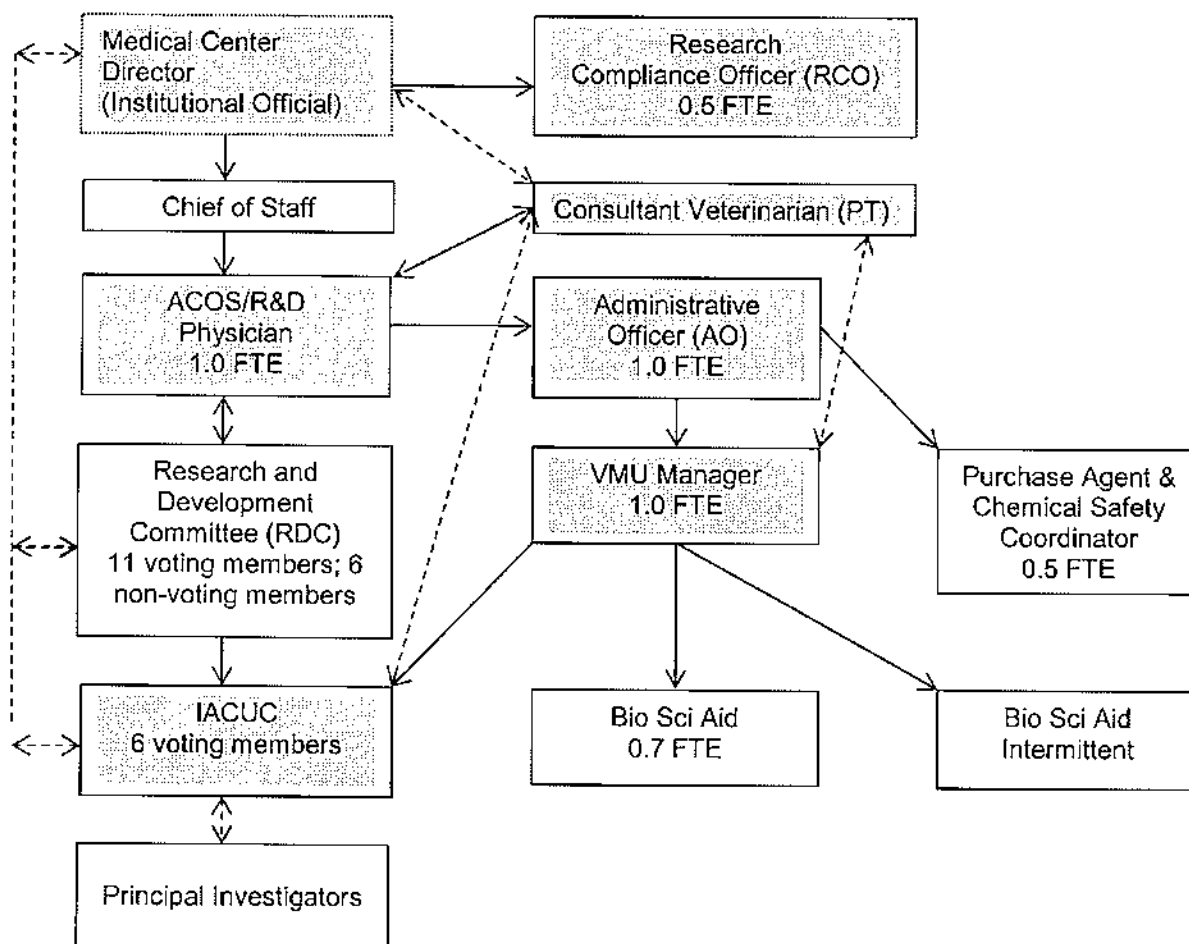
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All components of Boise VAMC that are physically located on the main campus in Bldg. 109, the Veterinary Medical Unit (VMU), at 500 West Fort Street, Boise, Idaho 83702. There are no off-campus satellite facilities and or other covered components.
- B. The following are other institution(s), or branches and components of another institution: None / Not applicable.

II. Institutional Commitment

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

III. Institutional Program for Animal Care and Use

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



Direct line of authority, administration and supervision →

Open communication, no direct supervision <----->

As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the consultant veterinarian and the IO.

Correspondence [e.g., meeting minutes, recommendations, reports, etc.] from the IACUC to the IO may be routed through administrative channels for informational purposes. However, such correspondence will not be changed, influenced, or delayed in any manner whatsoever.

Program compliance is conducted by the IACUC, the Research AO, VMU Manager and the RCO and supported by the IO and ACOS. The shaded boxes indicate those involved in compliance.

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

1. Name: (b)(6)

Qualifications:

- Degrees: D.V.M. from Colorado State University, College of Veterinary Medicine in 1974.
- Training and/or experience in laboratory animal medicine: Dr. (b)(6) is a (b)(6) who has 32 years of experience serving as Consultant Veterinarian to the Boise VAMC Animal Research Program. Dr. (b)(6) completed an intensive course conducted by the Department of Comparative Medicine, University of Washington. The course was in laboratory animal medicine and was conducted for outlying area veterinarians. In addition, he continues to attend continuing education opportunities offered by the American Association of Laboratory Science.

Authority: Dr. (b)(6) has delegated program authority and responsibility for the Institution's animal care and use program. He has unrestricted access to all of the animals.

Time Contributed to Program: At a minimum, one (1) hour per week with 100 percent of that time contributing to the animal care and use program. Dr. (b)(6) makes weekly visits to the VMU to provide consultation and inspection of the animals and the facility. He provides veterinary care as needed. He meets weekly with the VMU Manager, assists investigators in the development of animal research protocols, serves as a member of the Research Animal Studies Subcommittee, hereinafter referred to as the Institutional Animal Care and Use Committee (IACUC), and reviews all research applications for consideration of humane aspects of animal use. He also takes part in semiannual reviews, oversight reviews, and accreditations.

2. Provisions for Back-up Veterinary Care: Should Dr. (b)(6) be unavailable, emergency coverage will be provided by Drs. (b)(6)

3. Name: (b)(6)

Qualifications:

- Degrees: D.V.M. (Cornell University School of Veterinary Medicine 1980)
- Training and/or experience in laboratory animal medicine: Dr. (b)(6) has practiced veterinary medicine for 30 years. His training and experience in laboratory animal medicine is limited.

Authority: Dr. (b)(6) would not have authority or responsibility of the Institution's animal care and use program.

Time Contributed to Program: Dr. (b)(6) would be on call to back up Dr.

(b)(6)

in his absence for the evaluation and/or treatment of sick or distressed animals at the Boise VA Medical Center's Veterinary Medical Unit (VMU).

- C. The IACUC at this Institution is properly appointed in accordance with the PHS Policy and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The Medical Center Director, the highest operating official at Boise VAMC, appoints the members of the IACUC. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.a. Part VIII 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 six 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:

- The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
- The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
- To facilitate the evaluation, the Committee will use a standard VA checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- The evaluation will include, but not necessarily be limited to, a review of the following:
 - a. IACUC Membership and Functions;
 - b. IACUC Records and Reporting Requirements;
 - c. Husbandry and Veterinary Care (all aspects);
 - d. Personnel Qualifications (Experience and Training);
 - e. Occupational Health and Safety;
 - f. Emergency and Disaster Plans.
- In addition, the evaluation will include a review of the Institution's PHS Assurance.
- If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- No member will be involuntarily excluded from participating in any portion of the reviews.

2. Inspect at least once every six 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:

- At least once every six months at least two voting members of the IACUC and the consultant veterinarian will visit all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted.

Equipment used for transporting of the animals is also inspected.

- The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
- To facilitate the evaluation, the Committee will use a standard VA checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
- If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- No member will be involuntarily excluded for participating in any portion of the inspections.

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

- Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using a standard VA format that is based upon the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.
- The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
- The reports will identify specifically any departures from the provisions of the Guide and the PHS Policy that are not IACUC approved. These will be considered noncompliant and reported in the semiannual report and to OLAW. The IACUC will develop a reasonable plan and schedule for discontinuing the departure. The departures will be addressed by the IACUC in conjunction with the researcher to remove the departure and develop a scenario in which the departure no longer exists. The change would be presented to the IACUC for review. The change would be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6. If there are no departures, the reports will clearly state that there are no departures.
- The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
- If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.

- Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.

- Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.

- The process for tracking deficiencies to ensure that they are appropriately resolved is conducted by the Research Administrative Officer.

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

- Any individual may report concerns anonymously or by name to the IO, IACUC Chair, Consultant Veterinarian, Research Compliance Officer or the VA Inspector General or Office of Research Oversight hotline numbers. The VA Whistleblowers Act covers the individual reporting the concern. The individual and the person to whom the concern was reported must follow the procedures in the Act.

- Concerns regarding animal welfare or alleged violations of Federal, State, or local animal welfare regulations are reported verbally, in writing, or electronically.

- Notices posted on doors and bulletin boards within the Veterinary Medical Unit and listed in our VMU standard operating procedures advise individuals of how and where to report animal welfare concerns. The notices state that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. The research section of our website will be expanded to also include this information.

- All reported concerns will be brought to the attention of the full Committee.

- If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.

- Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.

- The Committee will report such actions in writing to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.

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:

- Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee.
- The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

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:

- For all animal research protocols, the IACUC must review and then either, approve, require modifications to secure approval, or withhold approval. This must be done for all research proposals involving USDA-regulated species and/or activities using and live vertebrate animals and when such research is supported by PHS or VA funds and/or conducted on VA premises. Evaluations of these Animal Component of Research Protocol (ACORP) forms are based on standards promulgated by the USDA as authorized by the AWA, the Guide, and the Interagency Research Animal Committee's "Principles for the Utilization and Care and of Vertebrate Animals Used in Testing, Research and Training."
- Animal research protocols, initial, continuing, and modifications are submitted to the Research Administration Office either hard copy or electronically using the most current ACORP version or appropriate form.
- Prior to the IACUC review, the consultant veterinarian and one member of the IACUC pre-review the ACORP. Any questions or changes required are discussed with the PI prior to submission of the corrected ACORP to the Research Administration Office.
- IACUC members are notified of protocols and modifications to review at least three days prior to the IACUC meeting. The proposals and modifications are sent to all IACUC members with the meeting agenda and other meeting materials.
- Meeting agenda, materials, and proposals are sent electronically to the IACUC members unless someone requests a hard copy. Hard copies are made by the Research Administration staff and mailed or delivered to the appropriate IACUC member.
- No member may participate in the IACUC review or approval of a protocol in

which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

- The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.
- The meetings are conducted in person with the ability for members to join via teleconference. The Chairman convenes each meeting. In the absence of the Chairman an Acting Chairman has been selected by the Chairman to convene the meeting.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-6-52 of March 24, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- Prior to the review, each IACUC member will be provided with written descriptions of activities that involve the care and use of animals. These are written in the ACORP. Any member of the IACUC may obtain, upon request, full-committee review (FCR) of those protocols.

Full-Committee Review (FCR)

- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- After review and discussion of the animal research protocol the Chairman asks if there are any questions. Questions are then discussed and resolved. The Chairman then asks for a motion. A voting IACUC member then motions to either approve as written, require modifications to secure approval, or withhold approval of the protocol, another voting IACUC member seconds the motion and the Chairman calls for a vote. The voting may be conducted verbally, by a show of hands, or if warranted by ballot.
- Outcomes of Full-Committee Reviews are approved, requires modifications to secure approval or withhold approval.
- Review of Required Modifications Subsequent to FCR: When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
 - a. FCR or Designated-Member Review (DMR) following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

OR

- b. DMR if approved unanimously by all members at the meeting at which the required modifications are developed delineated AND if the entire current Committee has previously approved and documented a policy of DMR for required modifications. However, if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.

Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

Designated-Member Review (DMR)

- Generally, the FCR method will be used. However, should a situation warrant it, the institution or IACUC may want to use the designated-member review (DMR) method. In such instances the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR.
- DMR is primarily used between scheduled IACUC meetings to assist the PI when a grant deadline falls between regularly scheduled meetings. All relative review materials are routed electronically to all IACUC members with an email calling for a DMR, attaching the appropriate forms submitted by the PI and explaining why the DMR is requested. Any IACUC member may request a full committee review of the research projects.
- Records of polling of members to obtain concurrence to use the DMR method and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.
- If full committee review is requested, approval of the research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- If a FCR is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications (to secure approval) or request full committee review of those protocols.
- Other IACUC members not conducting the DMR may provide the reviewer with comments or suggestions for the reviewer's consideration only. Agreement to allow the use of DMR, i.e., not call for FCR, may not be conditioned.
- If any DMR requires modifications, after all such modifications are made, a final revised protocol, i.e., an identical document with all of the DMRs required

modifications included, is submitted to all designated reviewers for review and approval.

- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
- The possible outcomes of DMR are either approval, modifications required to secure approval, or referral for FCR. Designated reviewers are not authorized to withhold approval. If the designated reviewers are unable to approve the protocol either as written or after specified modifications are made, the protocol must be referred to the full committee for review.
- Special or expedited reviews may be conducted for grant deadlines or if Just In Time (JIT) status of a research project is needed between scheduled IACUC meetings. The IACUC Chairman calls for a special session. The materials are sent electronically to all IACUC members. A quorum must be present to review the ACORP.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review by FCR or DMR of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
 - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator.
- 7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:**
- Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6 above.
 - Examples of changes considered to be significant include, but are not limited to changes:
 - a. in the objectives of a study
 - b. from non-survival to survival surgery
 - c. resulting in greater discomfort or in a greater degree of invasiveness
 - d. in the species or in approximate number of animals used
 - e. in Principal Investigator
 - f. in anesthetic agent(s) or the use or withholding of analgesics
 - g. in the method of euthanasia and
 - h. in the duration, frequency, or number of procedures performed on an animal.
- 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:**
- Principal Investigators are notified either by e-mail or letter from the IACUC Chair or his/her designee.
 - When the decision of the IACUC is to require modifications to secure approval, the required modifications are specified in the notification that is sent to the investigator.
 - When the IACUC decides to withhold approval of an activity, it sends a written notification to the investigator stating the reasons for its decision and gives the investigator the opportunity to respond in person or in writing.

- The Institutional Official is notified by receiving a copy of the IACUC meeting 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 three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

- **Post-approval Monitoring** – All ongoing activities and animal health status are monitored continuously by the animal care and use staff and the weekly visits by the consultant veterinarian. The consultant veterinarian also trains all animal research staff in all surgical procedures. Staff must be deemed proficient by the consultant veterinarian before they may begin in the project.

Annual protocol (post-approval) reviews are conducted by the IACUC members at the time of the project's annual review. The principal researcher completes an annual review form providing updates and outcomes from the year being reviewed. This information is recorded in the IACUC meeting minutes and the IACUC meeting minutes are reviewed and approved by the Committee and the Research and Development Committee.

Throughout the year, principal researchers wish to make modifications to their protocols. Prior to those reviews the researcher completes a modification request form. This is submitted for IACUC review. Post approval monitoring also occurs at this review. The modification review is conducted by the IACUC chair and the consultant veterinarian to see how the project is progressing.

Post approval monitoring is also conducted at the triennial review of animal protocols. IACUC members see past changes in the protocols and evaluate the changes with the project outcomes.

- **USDA Regulated Species** – The Boise VA Medical Center Animal Care and Use Program does not conduct research on USDA regulated species.
- Protocols are approved annually by the IACUC and a triennial review is done every three years. All reviews (initial, continuing review, modifications, and post approval monitoring are documented in writing in the IACUC minutes. IACUC members are informed of the reviews through an email sent with the IACUC agenda at least quarterly and all members are welcome to participate in the reviews
- If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.

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

as follows:

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the Institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.
- 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 an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the Institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation in writing to OLAW. Preliminary reports may be made verbally.

E. The occupational health and safety program at the Boise VAMC, is for personnel who work in the biomedical research laboratory and/or the Veterinary Medical Unit (VMU) and are involved with the use/and care of laboratory animal facilities or have frequent contact with animals. The program is as follows:

1. Administration/management

- Management of the occupational health and safety program is a joint responsibility of the Employee Health Office, represented by the Employee Health Nurse Practitioner and the Facility Safety Office which includes Safety Specialists and an Industrial Hygienist.
- The entity that assures all parties are doing their respective jobs is the Research Service Subcommittee on Research Safety (SRS). This group meets monthly. The Safety Office is a voting member of this subcommittee as are voting members of the IACUC and the VMU Manager. A member of the Research and Development Committee is also a voting member of the SRS. SRS monthly meeting agenda items include safety laboratory report: fire, environmental, violations, spills, and operations. A separate agenda item is injuries and health surveillance and safety inspections and facility drills.

2. Scope

- An annual collection of health history that meets federal, state and local HIPAA regulations is part of the risk assessment conducted for all research employees, regardless of their appointment (VA employee, Without Compensation-WOC, student interns, etc.). All research employees (administrative staff, biomedical staff, researchers and technicians, animal researchers and animal technicians including those with significant contact with animals and employees working in the animal

facility) are required to and complete a health history survey each year. The completed surveys are then sent to Employee Health. The Employee Health nurse reviews all surveys and takes care of any medical surveillance monitoring, other medical questionnaires and blood work for all. She also assures appropriate vaccinations. The Facility Safety Office is responsible for the environmental aspects (environment of care) of the program such as use of personal protective equipment, chemical and biological hazards use and disposal, respiratory protection, physical hazards, and safety and emergency management.

- The program covers all personnel (administrative staff, biomedical staff, researchers and technicians, animal researchers and animal technicians including those with significant contact with animals and employees working in the animal facility) involved in biomedical research and laboratory animal care and/or use at Boise VAMC. All research employees must complete the health history survey. This survey says that the understand they have been offered the opportunity to participate in the Employee Occupational Safety and Health Program at the Boise VAMC. Individuals who wish to decline participation must do so in writing. Even though all employees are required to complete a health history survey each year, about 50% of research employees decline further participation. VA cannot force employees to fully participate.

Individuals opting out of the occupational health and safety program will still receive care from Employee Health or an Emergency Department physician or Physician Assistant in the event of a health or safety incident.

- New employees are enrolled by the Research Safety Coordinator during new employee orientation to the biomedical lab and the VMU.

3. Health Histories and Evaluations

- All new VA employees involved in animal care and/or use receive a TB test as part of new employee orientation. During research orientation the new employee completes a medical questionnaire regarding their medical history, health history, allergens, and use and/or exposure to hazardous chemicals, drugs, radiation, and use and frequency of animal involvement. Employees declining/refusing to complete the questionnaire must do so in writing.
- Annually, all personnel involved in animal care and/or use are required to complete the medical questionnaire and are offered a blood test screening.
- Medical questionnaires and blood tests are evaluated by Employee Health Nurse Practitioner and a hospital physician if necessary. These medical surveillance health records are maintained in the Employee Health Services office.

4. Hazard Identification and Risk Assessment

- The program is based on hazard identification, risk assessment, and developing and implementing measures to minimize identified hazards and risks.

- Hazards are assessed by conducting annual walk-through and observation of the labs and the VMU to identify sources of hazards to research staff using the VMU, the likelihood of these hazards to occur, and the severity at which it could cause illness or injury. Hazards are assessed and categorized into the following groups: radiological, biological, chemical and physical hazards. The annual walk-throughs and observations are conducted by the hospital Environment of Care teams.
- Risk is assessed using the information from the hazard assessment and the associated health effects, threats, vulnerabilities, severity, and the probability of the hazards occurring. This is also done by the hospital Environment of Care teams.
- Hazard assessment and risk assessment are conducted annually in the VMU by the Environment of Care teams. These teams consist of various people from different hospital services or departments throughout the hospital each looking for hazards based on the hazards they might identify with their respective hospital department. Results are noted immediately to the VMU Manager and the Research Administrative Officer and placed on an electronic deficiency list sent to the Research Administrative Officer to assure each deficiency is addressed within two weeks of the assessments or a plan is developed to address them.
- On a semi-annual basis the IACUC conducts mandatory semi-annual reviews of the VMU noting any deficiencies and identifying plans to address the deficiencies. On an annual basis, the Regional Safety Officer conducts a review of the VMU during the Annual Workplace Evaluation. Written reports are sent to the Research Administrative Officer through the Facility Safety Office and deficiencies are addressed immediately or a plan is developed on how the deficiency will be addressed and when.

5. Procedures in Place to Alleviate Hazards and Minimize Risks

- Engineering methods and controls are used to
 - design the facility
 - select and use of equipment
 - develop or use process to eliminate the hazard
 - use an alternative that is not hazardous
 - contain the hazard with barriers
 - ventilation
 - regular care and following equipment and manufacturer instructions
 - annual service maintenance contracts for equipment that include quarterly inspections
 - annual inspections and certifications for equipment
- Institutional Policies and Subcommittees
 - Public Health Service Assurance
 - VHA Handbooks regarding Safety of Personnel Engaged in Research and Use of Animals in Research
 - Medical Center Memorandums, Service policies from the Safety Office

- and Research
 - VMU Standard Operating Procedures Manual
 - Research Chemical Hygiene Plan
 - Research Laboratory Safety Manual
 - The Guide for the Care and Use of Laboratory Animals, 8th edition
 - Annual Environment of Care inspections of the VMU and mandatory signage and labels are also methods to alleviate and minimize hazards
 - Review of animal and safety protocols by the Subcommittee on Research Safety (SRS) and the IACUC
- Plans, Procedures, Programs
 - VMU Standard Operating Procedure Manual
 - Chemical Hygiene Plan
 - Research Laboratory Safety Manual
 - All provide general and specific safety practice and precaution procedures on the hazardous storage, preparation, spills, decontamination, waste disposal, special procedures for using gases, hoods and other equipment
 - Signs, labels
 - Employee Health surveillance program
 - Protective clothing and equipment appropriate to the agents being used
 - Instructions on handling the animals, caging, and animal waste involving the use of hazardous agents are posted outside the animal room where they are readily visible for the duration of the experiment.
 - All research personnel receive Safety Data Sheet (SDS) training.
 - Pertinent SDS are maintained on the VISN 20 website.
- Training
 - Mandatory training for all new employees (fire, safety, radiation safety-when appropriate, infection control, etc.)
 - New employees receive instruction from the VMU Manager in animal handling, personal protective equipment, facility equipment operation, and procedures.
 - All personnel involved in using animals must complete Collaborative Institutional Training Initiative web-based training "Working with the VA Institutional Animal Care and Use Committee (IACUC)" and all modules relating to the species and the procedures included in their protocol before starting their study.
 - The consultant veterinarian also provides training and education regarding animal models, anesthesia, analgesia, and proper use of animals in research settings. He assesses the competency of personnel to perform the procedures as stated on the animal protocols.
- Use of Personal Protective Equipment (PPE)
 - Gloves, masks, shields, eyewear, goggles, ear protection, shoe covers, steel-toe boots, rubber boots, clothing (scrubs, lab coats, etc.), and fittings for respirators when needed.
 - PPE used to prevent potential needle sticks and contact with hazardous

- agents and waste.
- Gloves, mask, laboratory coat or scrubs will be worn when handling animals, cages, and related equipment.
- Animal holders, chain-mail gloves, etc. when handling animals to minimize animal bites or scratches.
- Using PPE requires hazard awareness and training. The PPE does not eliminate the hazard but reduces contact with the hazards including animal allergens.
- Personal Hygiene
 - Hands should be washed before leaving the facility, for breaks, and at the start and end of the work shift.
 - Employees should change gloves and wash hands with soap and water before handling animals or equipment in separate rooms of the facility.
 - Smoking, eating, drinking, and applying cosmetics are prohibited in the animal facility.
 - Scrub suits and laboratory coats are not to be worn into the common areas outside of the VMU such as the cafeteria or hospital areas.

6. Immunizations

- Vaccination against tetanus is provided by the Employee Health Service. Individuals who decline vaccination must do so in writing.
- Employee Health Service is able to provide any necessary immunizations. The medical center provides all employees with Flu shots if they desire. Immunizations are provided based on the research study content and the risk identified with those study agents.

7. Precautions taken during pregnancy, illness or decreased immunocompetence

- Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals.
- If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/or health care professional, human resources, etc. This is documented in the employee's health record maintained by Employee Health Service.

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used

- The housekeeping staff is not routinely allowed access to the VMU animal rooms. In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate Personal Protective Equipment (PPE)

and are then permitted in for a limited amount of time, being escorted by a member of the animal care staff. VA Police Service has PIV (Personal Identification Verification) badges and may scan in and out of the VMU. VA Police do not enter animal rooms unless accompanied by a member of the animal care staff or an animal researcher.

- If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.

9. Availability and procedures for treatment of bites, scratches, illness or injury

- All research and animal care staff have access to Employee Health Service in the event of an animal related injury, scratch, or bite. If the injury or bite is not life threatening, the employee reports the injury to their Manager who enters the information into an electronic safety surveillance system called ASISTS (Automated Safety Incident Surveillance and Tracking System). The Manager calls Employee Health Service, reports the injury and then escorts or sends the staffer to Employee Health to be treated and completes the necessary incident reports.
- Treatment is free and records are maintained by the Employee Health Service.
- Treatment is also available at the facility's Emergency Room if the injury occurs outside of normal business hours.

10. Procedures/program for reporting and tracking injuries and illnesses

- Occupational injuries are monitored by the Safety /Industrial Hygiene Office (through the Human Resources Department). Research Service's Subcommittee on Research Safety also monitors work-related injury and illness. An update of work-related injuries is provided at each monthly meeting.
- Reporting of all work-related illness and/or injury is mandatory within 24 hours of incident. This reporting requirement is covered during initial employee training and notices are posted throughout the facility.
- When a work-related injury occurs the Manager and the employee completes the electronic injury incident report which contains information about the employee, what they were doing, what the injury was, location on the body, date and time of occurrence, and treatment received.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals, by species, in each facility is provided in Part X., the 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:

1. IACUC Members

- Each IACUC member will be provided with a copy of the following:
 - a. The Institution's current/approved PHS/OLAW Animal Welfare Assurance
 - b. The PHS Policy for the Humane Care and Use of Laboratory Animals
 - c. The Guide for the Care and Use of Laboratory Animals
 - d. Boise VAMC animal care and use Medical Center Memoranda and Research Service animal research policies
- New IACUC members are oriented by the IACUC Chair and the Research Service Administrative Officer (AO). In a face-to-face meeting the IACUC Chair and AO review the PHS Policy, the Guide, and the Boise VAMC memoranda and policies with the new member. The new member is then given the copies of these items for their reference during their term on the IACUC.
- Annually, IACUC members review, update, and approve Boise VAMC Research Service memoranda, policies, and SOPs which all incorporate pieces of the Assurance in these documents. When the Boise VAMC's Assurance is due for renewal they also review and approve the document prior to submission.
- All members of the IACUC will complete the "Essentials for IACUC Members" curriculum located at the Collaborative Institutional Training Initiative (CITI) at the University of Miami <https://www.citiprogram.org/>. This training will be conducted every three years.

2. Animal Caretakers

- All animal care and use employees are made aware of the Assurance when they come on station to start a new animal research project. Anyone entering the VMU receives training from the VMU Manager or experienced animal care staff. This training contains review of the Assurance and its contents.
- Animal caretakers receive specific on the job training during orientation and ongoing training conducted by the VMU Manager as needed. Items covered include Boise VAMC animal research memoranda and policies, VHA handbooks, animal welfare laws, OLAW website and information, the Assurance, and training on the specific animal research studies and the testing methods that will be used to minimize the numbers of animals required to obtain valid results and limit animal pain or distress.
- Animal caretakers are required to take annual pertinent web-based training courses in the CITI training program, like training courses for protocols and specific animal species. Completion of CITI training is documented and maintained by the VMU Manager.
- Electronic records of the web-based training are also maintained by the Research Administration Office.

3. Investigators and Research Technicians

- Principal Investigators (PIs), research technicians, and the consultant veterinarian working with animals are made aware of the Assurance when they come on station to start a new animal research project. Anyone entering the animal facility receives training from the VMU Manager or experienced animal care staff on the humane and ethical use of animals in research. This training contains review of the Assurance and its contents. This initial animal facility training covers the laws and regulations for laboratory animal care and use with an emphasis on the contents of the Guide and the 3R's, Replacement, Reduction, and Refinement. PIs, research technicians and the consultant veterinarian also review the project protocol with the PI. At this time, training is conducted on research and testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).
- All personnel performing procedures using animals must be identified in the ACORP. The ACORP contains a description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures. ACORPs must be reviewed and approved by the IACUC prior to the study commencing.
- Any person needing additional protocol-specific training will be identified during the ACORP review process and such required training will be a condition of approval of the protocol.
- As part of animal care and use training, all individuals who handle animals must also take the web-based CITI training course, "Working with the VA IACUC" every three years. This module is a component of the VA training program and other trainings applicable to their specific research. Research staff working with animals must also take CITI modules for each species of animal they work with. Animal methodology, husbandry and veterinary medical books are available in the VMU for use and reference. The VMU Manager also distributes handouts and information pertaining to various web sites as new reference items becomes available.
- On-line training may be used and accepted in lieu in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.
- Training in experimental methods, i.e., specific animal manipulations and techniques, will be conducted based on the types of research being conducted at the institution.
- For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the

Institution's training is solely at the IACUC's discretion.

- If appropriate resources for training are unavailable on station, the IACUC may contact the University of Washington Department of Comparative Medicine and request training and/or technical assistance for the needed areas.
- Investigators requiring specialized training techniques for an approved ACORP are required to complete appropriate training. The Guide for the use of laboratory animals is also provided to the investigative staff which provides additional information on the policies, regulations and standards relating to the care and use of animals as well as information on anesthetics and analgesics.
- Procedures that cause pain and distress are reviewed closely by the Consultant Veterinarian for alternatives and methods of relief. The ACORP requires documentation that a literature search has been performed for alternatives to painful and stressful procedures, alternatives to animals and to avoid unnecessary duplication of research.
- If procedure competencies have not been assessed, the Boise VAMC Consultant Veterinarian will assess them prior to study initiation.

IV. Institutional Program Evaluation and Accreditation

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six 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 semi-annual 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. Semi-annual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semi-annual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.
- B. 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 semi-annual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. According to VHA Records Control Schedule (RCS – 10-1) this Institution will maintain all research records and documents according to Chapter 8, Office of Research and Development. The types of records being kept include the following:

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 semi-annual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Mr. David Wood, Director, Boise VAMC
 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 according to RCS 10-1, Chapter 8, Office of Research and Development.
- 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 semi-annual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Mr. David Wood, Director, Boise VAMC
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy

2. Any serious deviations from the provisions of the Guide
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORCEMENT AND PHS APPROVAL

A. Authorized Institutional Official	
Name: David Wood, MHA, FACHE	
Title: Medical Center Director	
Name of Institution: VA Medical Center	
Address: (street, city, state, country, postal code) 500 W. Fort Street Boise, ID 83702	
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: 7-23-18

B. PHS Approving Official (to be completed by OLAW)	
Name/Title: Neera Gopee, D.V.M., Ph.D., DACLAM, DABT Veterinary Medical Officer Office of Laboratory Animal Welfare (OLAW) 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (b)(6)	
Signature: (b)(6)	Date: 07-25-2018
Assurance Number: 016-00163 (A3256-01)	
Effective Date: 07-25-2018	Expiration Date: 07-31-2022

VIII. MEMBERSHIP OF THE IACUC

Date: May 2018			
Name of Institution: Boise VA Medical Center			
Assurance Number: A3256-01			
IACUC Chairperson			
Name*: (b)(6)			
Title*: Research Microbiologist		Degree/Credentials*: PhD	
Address*: (street, city, state, zip code) 500 W. Fort Street Boise, ID 83702			
E-mail*: (b)(6)		@va.gov	
Phone*: (b)(6)		Fax* (b)(6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b)(6)	DVM	Consultant Veterinarian	Veterinarian
(b)(6)	BA	Senior Research Technician	Scientist
(b)(6)	BA	Account Executive	Non-affiliated Member
(b)(6)	RD, LD	Nutrition Service Chief	Nonscientist
(b)(6)	MS	Speech Language Pathologist	Alternate Non-affiliated Member
(b)(6)	BS	VMU Manager, VA Research Service	VA Animal Facility Manager Non-scientist
(b)(6)	MS	Executive Director, Idaho State Department of Agriculture	Scientist
(b)(6)	MHE	Administrative Officer, VA Research Service	Ex Officio, Non-voting

* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	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: Research Administrative Officer	
Phone:	(b)(6)
E-mail:	(b)(6)@va.gov
Contact #2	
Name:	(b)(6)
Title: VMU Manager	
Phone:	(b)(6)
E-mail:	(b)(6)@va.gov

X. FACILITY AND SPECIES INVENTORY

Date: March 25, 2018			
Name of Institution: Boise VA Medical Center			
Assurance Number: A3256-01			
Laboratory, Unit, or Building*	Gross Square Feet <i>(include service areas)</i>	Species Housed <i>[use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]</i>	Approximate Average Daily Inventory
Building 109	6,706	Mice	1 mouse

*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.

Unless otherwise indicated, mice and rats means mice of the genus *mus* and rats of the genus *rattus* that are purposely bred for research.