# Harry S. Truman Memorial Veteran's Hospital (Truman VA)

# A3157-01

## **Animal Welfare Assurance for Domestic Institutions**

I, Mr. David Isaacks, as named Director/Institutional Official for animal care and use at Harry S. Truman Memorial Veterans Hospital (Truman VA), 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, Harry S Truman Memorial Veterans Hospital (Truman VA), has legal authority, included are those that operate under a different name:

Veterinary Medical Unit (VMU)

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

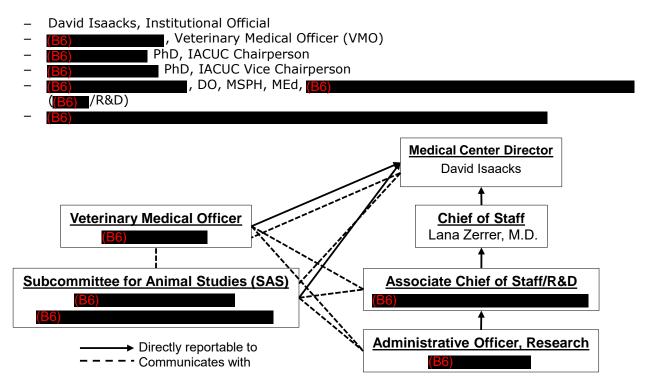
None

### II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the <u>Animal Welfare Act</u>, the *Guide*, *Eighth edition, VHA Handbook 1058.01* "*Research Compliance Reporting Requirements," AVMA Guidelines for Euthanasia*, and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "<u>U.S. Government Principles for the Utilization and Care of</u> <u>Vertebrate Animals Used in Testing, Research, and Training</u>," the *Guide, Eighth edition, VHA Handbook 1058.01* "*Research Compliance Reporting Requirements," AVMA Guidelines for Euthanasia.*
- 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*, *Eighth edition*).
- 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 and are annotated in Section VI:



- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:
  - 1) Name: (B6)

Qualifications

- Degrees: DVM, MS
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Diplomat of American College of Laboratory Animal Medicine Over Byears' experience with laboratory animal medicine

Authority: **(B6)** has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals. Veterinarians who participate in the Institution's animal care and use program have the authority to enter at any time, any supplies, and procedures involved in animal care and use. They also are authorized to establish minimal acceptable standards for procedures in laboratory animal husbandry, animal environment, preventive veterinary medicine, animal health monitoring, anesthesia and analgesia, surgery, postoperative care, and euthanasia consistent with the standards of the *Guide, Eighth edition*. **(E6)**, the Veterinarian/Veterinary Medical Officer (VMO) for the Truman VA, reports directly to the Institutional Official any concerns regarding animal welfare/health, animal research procedural concerns or surgeries, and program/facility deficiencies per the *Guide, Eighth edition and the Animal Welfare Act*.

Time contributed to program: 10%

- 2) Name: (B6) is backed-up by veterinarians employed by the Office of Animal Resources (OAR) at the University of Missouri. They are on-call whenever (B6) and is unavailable.
- 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.
- D. Please refer to Question VIII Membership of the IACUC. 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, Eighth edition,* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC/Subcommittee for Animal Safety (SAS) conducts semi-annual inspections following the regularly scheduled IACUC/SAS meeting in April and October. All members present at the meeting participate in the program/facility review.

The IACUC Chair appoints two groups; one group to conduct the program review and the other group to conduct the facility inspection. Members may specify which group they prefer to participate in. Typically, members rotate between the two groups after each review cycle. Members will review program policies and procedures, animal protocols, and amendments. Members use the VA Semi-Annual Program Review Checklist, Animal Welfare Act, and the *Guide, Eighth edition,* is used as a tool to facilitate the program review. Additionally, members review 10% of current protocols.

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:

The IACUC/SAS members inspecting the Veterinary Medical Unit (VMU) also inspect all laboratories animal procedures are performed. The VA Semi-Annual Facility Inspection Checklist, PHS Policy, Animal Welfare Act, and the *Guide, Eighth edition,* are used as tools to facilitate the inspection. All animal rooms and support rooms in the VMU are inspected. The IACUC/SAS conducts semi-annual inspections following the regularly scheduled IACUC/SAS meeting in April and October. All members present at the meeting participate in the facility inspection. The IACUC/SAS Chair appoints a group to conduct a thorough inspection of the facility inspection using the VA Semi-Annual Facility Inspection Checklist, Animal Welfare Act, policies and procedures, and the *Guide, Eight edition*. Typically, members rotate between the two groups each review cycle. The group will inspect the animal facility. Members use the VA Semi-Annual Program Review Checklist as a tool.

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 final Semi-Annual Inspections are prepared reports of the IACUC/SAS evaluations as set forth in the PHS Policy at IV.B.3 that are presented to the Institutional Official by the Veterinarian/VMO and the IACUC. The IACUC/SAS members report their findings to the Coordinator of the facility inspection and the program review. The Coordinator prepares a report, using the Semi-Annual Inspection application, for the Veterinarian/VMO, Chair and IACUC/SAS members' review and concurrence. The report will contain descriptions of, the nature and extent of adherence to the *Guide*, *Eighth edition*, PHS Policy and the Animal Welfare Act, and specifically identifies any departures from the provisions of the *Guide*, *Eighth edition*, PHS Policy and Animal Welfare Act. The report also indicates the reasons for each departure. The report distinguishes significant deficiencies from minor deficiencies. A reasonable and specific correction plan for each deficiency is included in the report.

Once members provide concurrence with the report findings and the report has been signed by a majority of IACUC/SAS members, with any minority opinions duly noted, the semiannual inspection will be presented to the Institutional Official by the Veterinarian/VMO, the IACUC/SAS Chair and IACUC membership. The ACOS/R&D and the AO/R&D are also invited to attend. Minority opinions, if applicable during the inspection process, will be fully documented within the application. If there are no minority opinions noted, the application will fully note none were presented.

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

IACUC/SAS procedures include posting fliers for reporting complaints or concerns regarding animal welfare on bulletin boards in all areas where animal research activities are conducted. The signage states that there will be no reprisal for reporting animal welfare concerns. General information about reporting of animal welfare concerns is also provided during the mandatory animal care and use training courses. All PIs and staff noted in animal protocols are required to complete the mandatory CITI training. Any individual may report a concern regarding the animal care program to any IACUC/SAS member, the Attending Veterinarian/VMO, the Research Office, or to the Inspector General. Concerns may be submitted verbally or in writing and may be submitted anonymously. The IACUC/SAS is obligated to review all concerns in five business days. Confidentiality will be maintained dependent upon the reported concern. The IACUC/SAS Chair and the VMO will review the complaint immediately to assess whether or not an immediate animal welfare situation exists. The Attending Veterinarian/VMO has the authority to institute any immediate clinical actions necessary to prevent animal pain and distress. The IACUC/SAS Chair can appoint a subcommittee of members to investigate the complaint and to report findings to the IACUC/SAS as a whole. The IACUC/SAS will then determine what actions are required and will notify the PI of the protocol in question. After the investigations are completed, the IACUC/SAS will take actions to maintain animal welfare that are in accord with all federal regulations. The Director/Institutional Official, in consultation with the IACUC/SAS, will review the rationale for those actions, implement necessary corrective measures, and communicate reportable actions with a full explanation, to OLAW, USDA-APHIS, AAALAC, Veterans Administration Central Office, Office of Research Oversight, and any agencies funding those animal activities.

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/SAS Chair will forward recommendations made by the IACUC/SAS to the Institutional Official. The ACOS/R&D, RCO, and the RDC Chairperson will also be notified.

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:

All new projects and triennial renewals receive a Full Committee Review (FCR) by a convened quorum of IACUC/SAS. Approval or all new projects and triennial renewals requires a majority vote of a fully convened IACUC/SAS. The IACUC/SAS review process is as follows:

- 1. The PI submits a new or triennial renewal animal protocol to the Coordinator who conducts a preliminary non-scientific review to ensure completeness. The animal protocol is then assigned an IACUC/SAS specific-number. The animal protocol is sent to the Veterinarian/VMO for review, which is documented on the animal protocol.
- Once the Veterinarian/VMO has reviewed the animal protocol, and if there are corrections, it is returned to the Coordinator who then documents the receipt date and sends the animal protocol to the PI for corrections.

- 3. Once the PI returns the corrected animal protocol, the Chair assigns a secondary reviewer of the animal protocol (PHS Policy IV.C.2). In instances where the Chair has a conflict, the Vice Chair will serve as the chair. The VMO and secondary reviewer results are presented at the next scheduled IACUC/SAS meeting. IACUC/SAS members that do not have a conflict of interest will review the new project/triennial renewed animal protocol and will make recommendations during the meeting. All voting members will vote unless a real or perceived conflict of interest exists. And the person(s) will recuse themselves from the meeting while the vote takes place.
- 4. The potential determinations/recommendation of FCR are:

a. <u>Approval</u> – IACUC/SAS approves the ACORP as submitted without further recommendations, changes or edits.

b. <u>Required Modifications to Secure Approval</u> – IACUC/SAS requires corrections or modifications before approval can be granted. The IACUC/SAS may request that the modified animal protocol undergo by either FCR and to require to the fully convened meeting or by designated member review (DMR) assigned by the Chairperson (or Vice Chairperson in the event the Chair has a conflict).

c. <u>Tabled</u> – IACUC/SAS does not believe that there is sufficient information to formulate a recommendation, a Tabled recommendation will be re-reviewed at a fully convened meeting. Investigators are notified of all IACUC/SAS determinations.

d. <u>Withhold Approval</u> – IACUC/SAS does not believe that the ACORP, in its current form, should be conducted at the Truman VA. The investigator may appeal the IACUC/SAS decision.

- 5. The IACUC/SAS determinations/recommendations will then be provided in writing to the PI and the ACOS/R&D.
- 6. In the event the IACUC/SAS determination/recommendation is "Required modifications to secure approval" and to use DMR, the process is as follows:
  - a. Prior to DMR, the amended new project or triennial renewal will be sent to IACUC/SAS members with the following information to be reviewed: (1) The PI name, (2) Animal protocol title, (3) Unique identifiers; and, (4) amended protocol.
  - b. If FCR is not requested after a three-day full committee review period, DMR will be conducted. The IACUC Chair then assigns the two reviewers (PHS Policy IV.C.2).
    - i. In the event there is more than one DMR, all DMR will review identical copies of the protocol and reviewers will be unanimous in their decision.
    - ii. In the event that DMR do not agree, the animal protocol is taken to the next fully convened IACUC/SAS meeting.
    - iii. In the event, a DMR makes a recommendation for revision, both DMR must agree on the requested changes.
  - *c.* Once the DMR is conducted, an e-signature will be used indicating approval, and the approved business item will be emailed to the investigator. The DMR decision will then be relayed as and FYI item at the next fully convened IACUC/SAS meeting. Any IACUC/SAS member may obtain, upon request, FCR at any point during protocol review. Following protocol approval, it is always possible for the IACUC/SAS to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns.
- 7. In the event the IACUC/SAS determination/recommendation is to approve the new projects and triennial renewals, the approval will then be communicated to the Research and Development Committee (RDC), the ACOS/R&D, the University of Missouri Animal Care and Quality Assurance (MU ACUC) with the approved animal protocol and the PI in writing.
- 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:

For all <u>amendments</u> to existing animal protocols, the PI must submit an amendment requesting changes to the IACUC/SAS. The process for submission to approval is as follows:

- a. The PI submits the amendment to the Coordinator who conducts a preliminary nonscientific review to ensure completeness. The amendment is then assigned an IACUC/SAS specific-number.
- b. The amendment is then sent to full committee review (FCR) and specifically to IACUC/SAS members whom do not have a conflict of interest to determine if there are significant or minor changes. If there are significant changes in the amendment, the request will undergo Full Committee Review (FCR). If there are minor changes, the amendment will be sent by the Chair for DMR. For both process if a IACUC/SAS member wishes to discuss an amendment at any point, the amendment will be taken to the next fully convened IACUC/SAS meeting.
- c. If there are significant changes, the process for FCR will be followed and reviewed at the next scheduled IACUC/SAS meeting as described above in III.D.6 for all amendments.
- d. If there are minor changes, the process as described above in III.D.6 for DMR will be followed for all amendments.
- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC/SAS Chair notifies the PI of all subcommittee decisions to either approve, withhold approval of animal protocols, or request modifications to secure approval. PIs may respond either in writing or by requesting to attend the next scheduled IACUC/SAS meeting to answer any questions IACUC/SAS members may have. All actions of the IACUC/SAS are recorded in the meeting minutes. The minutes are distributed to all IACUC/SAS members and reviewed/approved by the RDC. The Institutional Official is a member of the RDC and receives minutes of all IACUC/SAS meetings for review.

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

All PIs are required to submit an annual update of their animal protocol to the IACUC/SAS for review. The Coordinator uses the animal protocol tracking system to provide notification to the PI of the need for an annual update. The Request for Continued Approval of Animal Use will be completed and submitted by the PI the month prior to the deadline for renewal. The Coordinator then builds a review packet; i.e., annual renewal, census information, ACORP, amendments, etc., and sends to two reviewers suggested by the SAS Chair for DMR. Annual review and triennial renewal (de novo renewal) is required for all protocols as well as for USDA covered species and is conducted by FCR or DMR as described in III.D.6. Tools reviewers use are the *Guide, Eighth edition*, Animal Welfare Act, VHA Handbooks, etc., to ensure full compliance with federal regulations. Reviewers provide written comments to the IACUC/SAS and can approve, require modifications to secure continued approval, or request full subcommittee review. If needed, the PI then receives the request to submit an amendment from the Coordinator, and the amendment will go forward through the DMR process. Amendments as well as the annual renewal are documented on the IACUC/SAS meeting agenda and minutes.

During the semi-annual inspections, Post-Approval Monitoring (PAM) is conducted by the facility reviewers. The staff working in laboratories conducting animal research will be asked by reviewers what they are currently doing, what the process is for a specific procedure/surgery, etc., and explain in detail the process. Once the staff member has answered all reviewer questions, reviewers will ask the staff member where the animal protocol is located that they can use and study. If the staff member does not have know where the animal protocol is located or does not explain the procedure/surgery adequately to reviewers, the investigator will be contacted and informed that the staff member requires

more training either by him/herself or hands-on training via an animal handling workshop. The investigator will be required to document that the requested training has been completed and the Veterinarian/VMO and the IACUC/SAS Chair will conduct a second PAM session to ensure the staff member has received adequate training.

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:

Upon notification that an activity involving animals is not being conducted in accordance with applicable standards, the IACUC/SAS will investigate the matter and consider it in a fully convened meeting. If the majority of a quorum of IACUC/SAS members present votes for suspension, the Veterinarian/VMO and the IACUC/SAS Chair will notify the Institutional Official in writing by the most expeditious means available that the activity has been suspended and why the suspension occurred. The Institutional Official in consultation with the Veterinarian/VMO and the IACUC/SAS will review the reason for the suspension, take appropriate corrective action, and report that action with a full explanation to the ACOS/R&D, Research Compliance Officer (RCO), RDC and OLAW. Also notified will be USDA-APHIS, Veterans Administration Central Office, ORO, and any agencies providing funding to conduct those animal activities.

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

All personnel, investigators, staff, housekeeping, maintenance, contractors, and administration, are required to follow accepted safety practices as outlined in the Research Service "Chemical Hygiene and Laboratory Safety Manual" that is provided to each PI and applicable department within the Truman VA. Each PI has a hard copy located in their laboratory and an electronically copy for their files. The Research Service also provides a link to the Safety Manual on the Research Service website and staff are trained at time of hire and then annually. All research workers are required to participate in a Research Safety orientation program prior to beginning work that covers personal hygiene, personal protective equipment (PPE), hazard identification, risk assessment, chemical safety, biosafety, handling of wastes and risk of exposure to animal allergens and zoonoses. Precautions for work while pregnant, ill, or if immunocompromised are also discussed. Occupational health and safety precautions are included in the required webbased training courses as well. Annual research safety updates, including a web-based examination in the Truman VA's Talent Management System (TMS), are required annually to maintain employment. Specialized training, such as working with radioactive materials, is also given as required and updated annually. Truman VA policies and procedures are in place that address matters related to personal hygiene in accordance with the Guide, Eighth edition.

Per the Policies and Procedures for the Veterinary Medical Unit (P&P VMU) all staff are required to wear appropriate PPE for the working conditions when entering a laboratory or the VMU including, but not limited to; full length garments, closed shoes (or shoe covers), lab coats, gloves, masks, face shields, and head covers. <u>Work Clothing Provided</u> - All personnel (OAR and staff) are provided, upon request, uniforms and/or lab coats to wear while working in the VA and the VMU. In the context of the VMU, protective outer garments worn in VMU are not to be worn outside of the VMU (NRC 1997). Uniforms for personnel are provided by the VA and are laundered by hospital laundry services and/or disposed of as appropriate. <u>Shower/Change Facilities</u> - Lockers and shower facilities are provided outside the VMU. <u>Eating, Drinking and Smoking Policies</u> - Eating and drinking are prohibited in the VMU (DHHS 2009; NRC 1997; OSHA 1998a), but are allowed in the Animal Research Office. Eating or drinking containers must remain in the Animal Research Office and must be discarded in the trash. Smoking is prohibited in the entire hospital. <u>Hand-Washing</u> - All employees must wash their hands before and after handling or caring for animals.

The Research Service has both VA and University personnel working in laboratories. Both the VA Employee Health Service and University of Missouri's Occupational Health and Safety Program monitors every employee's health status at time of hire as well as annually and maintain the health records as outlined in the safety manual. They provide: (1) Pre-employment physicals for

new hires; (2) TB tine testing annually or optional annual chest radiograph if requested; (3) tetanus vaccinations, if requested; (4) rabies or hepatitis vaccine, if requested; (5) emergency medical care if injury or sickness occurs at work site. All VA research personnel are covered by this policy. University of Missouri employees are covered by the University Occupational Health and Safety Program, but emergency care is provided by the Truman VA. All injuries are reported to the appropriate supervisor and treatment is initiated as directed by VA Employee Health Services.

The PI must document the scientific justification for the use of animals as well as any chemicals or hazardous materials on the initial application to conduct research at the Truman VA. Animal experiments involving toxic chemicals, infectious agents or carcinogens must be approved by the Subcommittee for Research Safety (SRS) in addition to the IACUC/SAS. SRS works closely with the PI and the IACUC/SAS to determine risk assessments at the time of initial application and monitored annually through continuing review. If a hazard is identified during the application process, the SRS in communication with IACUC/SAS and the Truman VA Industrial Hygienist develops a plan for appropriate special training and/or precautions as well as monitoring of the hazard throughout the duration of the research. It should be noted non-human primates are not housed at this facility. All personnel are required to wear PPE (including disposable coats, booties, head covers, particle masks, and gloves) as required by animal husbandry procedures and monitored by periodically by the AO and ACOS/R&D during weekly walk rounds through the Research Service.

Further, the Truman VA Environment of Care Committee (EOCC) provides a multi-disciplinary approach to research safety, security, industrial hygiene and chemical hygiene, waste disposal, etc. Research facilities are surveilled annually with findings and areas for improvement tracked by executive leadership for completion. In addition, the Truman VA Industrial Hygienist, a voting member of the Subcommittee for Research Safety, surveils all Research laboratories on a quarterly basis with findings and recommended improvement areas tracked through committee until completion.

Truman VA policies and procedures are in place that address matters related to personal hygiene in accordance with the *Guide* 8<sup>th</sup> edition.

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.

The VMU square footage is **(B6)** (census #: 1,929), rabbits (census #: 42), and rats (census #: 191).

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

Basic training and instruction is available to and required of all scientists, animal technicians, IACUC/SAS members, and other personnel involved in animal care, treatment, and use at the Truman VA. The Truman VA provides training through the Collaborative Institutional Training Initiative (CITI) website. All persons engaged in animal research must take and pass the VA web-based training examinations on a triennial basis. This includes the general course, "Working with the IACUC," plus the relevant species-specific courses; e.g., "Working with Mice in a Research Setting." This applies to investigators responsible for supervising animal research that they themselves do not perform. This training includes specific training in the minimization of numbers of research animals used in experiments, and in pain and distress. The Table of Contents for the basic web-based training is shown below:

CITI Web-Site Course: Working with the IACUC

- 1) Introduction
- 2) Animal Research in the VA
- 3) Working with the IACUC

- 4) Federal Mandates
- 5) The Veterinary Consultation
- 6) Getting Started
- 7) Alternatives
- 8) Avoiding Unnecessary Duplication
- 9) USDA Pain/Distress Categories
- 10) Endpoint Criteria
- 11) Surgery
- 12) Antibody Production
- 13) Collecting Blood Samples
- 14) Personnel Training and Experience
- 15) Occupational Health and Safety
- 16) Using Hazardous and Toxic Agents in Animals
- 17) Housing Social Animals
- 18) Housing Rodents on Wire Floors
- 19) Dog Exercise
- 20) Primate Psychological Enrichment
- 21) Prolonged Restraint
- 22) Euthanasia
- 23) Using Patient Care Areas for Animal Research
- 24) Using Explosive Agents in the Animal Facility
- 25) Making Changes After You Receive Approval
- 26) The Secondary Veterinary Medical Review Program
- 27) Reporting Misuse, Mistreatment, or Non-Compliance

All personnel who handle animals are required to complete this training. Documentation of completed training is maintained by the Research Service administrative office. The training program provided by the OAR is a web-based course that covers each of the topic areas required by the PHS Policy and AWA regulations. Documented completion of the module is required before handling or using research animals. Documented completion of the module is required before handling or using research animals. Individuals who have completed the module are considered to have baseline training for animal care and use. PIs must have completed the modules before an animal care and use protocol can be approved. Also, the PI provides written assurance in the protocol that individuals involved in the protocol whose duties include animal procedures will be qualified by training or experience to perform such duties properly. OAR staff, veterinarians or other PIs provide specific practical skills in animal care and use. Past training and experience in the use of animals in research, including euthanasia, is also documented for all investigators and technicians in the animal protocol.

The IACUC/SAS members receive an e-copy of all communications; e.g., accreditation renewal requests/approvals, certification requests/approvals, to ensure a clear line of communication is open between the Director's Office, Research Service, R&D Committee, and the sister-IACUC at the University of Missouri.

Truman VA policy is to provide and document a full training program for all members of the IACUC/SAS so they understand, and can properly carry out, their responsibilities. New IACUC/SAS members receive the *Guide for the Care and Use of Laboratory Animals, Eighth edition*, an e-copy of the Animal Welfare Act, a facility tour, and selected references such as the Policy and Procedures Manual and the Report of the AVMA Panel on Euthanasia. In addition IACUC/SAS members have orientation meetings with the IACUC/SAS chairperson, the Veterinarian/VMO and the ACOS/R&D. Within one month of IACUC/SAS appointment by the Institutional Official, the new members are expected to have completed the CITI web-based training "Essentials for IACUC Members." The course is taken on a triennial basis. In addition, members are offered the opportunity to attend conferences such as "IACUC 101." Further, the Coordinator is expected to receive the same training opportunities and meet the same training requirements as voting members of the IACUC/SAS.

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Additional resources are provided to IACUC/SAS members including updates from the Veterans Administration Central Office and the the Office of Research Oversight (ORO) on changes in animal regulations and updates to the *Guide, Eighth edition,* as applicable. The IACUC/SAS maintains a record that documents the training of all animal workers and IACUC/SAS members.

#### 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 <u>Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)</u> . 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, David Isaacks.
  - 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
  - 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, David Isaacks
  - 5. Any minority views filed by members of the IACUC

- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
  - 1. Any serious or continuing noncompliance with the PHS Policy
  - 2. Any serious deviations from the provisions of the *Guide*
  - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

## VII. Institutional Endorsement and PHS Approval

A. Authorized Institu	tional Official	
Name: David Isaacks	, FACHE	
Title: Institutional Of	ficial	
Name of Institution: Ha	rry S Truman Memoria	l Veterans Hospital (Truman VA)
Address: (street, city, s	tate, country, postal co	ode)
800 Hospital Drive Columbia MO 65201-52	97	
Phone: <sup>(B6)</sup>		Fax: (573) 814-6309
E-mail: <sup>(B6)</sup>	<u>@va.gov</u>	
the Institution's response as specified above.	thorized capacity on be sibilities under this Ass	ehalf of this Institution and with an understanding of urance, I assure the humane care and use of animals
(B6) Signature:		Date: 9/23/2016
National Institut Bethesda, MD 2 (B6) @mail.n Phone:(B6) FAX: 301-451-5 (B6)	Senior Assurance O tory Animal Welfare es of Health 0892-7982 ih.gov 672	fficer
Signature		Date: $10/3/16$ (A3157-01)
Assurance Number:	)16-00097	(A3157-01)
Effective Date: 9/	26/16	Expiration Date: 8/31/20

## **VIII.** Membership of the IACUC

Date: 03/31/16					
Name of Institution:	a: Harry S. Truman Memorial Veterans Hospital				
Assurance Number:	A3157-01				
IACUC Chairperson					
Name <sup>*</sup> : ( <u>B6</u> )					
Title <sup>*</sup> : IACUC Chairperson Degree/Credentials <sup>*</sup> : PhD				dentials <sup>*</sup> : PhD	
Address <sup>*</sup> : <i>(street, city</i> Research Service 800 Hospital Drive Columbia MO 65201-5					
E-mail <sup>*</sup> : ( <mark>B6</mark> )	Dva.gov		1		
Phone <sup>*</sup> : <mark>(B6)</mark>	F		Fax <sup>*</sup> : (5	Fax <sup>*</sup> : (573) 814-6551	
IACUC Roster					
Name of Member/ Code <sup>**</sup>	Degree/ Credentials	Pos	Position Title***		PHS Policy Membership Requirements
(B6)	PhD	Chairperson			Practicing Scientist/Voting
(B	PhD	VA	Staff		Practicing Scientist/Voting
(B6)	DVM, MS	VM	0		Veterinarian/Voting
(B	BS	Non-Affiliated Member (Primary)/Grant Writer			Voting
B	MS	No (Al		d Member	Voting [when primary non- affiliated member is not in attendance]
(B	PhD	SAS/SRS Liaison		aison	Practicing Scientist/Voting
В	MD	VA	VA Staff		Practicing Scientist/Voting
В	PhD	VA	VA Staff		Practicing Scientist/Voting
В	DVM, PhD	VA	VA Staff (Alternate)		Practicing Scientist/Voting
(B6)	PhD	MU	MU Staff		Practicing Scientist/Voting
(B	PhD	VA	VA Staff		Practicing Scientist/Voting
B	PhD		MU Staff		Practicing Scientist/Voting
<u>(B</u>	JD		Non-Scientific Member/Lawyer		Voting
(B	BS	1	AO/R&D		Administration/Non-Voting
(B6)	DO, MSPH, MEd	AC	ACOS/R&D		Administration/Non-Voting
(B	PhD	RC	RCO		Administration/Non-Voting
	AA	Co	ordinator		Administration/Non-Voting
<u> </u>	1				

<sup>\*</sup> This information is mandatory.

<sup>\*\*</sup> 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.

<sup>\*\*\*</sup> 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: (B6), MSPH, MEd	, DO, MSPH, MEd		
Title: (B6)			
Phone: (B6)	E-mail: (B6) @va.gov		
Contact #2			
Name:			
Title:			
Phone:	E-mail:		

## X. Facility and Species Inventory

Date: 03/31/16			
Name of Institution: H	larry S Truman Me	morial Veterans Hospital (Truman	VA)
Assurance Number: A	3157-01		
Laboratory, Unit, or Building <sup>*</sup>	Gross Square Feet [ <i>include</i> <i>service areas</i> ]	Species Housed [ <i>use common</i> names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
Veterinary Medical Unit (VMU)	4,844	Mice; rats; rabbits	1,929; 191; 42

<sup>\*</sup>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.