

Annual Report to OLAW

Institution: WJB Dorn VA Medical Center

Assurance Number: D16-00008

Reporting Period: January 1, 2019 – December 31, 2019

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes [Select A or B]

- ☐ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. [Skip to Item II.]
- ☒ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. (FAQ 6)

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).
- ☐ AAALAC Accredited – Category 1
- ☐ Non-Accredited – Category 2
- ☒ This institution's program for animal care and use has changed (PHS Policy IV.A.1.a-i.). [Attach a full description of the changes.]
- ☐ The individual designated by this Institution as the Institutional Official has changed. [Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]
- ☒ The membership of this institution's IACUC has changed. [Provide current roster of members in Item VI.]

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the Institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. [Do not provide semiannual reports unless they include a minority view.]

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.]

Date 1: 01/10/2019

Date 2: 07/11/2019

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B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]

Date 1: 01/10/2019

Date 2: 07/11/2019

III. Minority Views [Select A or B]

- [X] A. There were **no minority** views during this reporting cycle.
- [] B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	Institutional Official
Name: (b)(6)	Name: David L. Onyiah, DRT, MHA, MS
Signature: (b)(6)	Signature: (b)(6)
Date: Jan 9, 2020	Date: 1/15/20

V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Name of Institution:	
Address: [street, city, state, zip code]	
E-mail:	
Phone:	Fax:

VI. Change in IACUC Membership [*Current roster*]

Institution: WJB Dorn VA Medical Center			
IACUC Contact Information			
Address:			
(b)(6)			
Administrative Officer, Research Building (b)(6)			
6439 Garner's Ferry Road Columbia, SC 29209			
E-mail: (b)(6)@va.gov			
Phone: (803) 776-4000 ext. (b)(6)		Fax:	
IACUC Chairperson			
Name: (b)(6)			
Title: IACUC Chair		Degree/Credentials: PhD	
PHS Policy Membership Requirements***: Scientist			
IACUC Roster [<i>Provide below or attach</i>]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b)(6)	DVM, PhD, DACLAM	Attending Veterinarian	Veterinarian
28	PhD	Dorn VAMC and USC School of Medicine	Scientist
143	PhD	USC School of Medicine	Scientist
127	MBA	IT Consultant	Non-scientist, non-affiliated
38	PhD	USC School of Medicine	Scientist

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report 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 (for example, 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.]

I-B: Changes to the animal care/use program.

PHS Assurance D16-00008, Part III-D-6: IACUC review process changes

Requests for animal use are made by submitting an Animal Use Proposal (ACORP) form to the IACUC via IRBnet. De novo ACORPs may undergo Designated Member Review (DMR) or Full Committee Review (FCR). Amendments to approved ACORPs may undergo Administrative Review (AR), DMR, or FCR.

The following situations require FCR:

1. De novo protocol involving procedures with pain and distress category E
2. De novo protocol involving procedures with survival surgery
3. De novo protocol involving procedures with USDA Species
4. Amendments to existing protocols that result in greater pain, distress, or invasiveness
5. Amendments that request a change in housing and/or use of animals in a location that is not part of the animal program overseen by the VA IACUC

Amendments meeting any of the following criteria are eligible for AR:

1. Change in personnel other than the PI
2. Change of protocol title
3. Addition of new funding sources with no change in procedures
4. Correction of typographical errors, grammar, and contact information updates
5. Change in IACUC-approved animal housing/procedure room
6. Change in animal source involving a DLAR-approved vendor

ACORPs and amendments not required to undergo FCR, but ineligible for AR, are eligible for DMR. For those de novo ACORPs and amendments, all IACUC members are provided with a copy of the ACORP and allowed a reasonable amount of time to request FCR. If no member requests FCR, then the ACORP or amendment undergoes DMR.

Review Processes:

FCR

Two committee members are assigned as principal reviewers for each ACORP or amendment. The principal reviewers present their analysis of the ACORP to the committee at a convened meeting. All members are afforded the opportunity to comment and/or ask questions about the ACORP or amendment. Members who cannot attend a meeting may relay questions or comments via the Chairperson, another committee member, or via the electronic protocol system program. A quorum must be present at the meeting to vote on any recommended actions.

Following the committee review, the members may vote to (1) approve, (2) require modifications, or (3) withhold approval of the ACORP or amendment. If by majority vote, the IACUC requires modifications to secure approval, the committee will (1) assign one or more members as designated reviewers for the modified ACORP/amendment or (2) require FCR of the modified ACORP/amendment.

The default process is for the modified ACORP/amendment to be reviewed by a Designated Reviewer; however, any committee member, present or not, may request FCR of the modified ACORP/amendment. If the IACUC uses a Designated Reviewer for the modified ACORP/amendment, the IACUC Chair assigns one or more members who may (1) approve, (2) require additional modifications to secure approval, or (3) refer the ACORP/amendment back to the IACUC for FCR. If more than one Designated Reviewer is assigned, the modified ACORP/amendment is either approved unanimously by the Designated Reviewers or it must undergo FCR.

If the IACUC votes to withhold approval, the investigator may present a new ACORP for de novo review.

DMR

The ACORP or amendment is reviewed by the Attending Veterinarian and one or more Designated Reviewer(s) who are assigned by the IACUC Chair. After reviewing the ACORP or amendment, the reviewers may (1) approve the ACORP or amendment, (2) require modifications to secure approval or (3), require FCR. If there is not a unanimous decision between the Attending Veterinarian and the Designated Reviewer(s), the ACORP or amendment is referred to the IACUC for FCR.

AR

For amendments eligible for AR, the IACUC Administrator may (1) approve the amendment, (2) require modifications to secure approval, or (3) refer the amendment to DMR or FCR as appropriate. Member attendance is documented and kept as part of the meeting minutes. A quorum is required for convening a meeting and voting on reviews or other business. A committee member who may have a conflict of interest on a specific ACORP or amendment, e.g., Principal Investigator or Protocol Associate, is required to leave the meeting during review of that ACORP and may not vote on the ACORP.

William Jennings Bryan Dorn VA Medical Center
Assurance Number: D16-00008 (A3014-01)

Animal Welfare Assurance for Domestic Institutions

I, David L. Omura, DPT, MHA, MS, as named Institutional Official for animal care and use at William Jennings Bryan Dorn VA Medical Center provides 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 the William Jennings Bryan Dorn VA Medical Center that are physically located on the center's campus in Columbia, SC. There are no off-site satellite facilities and or other covered components.
- B.** The following are other institution(s), or branches and components of another institution: None

II. Institutional Commitment

- A.** This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B.** This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C.** This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use
- D.** This Institution has established and will maintain a program for activities involving animals according to the Guide for the Care and Use of Laboratory Animals (Guide).
- E.** This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (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 shown in Appendix 1 (attached).
- B.** The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

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

Qualifications

(b)(6)

2. Provisions for Back-up Veterinary Care/Service:

Name: (b)(6)

Qualifications:

(b)(6)

- 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 Director, as Chief Executive Officer (C.E.O.), appoints the members of the IACUC. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1.** Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
 - The IACUC members, including the consulting veterinarian, use the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for evaluation.
 - To facilitate the evaluation, the Committee uses a standard VA checklist based on the OLAW Program and Facility Review Checklist from the OLAW website.
 - The evaluation includes, but is not 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. All related SOPs; and
 - g. Emergency and Disaster Plans.
 - In addition, the evaluation includes a review of the Institution's PHS Assurance.
 - If program deficiencies are noted during the review, they are categorized as significant or minor and the Committee develops 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 is involuntarily excluded from participating in any portion of the reviews. All members are invited to participate in the semiannual program review.
- 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:
 - At least once every six months at least two members of the IACUC will visit all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, animal surgery 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. All members are invited to participate in the semiannual facility inspection.
- 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 convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, drafts the reports using a standard VA format that is based on the OLAW Semiannual Report to the Institutional Official format.
 - The report contains a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
 - The reports identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy and states the reasons for each. If there are no departures, the report will so state.
 - Approved departures must 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.
 - Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
 - The report distinguishes significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports 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 reports will identify those facilities as such. Currently, all of the institution's facilities are accredited by AAALAC.
 - Copies of the draft report will be reviewed, revised as appropriate, and approved by the Committee.
 - The final reports that are submitted to the IO are signed by a majority of the IACUC members and include any minority opinions. If there are no minority opinions, the reports will so state.
 - Following completion of each evaluation, the completed report is submitted to the Institutional Official in a timely manner.
 - The Consulting Veterinarian, the IACUC Chair and the ACOS-R meet semi-annually with the IO to present and discuss the report.

- Deficiencies will be tracked by the IACUC Coordinator to ensure that they are appropriately resolved.
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 to the IO, IACUC Chair, Consulting Veterinarian, or any member of the IACUC.
 - Concerns may be reported verbally, in writing or by email; and may be anonymous. This information is addressed during training. Notices are also located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. These notices are reviewed during the Semi-Annual Inspections. The Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017 will be applied and implemented as appropriate.
 - All reported concerns are brought to the attention of the full Committee.
 - If necessary the IACUC Chair convenes a meeting to discuss, investigate, and address any reported concern.
 - Reported concerns and all associated IACUC actions are 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:

Submissions and Pre-reviews

- Protocols are submitted to the Research Office Intake mailbox in electronic format.

Domestic

- The protocol must be submitted using the approved ACORP forms as well as⁵

the other required Research Service Line forms for review by all required committees (COI, Safety, etc.)

- The attending veterinarian pre-screens the protocol for the science, humane animal care, methods, and adherence to veterinary standards.
- Upon release from the consulting veterinarian, the Chair of the IACUC assigns at least two voting members as primary reviewers, who are notified by the IACUC staff member.
- The meeting agenda and materials for review are made available to the IACUC members electronically at least three days before the meeting. In cases where the member cannot access the documents electronically, paper copies will be provided.
- The primary reviewers complete the pre-review for all assigned protocols using a checklist to ensure that all the required elements of the review are addressed. The checklist reminds the reviewer to address the following areas:
 - 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.
 - e. 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.
 - f. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 - g. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - h. If euthanasia is proposed in the methods, it 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.

IACUC Review (Full-Committee Review or Designated-Member Review)

- 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.
- Meetings are conducted in person. When a member is unavailable to attend the meeting in person, they may call into the meeting on the conference phone, allowing them to fully participate in the meeting discussions.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-052 of March 24th, 2006, entitled "Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals".

Full-Committee Review (FCR)

- The primary reviewer presents his/her review to the IACUC for full committee review (FCR) and discussion.
- The IACUC then votes by voice, indicating "yay" or "nay" as the question is called on each protocol, with the majority determining the final outcome.
- The possible outcomes of FCR are as follows:
 - a. Approval
 - b. Modifications Required (to secure approval)
 - c. Tabled (for discussion/review at a later time)
 - d. Approval Withheld.
- 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 DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

OR

- b. DMR may be used if approved unanimously by all members at the meeting at which the required modifications are developed and delineated AND The default process, described in a written policy, is for the modified request to be reviewed by a designated reviewer(s). However, if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR. The DMR-subsequent-to-FCR process is agreed to by every IACUC member, in writing, every three years or as required by circumstances (e.g., changes in committee membership).
- c. 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)

- Should a situation warrant, or in the case of a protocol meeting the criteria for expedited review, the IACUC may use the designated-member review (DMR) method. In such instances the protocol is distributed to all IACUC members to allow all members the opportunity to call for FCR; 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 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.
 - If FCR is not requested, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request FCR of those protocols.
 - Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditional.
 - After all required modifications are made, a final revised protocol, i.e. an identical document with all 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.
 - A DMR may approve, require modifications to secure approval, or request FCR of the protocols.
 - 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 activities 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 requirements delineated in the aforementioned checklist (see submission and pre-review section above).
- 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:**
- All significant changes, whether in the form of a protocol amendment or new protocol, will be handled in the same manner as new protocols, i.e. as delineated in Part III.D.6 above.
 - Examples of changes considered to be significant include, but are not limited to:
 - a. changes in the objectives of a study;
 - b. changes from non-survival to survival surgery;
 - c. changes resulting in greater pain, distress, discomfort, or degree of

- invasiveness;
- d. changes in the species or in approximate number of animals used;
 - e. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
 - f. changes in Principal Investigator;
 - g. changes in anesthetic agent(s), sedation, experimental substances, or the use or withholding of analgesics;
 - h. changes in the method of euthanasia (must be AVMA-approved); and
 - i. changes in the duration, frequency, type, or number of procedures performed on an animal.
 - j. changes that impact personnel safety.
- Minor amendments (i.e., non-significant changes) may be expedited by the Chair and Attending Veterinarian.
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 Chairperson.
 - The IACUC's decision to require modifications will be communicated in either an e-mail or letter and the modifications clearly delineated in the communication.
 - If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
 - The Institutional Official is notified by receiving a copy of the PI's notification letter and/or 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 3 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 are monitored continuously by the animal care and use staff. No other procedures will be used. All animals are checked daily by animal care staff to detect any issues related to animal health and/or protocol noncompliance (e.g., exceeding humane endpoints, feeding/watering/diet, etc). Issues are referred to veterinary staff, and research personnel are required to be trained in animal handling to include surgical/post-surgical topics as appropriate, regulatory compliance, reporting of concerns, and evaluation of outcomes.
 - USDA Regulated Species - Any protocols involving USDA-Regulated species will be reviewed by a member or members of the IACUC at least annually.

- Non-USDA Regulated Species - All protocols are reviewed by a member or members of the IACUC at least annually.
- Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.
- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.
- 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 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:

1. Administration/management.

- The VA Employee Health Clinic is responsible for the planning and monitoring of the Occupational Health and Safety Program for VA personnel involved in the care and/or use of laboratory animals.

2. Scope.

- The program covers personnel involved in laboratory animal care and/or use at the VA. Participation in the program is mandatory. Personnel are enrolled as they are added to the protocol and the Employee Health Clinic is notified. Individuals who wish to decline participation must do so in writing. To date, less than one percent of covered personnel have declined to participate. Declining OHSP enrollment precludes any live animal contact as well as access to the animal facility.

3. Health Histories and Evaluations.

- The VA Employee Health Clinic annually reviews enrollees to detect problems in the early stage and ensure that required immunizations are current. A medical

evaluation or collection of a health history that meets federal, state and local HIPAA regulations is part of the risk assessment process required in the occupational health and safety program. This evaluation is in the form of a questionnaire.

- All personnel are required to complete a health history questionnaire.
- Each questionnaire along with the applicable individual hazard identification and risk assessment form are evaluated by the Employee Healthcare Provider.
- This process is completed initially and updated/repeated at least annually.
- The health history forms are maintained by the Employee Health Clinic.
- University of South Carolina faculty and staff with VA appointments may participate in the program of either institution. The USC OHSP program was reviewed and approved by OLAW in 2017.

4. Hazard Identification and Risk Assessment.

- The program is based on hazard identification and risk assessment with development and implementation of measures to minimize identified hazards and risks. Health histories, review of protocols by the Safety Committee, and the Semi-Annual Review are used to identify risks and hazards.
- The VA has institutional policies regarding personal hygiene, use of hazardous agents, and personal protection.

5. Procedures in Place to Alleviate Hazards and Minimize Risks.

- Allergic reactions are among the most common conditions that adversely affect the health of personnel working with laboratory animals. Major sources of allergens include rodent urine and saliva.
- Training in zoonoses, allergies, and hazards is provided institutionally through required training; OHSP risk assessment, evaluation and consultation; and ongoing communications with staff and personnel.

6. Immunizations.

- Vaccination against tetanus is required and provided by the Medical Center.

7. Precautions taken during pregnancy, illness or decreased immune-competence.

- Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immune-competence 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/her health care professional, human resources, etc.

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 animal facilities. 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. A member of the animal care staff will be available for escort if needed. 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 staff have access to the medical center in the event of an animal related injury, or bite. Instructions on how and where to obtain health care, including after-hours care, is posted with the VA animal facility and procedure area.
- Treatment is free and records are maintained by the Center's Employee Health Clinic.

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

- Occupational injuries are monitored by the Environmental Health and Safety Office (through the Human Resources Department).
- Report of all work-related illness and/or injury is mandatory. This requirement is covered during OH&S training and Animal Care & Use Training.

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 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

- Each IACUC member is provided with a copy of the following:
 1. The PHS Policy for the Humane Care and Use of Laboratory Animals;
 2. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
 3. A copy of this Assurance;
 4. Medical Center SOPs on Animal Care and Use.
- All committee members complete the "Essentials of IACUC" and "Working with the VA IACUC" training. This training may be completed online at <https://www.citiprogram.org> or, for VA IACUC members who are also University of South Carolina faculty or staff, training received via <https://aalaslearninglibrary.org> is accepted.
- Training in experimental methods, i.e., specific animal manipulations and techniques, is conducted based on the types of research being conducted at the institution. Committee members receive formal and informal training on implementation of the 3Rs by the VA's CVO at IACUC meetings.
- Training completion records are tracked by the Research Administration Office. Additional training may be conducted on-site by the AV as necessary.
- VA IACUC members who are also University of South Carolina faculty or staff may participate in the training program of either institution.

2. Animal Care and Use Personnel

Domestic All personnel involved in animal care and/or use will be given a copy of the OLAW

Assurance.

- All research personnel handling animals must be certified as to training in specific procedures and species. This training may be completed online at <https://www.citiprogram.org> or, for VA IACUC members who are also University of South Carolina faculty or staff, training received via <https://aalaslearninglibrary.org> is accepted.
- All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol.
- A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be available for IACUC review.
- Any person needing additional protocol-specific training is identified during the review process and such required training is a condition of approval of the protocol.
- All persons involved in animal care and use are required to attend an orientation seminar given by the IACUC Chair, Consulting Veterinarian, or other qualified individual(s). The training covers the laws and regulations for laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's.
- The training includes instruction on research or testing methods that minimize the number 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). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:
 1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
 2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress.
 3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
 4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
 5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - a. On appropriate methods of animal care and use;
 - b. On alternatives to the use of live animals in research;
 - c. That could prevent unintended and unnecessary duplication of research involving animals; and
 - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training must be documented.

- Training in experimental methods, i.e., specific animal manipulations and techniques, is conducted based on the types of research being conducted at the institution. Additionally, Animal Care and Use Personnel complete the appropriate modules at <https://www.citiprogram.org> and are provided copies of the Medical Center's SOPs on Animal Care and Use.
- For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some institutionally-required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

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 re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.8.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to 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.
- 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 semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A.** This Institution will maintain for at least three 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. The Director of the WJB Dorn VA Medical Center is the Institutional Official.
 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 Domestic

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PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A.** The Institutional reporting period is the calendar year (January 1 - December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked).
 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance.
 3. Any change in the IACUC membership.
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official. The Director of the WJB Dorn VA Medical Center is the Institutional Official.
 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.

Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC. Institutional Endorsement and PHS Approval.

A. Authorized Institutional Official	
Name: David L. Omura, DPT, MHA, MS	
Title: Medical Center Director	
Name of Institution: WJB Dorn VA Medical Center	
Address: (street, city, state, country, postal code)	
6439 Garners Ferry Road Columbia, SC 29209	
Phone: (803) 776-4000 x (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: 7/24/18

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

Name/Title: (b)(6) Veterinary Medical Officer
 Office of Laboratory Animal Welfare (OLAW)
 National Institutes of Health
 6700B Rockledge Drive
 Suite 2500, MSC 6910
 Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817)
 Phone: +1 (b)(6)

(b)(6)

Signature:

Date: July 26, 2018

Assurance Number: **D16-00008 (A3014-01)**Effective Date: **July 26, 2018**Expiration Date: **July 31, 2022****IV. Membership of the IACUC**

Date: 7/13/2018

Name of Institution: WJB Dorn VA Medical Center

Assurance Number: D16-00008/A3014-01

IACUC Chairperson

Name: (b)(6)

Title: (b)(6)

Degree/Credentials: Ph.D.

Address: (street, city, state, zip code)

 6439 Garners Ferry Road (b)(6)
 Columbia, SC 29209

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

Phone: (803) 776-4000 x (b)(6)

Fax: (b)(6)

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b)(6)	Ph.D.	Research Scientist	Scientist
	D.V.M., Ph.D, DACLAM	USC Veterinarian (b)(6)	Veterinarian

Domestic

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(b)(6)	Ph.D.	Professor	Scientist
		IT Consultant	Non-Scientist, Non-Affiliated Committee Member
	Ph.D.	Associate Professor	Scientist
	Ph.D.	Associate Professor	Scientist

* This information is mandatory.

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

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

**** PHS Policy Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

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

V. 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: Administrative Officer	
Phone: 803-776-4000	(b)(6)
E-mail:	(b)(6)@va.gov
Contact #2	
Name:	(b)(6)
Title: IACUC Coordinator	

Phone: (b)(6) E-mail: (b)(6)

VI. Facility and Species Inventory

[illegible]

¹ Mice and rats means mice of the genus *mus* and rats of the genus *rattus* that are purposely bred for research.

Appendix 1

ORGANIZATION CHART

Wm. Jennings Bryan Dorn, VA Medical Center , Columbia, SC 29209

