Edward Hines, Jr. VA Hospital D16-00374 (A3616-01) Animal Welfare Assurance

I, James Doelling, as named Institutional Official for animal care and use at the Edward Hines, Jr. VA Hospital, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

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

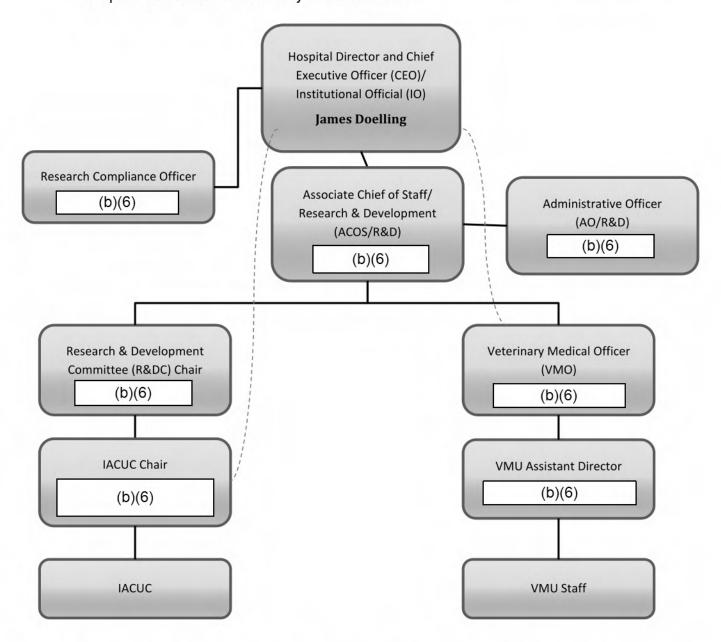
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: The Department of Veterans Affairs, Edward Hines, Jr. VA Hospital: The Veterinary Medical Unit (VMU), and principle investigator laboratories within Research Service at the Department of Veterans Affairs, Edward Hines, Jr. VA Hospital and the Chicago Association for Research and Education in Science (CARES). All of these components are physically located on the hospital main campus at 5000 South 5th Ave., Hines, Illinois 60141. There are no off-campus satellite facilities or other covered components.
- B. The following are other institution(s), or branches and components of another institution: None / Not Applicable.

II. Institutional Commitment

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

III. Institutional Program for Animal Care and Use

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



- As indicated by the dashed lines above there exist direct and open lines of communication between the IACUC and the IO and between the VMO and the IO. If issues are not reconcilable through the existing hierarchy, the VMO and/or the IACUC may bring any concerns regarding the animal care and use program directly to the IO's attention.
- Correspondence [e.g., meeting minutes, recommendations, reports, etc.] from the IACUC to the IO may be routed through administrative channels for informational purposes. However, such correspondence will not be changed, influenced, or delayed in any manner whatsoever.

will participate in the program are as follows: Name: (b)(6)Qualifications: Degrees: D.V.M., University of Illinois, 1975; Ph.D., Cell and Molecular Pathology, University of Chicago, 1992 Training or experience in laboratory animal medicine or in the use of the species at the institution: (b)(6) is the Veterinary Medical Officer (VMO) for the Edward Hines, Jr. VA Hospital VMU. (b)(6 has specialization and experience in pathology and infectious diseases, and (b)(6) has experience in laboratory animal medicine for over 25 years. (b)(6 training includes a Ph.D. in experimental pathology with research in rodent viral diseases, with the Ph.D. and post-doctoral position completed at The University of Chicago. has direct program authority and responsibility for the Institution's Authority: (b)(6)Animal Care and Use Program, including complete access to all animals. reports directly to the Associate Chief of Staff, (ACOS) for Research Service. As the VMO, (b)(6) has complete authority and responsibility to implement the PHS policy and the recommendations of The Guide. Time contributed to program: (b)(6) is present at the Institution an average of approximately 64 hours per month. One-hundred percent of this time is contributed to the animal care and use program. In addition, (b)(6) contributes on average approximately 15-20 hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics. 2. Provisions for Back-up Veterinary Care: Since the VMO's time is divided among several institutions, each institution depends on the training and experience of the animal care staff in recognizing clinical illness. The supervisor of the VMU is (b)(6) (b)(6)is certified by AALAS at the A.L.A.T. level and has more than 20 years' experience in laboratory animal medicine. In case of emergency when the VMO is not available, the VMU has formal arrangements for backup veterinary (b)(6)DVM, Oklahoma State University, 1959-1965; coverage with Director of Centers for Comparative Medicine at Northwestern and Rush [DVM, University of Missouri, 1977; Head Universities]. (b)(6)Veterinarian at Brookfield Zool, and [DVM, Clinical (b)(6)Veterinarian, Loyola University Medical Center). 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 Chief Executive Officer (CEO) also serves as the Institutional Official (IO) and directly appoints the members of the IACUC. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their degrees, profession, titles or specialties, and institutional affiliations.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who

D. The IACUC will:

- Review at least once every six months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
 - The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
 - The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
 - To facilitate the evaluation, the Committee will use a standard VA checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
 - The evaluation will include, but not necessarily be limited to, a review of the following:
 - a. Institutional and individual responsibilities;
 - b. IACUC membership and functions;
 - c. IACUC member qualifications and training;
 - d. Personnel qualifications (experience and training);
 - e. IACUC records and reporting requirements;
 - f. Husbandry and veterinary care (all aspects);
 - g. Memoranda of understanding with associated institutions;
 - h. Husbandry and veterinary care (all aspects);
 - i. Occupational health and safety;
 - j. Emergency and disaster plans;
 - k. System for review of Standard Operating Procedures;
 - System for reporting concerns about animal welfare;
 - m. Animal procurement and transportation;
 - n. Preventive medicine:
 - o. Waste disposal and pest control;
 - p. Emergency and after-hours animal care;
 - q. Policies on surgery, pain management, and euthanasia;
 - r. Conduct of procedures according to approved protocols;
 - s. Facility security; and
 - t. Personnel security and safety.
 - The review may also involve a review of the institution's Assurance.
 - If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
 - Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.

- 2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - At least once every six months at least two voting members of the IACUC will inspect all of the institute's animal facilities and animal surgical areas. Generally, in accordance with VA Policy at least three voting members participate.
 - The areas inspected include, but are not necessarily limited to the following: any and all buildings, rooms, areas, enclosures, or vehicles and equipment, including satellite facilities, used for animal confinement, transportation, maintenance, breeding, or experiments inclusive of surgical manipulation
 - 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 inspection.
 - 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.
 - Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded for participating in any portion of the inspections.
- 3. Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:
 - Individual IACUC members will convey their observations to the IACUC Coordinator or Chairperson who, in turn, will draft the reports using the standard VA format that is based on the sample OLAW Semiannual Report to the Institutional Official from the OLAW website.
 - The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy
 - The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures from provisions of the Guide and PHS Policy, the reports 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 provisions of the Guide and the PHS Policy that are not IACUC approved are considered deficiencies and will be addressed as such. All departures are evaluated to determine if they are non-compliant with the PHS Policy and/or the Guide. In this event, they are reported to OLAW, and the IACUC will develop a reasonable plan and schedule for discontinuing the departure, or for having the departure properly reviewed and approved.
- The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
- If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.
- Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. This is generally done at the next IACUC meeting.
- The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
- Once the report is approved by the IACUC, it may not be altered.
- The completed reports will be submitted to the Institutional Official for review and signature within 60 days following the evaluation.
- A signed copy of the report is sent to VA Central Office, plus a copy is maintained on file within the Department of Research.
- Until resolution is complete, deficiencies remain on the IACUC agenda and are tracked in the IACUC minutes.
- 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, Institutional Veterinarian, or any member of the IACUC.
 - Notices are 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.
 - All reported concerns will be brought to the attention of the full Committee.
 - If necessary, the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.

- Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
- The Committee will report such actions 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 documents. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.
- The institution maintains a Standing Operating Procedure (SOP) available to all Research employees to define the procedure for reviewing complaints or concerns about animal welfare. Such complaints can be made anonymously. As stated in the VHA Handbook 1200.07 and this SOP, "Initiating such concerns in no way places an employee, volunteer, student, or other staff member at risk to be discriminated against or be subject to any reprisal for reporting perceived violations of any regulation or standard." The Whistleblower Protection Act (5 U.S.C.S2302-b) protects all such individuals at our Institution, and yearly training is required of all personnel.
- 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.
 - The IACUC generally submits its recommendations in writing to the IO through the R&D Committee. The R&D Committee will, in turn, take appropriate action, note this action in the R&D Committee's minutes, and forward them along with the IACUC meeting minutes to the IO for final approval.

Notes:

- a. Once IACUC meeting minutes and recommendations are approved by the IACUC, they must be forwarded without revision or alteration to the IO.
- b. As delineated in Part III.A. above, there exist direct and open lines of communication between the IACUC and the IO. If deemed to be warranted, the IACUC may submit recommendations directly 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:

Submission Procedures

- An Animal Component of Research Protocol (ACORP) is prepared by the PI and uploaded to a secure server, www.gov.irbnet.org. The Research Office identifies the project under which work is to be conducted and disseminates the submission to the IACUC coordinator. When appropriate for a new project, project application materials and associated grant are included with the submission to the IACUC.
- The VMO is notified of the submission automatically, or by the IACUC Coordinator and performs a veterinary pre-review of the submission.
- Meeting materials (Protocols, Agenda, Minutes of previous meetings, and any other relevant materials) are distributed to all IACUC members via electronic access through the electronic protocol review system, as an electronic pdf via email, and/or as a hard copy delivered by inter-office mail, or by UPS.

IACUC Reviews

- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
 - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort.
 - 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.
 - 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. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals unless a deviation is justified for scientific reasons in writing by the investigator.
- 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.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24, 2006, entitled <u>Guidance on Use of Telecommunications</u> for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- Prior to the review, each IACUC member will be provided with a list of proposed activities/projects to be reviewed and written descriptions of activities/projects (protocols) that involve the care and use of animals shall be provided or available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols.

Review Processes

Full-Committee Review (FCR)

- In accordance with VA Policy, FCR is the default method that is generally used.
- 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.
- The IACUC Chair usually assigns two primary reviewers to each protocol. These reviewers review the protocol, and lead the discussion at a convened IACUC meeting. They also perform a congruency check between the ACORP and the associated grant.
- A minimum of three days prior to a scheduled IACUC meeting, ACORPs are distributed as an electronic document and/or as a hard copy to each IACUC member. Members also receive an agenda identifying the two members assigned as primary reviewers for each protocol.

- Meetings are generally conducted in person. However, one committee member is located off-site, and a video teleconferencing system is used to allow this member to participate in convened meetings.
- On occasions when public health guidance does not allow for in-person meetings, IACUC meetings may be held through the use of video teleconferencing that allows real-time verbal interaction between all members present. Members are always informed in advance of meetings, and all meeting materials are supplied to all members.
- Other than a quorum (more than 50% of voting members or their alternates) of IACUC members, there are no other specific attendance requirements. Participation of alternates is in accordance with PHS policy (NOT-OD-01-017).
- Review, discussion and committee action follow the guidelines in VHA Handbook 1200.07. A quorum must be maintained for each vote to occur.
- Voting follows Parliamentary Procedures. When discussion has concluded, a motion summarizing the outcome of the discussion is made, and must be seconded. Official votes are tallied by yeas, nays and abstentions. A vote of more than 50% carries the motion. Any votes opposed to the motion, or abstaining from the motion are noted, and minority opinions are reported in the minutes. At all times, a quorum is maintained. The outcome of the vote, quorum status, and recusals are noted in the meeting minutes. Any member may request a minority opinion to be included in the minutes. After review at a convened meeting of a quorum of the IACUC and with the vote of a majority of the quorum present, the possible outcomes are listed below:
- The possible outcomes of FCR are as follows:
 - a. Approval,
 - b. Require modifications (to secure approval),
 - c. Withhold Approval, and
 - d. Tabled for review at a later time (this occurs when there is insufficient information to make a determination).
- Required Modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
 - a. FCR following the applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

OR

 Designated Member Review (DMR)-(All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous consent to use DMR subsequent to FCR when modification is needed to secure approval). However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The IACUC Chair appoints the DMR.

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)

- As stated above, FCR is the default method for ACORP review. However, if warranted, the IACUC may use DMR.
- Prior to the review, each IACUC member will be provided with a list of proposed activities/projects to be reviewed and written descriptions of activities/projects (protocols) that involve the care and use of animals shall be provided or available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols.
- 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 <u>not</u> requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request FCR of those protocols.
- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, will be submitted to all designated reviewers for review and approval.
- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
- The possible outcomes of DMR are as follows:
 - a. Approval;
 - b. Require modifications (to secure approval); and
 - c. Referral for FCR.

"Withhold approval" is not a possible outcome of DMR.

Special or Expedited Reviews

 No procedures exist for special or expedited review. All protocols are reviewed using the methods described 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:
 - Other than the specific exceptions delineated in OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014 and as delineated below and in IACUC approved policies, review and approval of significant changes will be handled in the same manner as new protocols. See Part III.D.6. above.
 - Examples of changes considered to be significant include, but are not limited to, changes:
 - a. in the objectives of a study;
 - from non-survival to survival surgery;
 - c. resulting in greater discomfort or in a greater degree of invasiveness;
 - d. in the housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
 - e. in the species
 - f. in Principal Investigator;
 - g. that impact personnel safety;
 - h. in anesthetic agent(s) or the use or withholding of analgesics;
 - i. in the method of euthanasia;
 - j. in the duration, frequency, type or number of procedures performed on an animal
 - k. in approximate number of animals used
 - Review and approval of items a. g. must be by FCR or DMR. See Part III.D.6. above.
 - Review of items h. j. and subsequent approval by FCR or DMR may also be handled administratively in consultation with an Edward Hines, Jr. VA Hospital veterinarian who is appointed by the IACUC and authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare. The consultation and the verification will be documented in IRBNet.
 - Review and approval of item k. may also be handled administratively, but without requiring additional veterinary consultation, as described in IACUC approved written policies that are compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will address the rational for the original number of animals used, approved study objectives, the rational for the additional animals, and possible negative impacts on animal welfare.
 - All such aforementioned policies related to administrative review will be adopted by formal action by the IACUC.

- All authorizations of individuals by the IACUC to handle changes administratively will be specific (by name or position title and change(s) authorized to handle) and in writing.
- All such aforementioned policies and authorization of individuals related to administrative review may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.
- If the IACUC wishes to continue the procedures/policies and/or authorizations beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC using FCR or DMR.
- All approved changes will be documented in the associated protocol file.
- 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 by email through the secure server www.gov.irbnet.org.
 - A request by the IACUC for further Clarifications/Modifications, whether after DMR or FCR of a new ACORP, three-year renewal of an ACORP, or ACORP modification request is communicated to the Investigator in the form of a formal memo from the IACUC coordinator delineating the specific changes that are required, and instructions to the Investigator for their response.
 - If the IACUC decides to withhold approval or table an ACORP, the written notification to the PI will include a statement of the reasons for its decision and will give the Investigator an opportunity to respond in person or in writing. Their response will be reviewed by the IACUC at a convened meeting, and they will vote as to allow the PI to resubmit the ACORP for review. This outcome will be conveyed to the PI in a written memo through IRBNet. When the IACUC reviews the resubmitted protocol, it will be reviewed in the standard method by FCR or DMR, as described in section IIID6.
 - The IO 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 three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Post Approval Monitoring

- Post-approval monitoring is done by the annual certification process, as well as, during the semi-annual review. During the semi-annual review an inspection of all areas where animal research is conducted is completed, this includes investigator laboratories. During the visits, the semi-annual inspection team asks the investigative staff open-ended questions that pertain to the work that is being conducted. This allows the IACUC to verify that procedures used in the laboratory are the same as approved in the IACUC protocol(s).
- All ongoing activities are monitored continuously by the animal care and use staff. All animals housed in the VMU are inspected on a daily basis, and environmental controls are monitored continuously to ensure the health and safety of the animals. Informal post-approval monitoring is accomplished during routine husbandry and veterinary rounds.

Continuing / Periodic Protocol Review

- USDA Covered Species Protocols involving USDA regulated species are reviewed by a voting member or members of the IACUC at least annually. Currently, as part of the continuing review process at the first and second anniversary of initial approval, the IACUC also reviews a standard form giving current basic information such as IACUC approval number, IACUC approval date, title of project, and species used. Most recent IACUC training dates for all personnel listed on the protocol are also given. The investigator then notes that either no changes have taken place, or describes any changes that have occurred. Any changes to the protocol must be reviewed and approved by the IACUC prior to their implementation.
- Non-USDA Covered Species Protocols involving only non-USDA regulated species are reviewed in the same manner as USDA regulated species, as described above, and including a complete three-year review, prior to the expiration date, by FCR or DMR, as described in Part III.D.6.
- 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.3. above.
- Administrative extensions of approved protocols are not permitted. A *de novo* review must be completed every three years. No extensions to the three year timeline can be granted.

- 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 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 institution uses guidelines prepared by the VA to provide an Occupational Health and Safety Program (OHSP) for those with laboratory animal contact.
- This comprehensive employee health program based on risk assessment and hazard identification is operated by the Edward Hines, Jr. VA Hospital Occupational Health Service (OHS), and an occupational health professional in that department is involved in the planning and monitoring of the program for the Research Service.
- The Research Service is responsible for identifying individuals who must participate in the OHSP, and for categorizing the risks specific to each individual.
- The Research Safety Subcommittee (RSS) also manages a comprehensive safety program for all Research employees.

2. Scope and Procedures for Enrollment in the Program.

 Personnel monitored by the OHSP include those involved in the direct care of animals and their living quarters as well as those individuals who have direct contact with animals (alive or dead), their viable tissues, body fluids, or wastes. This includes all VMU staff, some investigators and lab assistants, all personnel named on an active ACORP, IACUC members, and visiting students, technicians, or faculty who will work with animals or within the VMU. • Personnel who will be working with animals are identified when they are named on or added to an ACORP.

3. Health Histories / Evaluations and Risk Assessment.

- Individuals must complete an "Employee Health Annual Questionnaire for Animal Care Staff" form, and a "Medical Surveillance Annual/Final Clearance" form. These forms identify exposure risks for all personnel, and give every individual the opportunity to meet with a health care professional and receive any necessary vaccinations, or to decline this service.
- All individuals working with animals must complete the Medical Surveillance Annual/Final Clearance" form annually. This form identifies risks associated with the performance of the individual's job, including waste anesthetic gas exposure, paraformaldehyde exposure, inhalation hazards, carcinogen exposure, laser exposure, or hazards associated with non-human primates.
- If the individual wishes to fully participate in the OHSP, they must also complete the "Employee Health Annual Questionnaire for Animal Care Staff" form annually. This form asks detailed questions about the risks associated with animal care and use for the individual. The forms are evaluated by an OHS health care professional.
- Any individual who opts to fully participate in the OHSP also meets with an OHS
 health care professional on an annual basis where their risks and options for
 preventative care are discussed in detail.
- Individuals are only permitted to "opt out" of full participation in the program if they are already enrolled in an equivalent program at another institution. These individuals are required to show evidence of their enrollment in another program to OHSP.
- On an annual basis, all individuals with animal contact must complete these forms and either decline the optional health services or complete the necessary forms and meet with a health care professional.
- Upon employment; all individuals must meet with an Edward Hines, Jr. VA Hospital OHS healthcare professional.
- Subsequently, on an annual basis, all Research personnel who have contact with animals receive, as necessary:
 - a. The opportunity to fill out a detailed health questionnaire and meet with an OHS healthcare professional to discuss in detail any relevant health concerns relating to their duties.
 - b. The opportunity to enter a monitoring program for health effects related to specific employment hazards including: waste anesthetic gas exposure, paraformaldehyde exposure, inhalation hazards, carcinogen exposure, laser exposure, or hazards associated with non-human primates.

- c. The opportunity to receive the rabies vaccinations series or to have a serum drawn to monitor their rabies antibody titer free of charge.
- d The opportunity to receive the hepatitis B vaccination series or to have serum drawn to monitor their hepatitis B antibody titer free of charge.
- e. The opportunity to update their tetanus vaccination status. Records of employee vaccinations are maintained by OHS.
- g. Any other vaccine that is considered safe and relevant to their research work.

4. Hazard identification and risk assessment.

- Hazard identification and risk assessment are accomplished through several means:
 - a. All protocols require initial review and approval, and annual review thereafter by the Edward Hines, Jr. VA Hospital Research Safety Subcommittee (RSS).
 - b. All significant changes to protocols that may impact personnel safety require review and approval by the RSS.
 - c. All employees are required to complete the "Medical Surveillance Annual/Final Clearance" form annually to identify potential risks associated with their duties. Individuals may opt to receive an annual health assessment with Occupational Health Service (OHS).
 - d. Laboratory safety inspections are performed at least annually by Research Safety personnel.
 - e. IACUC semiannual evaluations include review of processes for hazard identification and risk assessment, including review of:
 - i. Occupational Health and Safety Program (OHSP) policies, practices, and methods for risk assessment for all personnel working with animals.
 - ii. Facility safety engineering controls
 - iii. Availability of personal protective equipment
 - iv. Presence of appropriate safety signage
 - v. Policies for safety training of personnel
 - vi. Equipment and facilities which could pose a hazard
- The IACUC and RSS review hazardous agents and activities listed on ACORPs and identify individuals associated with these risks. This information is provided to OHS.

5. Procedures in place to alleviate hazards and minimize risks.

All new employees must attend new employee orientation which includes an
extensive safety overview. All Research employees are required to take and pass
online safety training annually.

- The most common hazards and risks include animal allergies, waste anesthetic gas, formaldehyde, carcinogens, inhalation hazards, infectious agents, biohazards, and hazards associated with non-human primates. To minimize these and other unanticipated risks, the following procedures and equipment are in place:
 - a. Mandates to use personal protective equipment (PPE) appropriate for each hazard. Appropriate PPE is provided in numerous locations in the animal facility, and may include gloves, eye protection, face mask, N95 respirator, cap, sleevelets, shoe covers, gown or Tyvek suit.
 - b. Education of investigators, lab personnel and VMU staff about risks, proper use of PPE, proper use of safety equipment, precautions, and appropriate responses in an emergent situation. This includes distribution of a Research Safety Manual, a VMU Emergency/Disaster Response Manual, mandated annual online safety training, and physical inspections of all laboratories. Online safety training includes the area of zoonoses, chemical, biological and physical hazards, handling of waste materials, personal hygiene, use of PPE as well as other risks imposed by the work environment. This training also includes precautions to be taken during pregnancy, illness or decreased immunocompetence.
 - Assessment of previous allergies and provision of PPE to prevent exposure to allergens.
 - d. A vented dumping station for dumping of soiled cages, and a requirement to wear N95 masks during the dumping of dirty bedding.
 - e. Air sampling for anesthetic gases by the hospital hygienist.
 - f. Chemical fume hoods for containment of chemical inhalation hazards, and optional monitoring for formaldehyde exposure.
 - g Class I and Class II Biosafety cabinets for containment of biohazards.
 - h. Proper maintenance of all facility safety equipment including regularly scheduled evaluations of anesthetic vaporizers, fume hoods, biosafety cabinets, fire extinguishers, safety showers, and eye wash fountains.
- Animal protocols involving hazardous agents (infectious or hazardous treatments that could pose a risk to personnel) are identified and reviewed by the IACUC and the RSS. Appropriate containment procedures and staff training must be in place prior to protocol approval.
- Such protocols are discussed with VMU staff so that procedures and animal housing can be located in ABSL-2 animal housing rooms to allow appropriate containment. Procedures for hazard containment may include: provision of biosafety cabinets, sticky mats, biohazard bins, sharps containers, and appropriate PPE.

 Research Service maintains SOPs to specify procedures for handling animals, caging, waste, and carcasses contaminated with infectious or otherwise hazardous agents.

6. Immunizations.

- All Research personnel who have contact with animals receive, as necessary:
 - a. The opportunity to update their tetanus vaccination status.
 - b. Any other vaccine that is considered safe and relevant to their research work.
- Records of employee vaccinations are maintained by OHS.

7. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Personnel are advised during training that if they are pregnant, planning to become pregnant, or are immunocompromised that they should consult with a health care provider to discuss their risks, and any additional safeguards they can take to reduce their individual risks. Appropriate PPE must always be worn.
- Special precautions are in place for these individuals. Pregnant women do not handle cage cleaning in any cat areas and are generally not permitted in radiology or where gas or anesthetics are used.
- All personnel are required to complete an annual form for the OHS which identifies their potential risks. Personnel may work directly with OHS, or their own personal health care provider.
- If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, and Research human resources.

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.

- Individuals, including maintenance personnel, delivery personnel, and hospital police receive information describing their potential risks, and must wear appropriate PPE where required.
- When necessary, such personnel are accompanied by VMU staff.
- Whenever possible, animals are removed from areas where maintenance work must be performed.

9. Response in the event of bites, scratches, illness, or injury.

• Bite wound first aid kits are available in visibly posted locations. OHS is available to offer care for minor injuries during normal business hours of operation. Emergency

room care is available in the hospital 24 hours per day, 7 days per week for more serious injuries.

• Following immediate care in OHS or the hospital ER, individuals who have sustained injuries are advised to follow up with their regular physician.

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

- Employees must immediately report all work-related injuries, including animal bites or scratches to their supervisor.
- Following treatment, the individual has 48 hours to report the details of the injury into the web-based employees' compensation operations and management program (eCOMP) database, which then generates an electronic report to the person's supervisor, and to Human Resources. OHS maintains records of illnesses and injuries, and Human Resources maintains eCOMP records of accident reports.

11. Additional precautions for personnel working with non-human primates.

- Research involving non-human primates is not conducted by Hines VA investigators. If non-human primates are to be housed on-site, the following will apply:
- Additional health and safety measures are in place for individuals who work directly with non-human primates. These include:
 - a. The OHS maintains an SOP (updated annually) detailing procedures to respond in the event of a bite or scratch by a non-human primate. Contact information is given for local and national experts in *Macacine herpesvirus* 1 (Herpes B virus).
 - An in-house training program which covers safe handling, possible zoonotic diseases including Herpes B virus, and precautions necessary when working with non-human primates.
 - c. Additional PPE (eye protection, face mask, N95 respirator, cap, gloves, sleevelets, shoe covers, gown or Tyvek suit) are available in the VMU and required as necessary for work with non-human primates.
 - d. Bite wound care kits are available in areas that house non-human primates.
 - e. Personnel who have contact with non-human primates as part of their duties must at a minimum successfully complete a tuberculin skin test or a chest radiograph (for tuberculin reactors) annually.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory of animals by species, in each facility is provided in Part X., Facility and Species Inventory.

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

1. IACUC Members

- Each IACUC member is provided with access to the Edward Hines, Jr. VA Hospital Research SharePoint site containing the regulatory and instructive information listed below for animal care and use personnel. This information is updated as necessary, and members are notified when new information is available.
- IACUC members are required to take and pass the online CITI Program courses, "Working with the IACUC" and "Essentials for IACUC Members." Working with the IACUC must be repeated every three years.
- IACUC members are given additional information and training on IACUC composition, responsibilities, procedures, authority, and regulation. This training is provided in the form of in-person instruction by the Chair, and an IACUC Member Training Manual that is provided to each member and updated annually.
- The Research Service may support attendance of IACUC Staff and members at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC, or SCAW meeting if desired.

2. Animal Care and Use Personnel

- Edward Hines, Jr. VA Hospital Research maintains an Intranet SharePoint site. All animal care personnel, IACUC members, IACUC staff, key Research administrative staff, and Research personnel involved in animal use are provided access to the instructive documents stored on this site.
- Personnel are notified when new documents are made available. These documents include:
 - a. The Edward Hines, Jr. VA Hospital VA PHS Animal Welfare Assurance,
 - b. AAALAC Program Description,
 - c. VHA Handbook 1200.07,
 - d. PHS Policy,
 - e. USDA Animal Care Policy Manual (2015),
 - f. The Guide,
 - g. The IAMLACU Booklet, and
 - h. Department of Defense instructions on the use of animals
 - i. IACUC forms.
 - j. Animal care SOPs,
 - k. Policies, and instructive guidelines,
 - I. OHSP forms and information,
 - m. The VMU and hospital emergency/disaster response manuals,
 - n. The AVMA Guidelines on Euthanasia (2020), and The AWA and USDA Regulations.

- All personnel involved in animal husbandry duties within the VMU must have appropriate training and experience for the positions they hold. VMU staff has multiple continuing education opportunities, including in-house training, Research Service or VA training, and Chicago branch AALAS meetings.
- All personnel involved in research animal use at Edward Hines, Jr. VA Hospital must take and pass required online courses at citiprogram.org, including "Working with the IACUC" and any relevant species specific course. This training includes concepts important in the humane use of research animals. It covers topics such as the three R's, the use of analgesics and anesthetics, USDA pain and distress categories, and how to perform a power analysis. CITI training must be completed by all personnel at least every three years.
- All personnel working with animals must take and pass additional online training mandated by VA through the Talent Management System (TMS) annually. Such training includes laboratory safety, information security, and other relevant training required by VA. Research Service maintains records of completion of all required training for all Research personnel as per the VA Records Control Schedule 10-1.
- All personnel performing procedures using animals must be identified in an IACUC approved ACORP.
- Prior to approval of any protocol requesting the use of animals, the VMO and the IACUC evaluates the qualifications and experience of all research staff (including principle investigators, research technicians, students, and all other personnel) listed on the protocol. Approval may only be granted once the VMO and the IACUC are satisfied that the personnel are qualified to carry out any procedure listed in the protocol, or that an appropriate plan for training of personnel is in place.
- Prior to addition of any new personnel to an approved ACORP, the qualifications/ experience of the individual is evaluated by the IACUC office, and the individual must take and pass all required online training courses including mandated CITIProgram courses, and VA TMS training.
- Laboratory Principal Investigators are responsible for ensuring that all personnel
 in their laboratory receive any project-specific instruction necessary for the
 performance of their duties before they are permitted to conduct any procedures on
 live animals. Such training plans must be specified and approved by the IACUC in
 an ACORP.
- For investigators transferring from other facilities at which they have received similar training, verification of previous training <u>may</u> be accepted in lieu of <u>some</u> Institutional 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 reevaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC 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.

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 Hospital Director.
 - 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 three 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 October 1-September 30. The IACUC, through the Institutional Official, will submit an annual report to OLAW by December 1 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.
- 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 Hospital Director.
- 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. Authoriz | zed Institutional Official | |
|-------------|--|---|
| Name: Jam | nes Doelling | |
| Title: Hosp | ital Director | |
| Name of In | stitution: Edward Hines, Jr. | VA Hospital |
| Address: (s | street, city, state, country, p | ostal code) |
| 5000 South | n 5 th Ave., Hines, IL 60141-3 | 3030 |
| Phone: | (b)(6) | Fax: (b)(6) |
| E-mail: | (b)(6) @va.gov | |
| understand | The state of the s | ity on behalf of this Institution and with an onsibilities under this Assurance, I assure the pecified above. |
| Signature: | (b)(6) | Date: 01/25/2021 |

| B. PHS Approving Official (to be completed | d by OLAW) | | |
|--|-----------------------------------|--|--|
| Name/Title: | Paula Knapp, Assurance Officer | | |
| Office of Laboratory Animal Welfare (OLAW National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465 | (b)(6) | | |
| Signature: | Date: January 27, 2021 | | |
| Assurance Number: D16-00374 (A3616- | -01) | | |
| Effective Date: January 27, 2021 | Expiration Date: January 31, 2025 | | |

VIII. Membership of the IACUC

| Date: September 13 | , 2020 | | | | | | |
|--|------------------------|--|------------------------------|--|--|--|--|
| Name of Institution: I | | | | | | | |
| Assurance Number: | D16-00374 (A36 | 616-01) | | | | | |
| IACUC Chairperson | | | | | | | |
| Name*: (b)(6) | (b)(6) | | | | | | |
| Title*: Chief, Neuroso | | 1 | Degree/Credentials*: MD, PhD | | | | |
| Address*: (street, city Research Services (Edward Hines, Jr. VA 5000 South 5 th Ave., | 151) A Hospital | 9) | Ü | | | | |
| E-mail*: (b)(6) | @va.gov | | | | | | |
| Phone*: (b)(6) | | Fax*: | (b)(6) | | | | |
| IACUC Roster | | | | | | | |
| Name of Member/ Code** | Degree/ Credentials | Position Title*** | | PHS Policy Membership Requirements**** | | | |
| (b)(6) | MD, PhD | Chief, Neuroscience Research | | Scientist, Chair | | | |
| (b)(6) | DVM, PhD | Veterinarian | | Veterinarian/VMO | | | |
| Member 1 | PhD Research Scientist | | eientist | Scientist, Associate Chair | | | |
| Member 2 | PhD | Research Scientist | | Scientist | | | |
| Member 3 | MD | Research Sc | eientist | Scientist | | | |
| Member 4 | PhD | Research Scientist, Loyola Representative | | Scientist | | | |
| Member 5 | PhD | Research Scientist, Lovell FHCC Representative | | Scientist | | | |
| Member 6 | PhD | Research Scientist | | Scientist | | | |
| Member NA | MA | Manager, Retired | | Non-affiliated Member | | | |
| Member NS | BBA | Military Colonel, Ret. | | Nonscientist | | | |
| Alternate 1 | MD, PhD | Research Scientist | | Alternate Scientific Member | | | |
| Alternate 2 | PhD | Research Scientist | | Alternate Scientific Member | | | |
| 0 " | | 140110.0 | | | | | |
| Coordinator | | IACUC Coor | ainator | Nonvoting Member | | | |

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

Nonscientist A member whose primary concerns are in a nonscientific area In

evaluating the qualifications of an individual to serve as a nonscientific member, the CEO should consider appointing those with a naïve attitude with regard to science and scientific activities. A person without scientific training meets the Policy's intent, such as an ethicist, lawyer, or member of the clergy, as the Policy gives as examples. Some other examples include librarians, those working in business or finance, or instructors in English, history, or other liberal arts disciplines. When the rationale for categorizing an individual as a nonscientist is not apparent based on their

occupation or training, the institution should maintain written

documentation of the reason for the categorization

Nonaffiliated The nonaffiliated member must represent the general community interests

in the proper care and use of animals. The nonaffiliated member must not be (1) a laboratory animal user or former user, (2) affiliated with the institution, or (3) an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling. In evaluating the qualifications of an individual to serve as a nonaffiliated member, the CEO should confirm the appointee has no discernible ties or ongoing affiliation with the institution. Regarding service of former employees or students as nonaffiliated members, the appointing official must be assured that the person is not in any way obligated to the institution. Real or perceived conflicts of interest must be avoided to ensure the IACUC's and the institution's integrity. Appointment of an individual who is unambiguously unaffiliated is the most effective way to

fulfill the intent of the Policy

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: Lynn Gardella | |
| Title: IACUC Coordinator | |
| Phone: 708-202-5836 | E-mail: lynn.gardella@va.gov |
| Contact #2 | |
| Name: Phillip Williams | |
| Title: VMU Supervisor | |
| Phone: 708-202-2935 | E-mail: phillip.williams@va.gov |

X. Facility and Species Inventory

| Date: September 17, 2020 | |
|--|--|
| Name of Institution: Edward Hines, Jr. VA Hospital | |
| Assurance Number: D16-00374 (A3616-01) | |

| Laboratory, Unit, or Building [*] | Gross Square Feet [include service areas] | Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog] | Approximate Average Daily Inventory |
|---|---|---|--|
| Edward Hines, Jr. VA Hospital | 28000ft ² | Rats | 55 |
| u | | Mice | 121 |
| " | | Dogs | 0 |
| u | | Hamsters | 0 |
| u | | Pigs | 0 |
| ш | | Guinea Pigs | 0 |
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Unless otherwise indicated, mice and rats means mice of the genus *Mus* and rats of the genus *Rattus* that are purposely bred for research.