Syracuse Department of Veterans Affairs Medical Center

Assurance Number A3436-01

Animal Welfare Assurance

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

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, NASA 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 Syracuse VAMC are physically located at 800 Irving Avenue Syracuse, NY 13210. There are no off-campus satellite facilities and/or other covered components.

B. The following are other institution(s), or branches and components of another institution: The Central New York Research Corporation (CNYRC), the VAMC's affiliated non-profit organization, which is also physically located at 800 Irving Avenue, Syracuse, NY 13210. The CNYRC administers all non-VA grants and contracts. By written agreement all such research activities of the CNYRC are governed by the policies of the Syracuse VA Medical Center. The VAMC's affiliate SUNY Upstate Medical University has its own separate Assurance.

II. Institutional Commitment

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

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

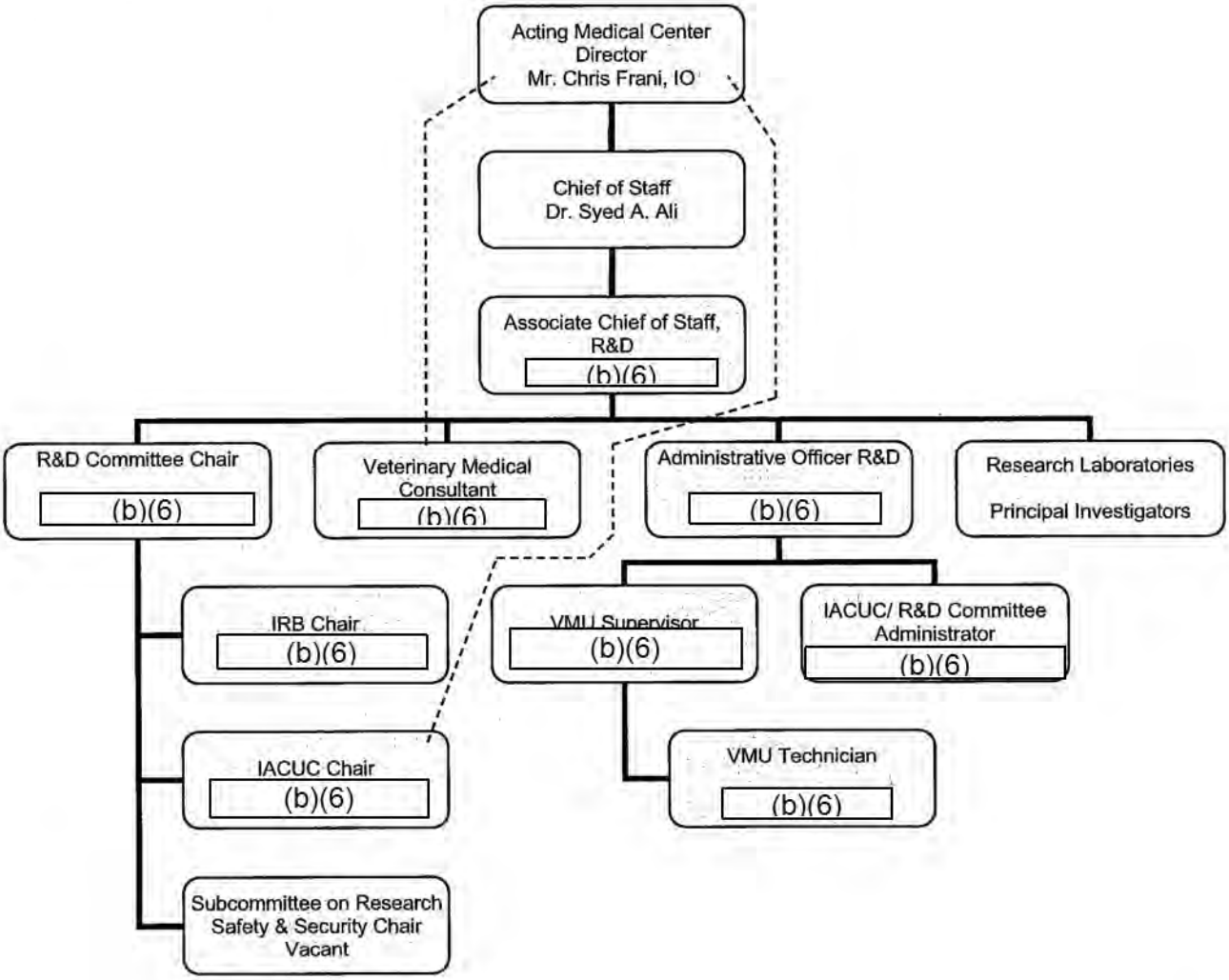
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand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

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

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

III. Institutional Program for Animal Care and Use

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



- As depicted above, there are open and direct lines of communication between the Institutional Official (IO) and the IACUC and between the IO and the Consulting Veterinarian. The IACUC Chair meets with the IO on a semiannual basis and acts as the conduit for any issues the members may have. The semiannual report previously approved by the IACUC is also reviewed and signed by the IO at this meeting. IACUC members can also contact the IO directly, if they wish to do so.

- While reports and other written communication may be routed through administrative channels, they can be neither influenced nor changed by any person(s) or entity(ies) in such channels after being submitted by the originator.

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) Director of the Department of Laboratory Animal Resources and Attending Veterinarian at SUNY UMU & Veterinary Medical Consultant, Syracuse VAMC

   Qualifications:
   - Degrees: D.V.M., Colorado State University, 1991.
   - Training and/or experience in laboratory animal medicine: Three-year residency in laboratory animal medicine at the University of Michigan; Diplomate, American College of Laboratory Animal Medicine (ACLAM); Member of National AALAS since 1993 and a member of the Upstate Branch since moving to New York in 2000. (b)(6) has been active on several committees at the national level for both AALAS and ACLAM and is currently a member of AAALAC International's Council on Accreditation.

   Authority: (b)(6) has delegated program authority and responsibility for the Institution's animal care and use program, including unfettered access to all animals. (b)(6) is empowered to unilaterally intervene in any aspect of any animal research program that (b)(6) believes to depart from an approved protocol, or to examine and treat any animal that is in (b)(6) judgment in need of such examination or treatment.

   Time Contributed to Program: (b)(6) is present at the Institution an average of approximately 4 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 three 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/Services: In (b)(6) absence, Cornell University veterinarians cover back-up services on a rotating basis. These veterinarians have delegated program authority and responsibility to implement the PHS Policy and the recommendations of the *Guide*. Cornell University is a 1-hour commute to the facility and the veterinarian on call will maintain constant access via cell phone. The amount of time contributed to the program is as needed to provide required back-up support.

   Name: (b)(6) Director of the Center for Animal Resources and Education (CARE) at Cornell University and CARE veterinarian team members

   Qualifications:
   - Degrees: D.V.M. , Diplomate European College of Laboratory Animal Medicine (DECLAM), State University Ghent, Belgium; AVMA ECFVG certificate; licensed in California

- Training or experience in laboratory animal medicine or in the use of the species at the institution: Over 41 years in lab animal medicine, clinical veterinary practices, administration of animal programs, resources and facilities.

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy, IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations. The Institutional Official appoints the members of the IACUC.

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 evaluations 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 be limited to, a review of the following:
     a. Institutional and Individual Responsibilities
     b. IACUC Membership and Functions;
     c. IACUC Records and Reporting Requirements;
     d. Husbandry and Veterinary Care (all aspects);
     e. IACUC Member and Personnel Qualifications (Experience and Training);
     f. Occupational Health and Safety;
     g. Emergency and Disaster Plans;
     h. Safety and Security (institutional and personnel)
     i. Physical Plant (functional areas and operations)

   - If program deficiencies are noted during the review, they will be categorized as significant or minor and the IACUC 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 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 will adhere to flexibilities indicated within NIH Notice NOT-OD-20-088, of which under special circumstances the timing of facility inspections may extend 30

days beyond the six-month interval from the last review, if there is no forward drift of the date from year to year, as well as participant guidelines. 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 procedural areas.

- The areas inspected include, but are not 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 IACUC 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 IACUC 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 IACUC 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 from participating in any portion of the inspections.

- For individual facilities that house or involve only non-USDA covered species, the IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

3. Prepare reports of the IACUC evaluations as set forth in the 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 Administrator or Chairperson who, in turn, will draft the reports using the standard VA format that is based on 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 the reports will so state. Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using Full Committee Review (FCR), Designated Member Review (DMR), or Veterinary Verification and Consultation (VVC) 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, e.g., 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.

- Until resolution is complete, deficiencies remain on the IACUC agenda and are tracked in the IACUC minutes.

- 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 IACUC. This is generally done at the next IACUC meeting.

- The final reports will be signed by a majority of voting 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 120 days following the evaluation.

- A signed copy of the report is sent to the VA Chief Veterinary Medical Officer, plus the original is maintained on file within the Department of Research.

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

- It is the policy of this Institution that there are no restrictions on who can report an alleged incident or concern.

- Upon hire, individuals working with animals are provided a document entitled, *Whistleblower Instructions and Contact Information,* which explains how and where to report animal welfare concerns. Each individual must sign and date this document declaring they have read and understand the instructions. This document is also posted in the first-floor hallway of Research Service, on the IACUC Administrator's door, and within the Veterinary Medical Unit. An envelope is available on the IACUC Administrator's door for anonymous submissions. These instructions are not posted on the institutional website as it is not suitable for such purposes.

- Any individual may report concerns to the IO, IACUC Chair, Veterinary Medical Consultant, Research Administration, or any member of the IACUC. Any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.

- Contact information is available for all VA employees via an electronic facility directory, and contact information for key personnel is posted.

- Individuals involved in biomedical research receive a packet of policies and procedures when completing the training program and this packet includes a list of contact information for submitting anonymous reports of deficiencies.

- All reported concerns will be brought to the attention of the full IACUC. Unless they are of a sufficiently serious nature to warrant holding a special meeting, such issues or concerns will be discussed at the next regularly scheduled IACUC meeting.

- The Veterinary Medical Consultant, the IACUC Chair and/or the Associate Chief of Staff for Research and Development, will determine if the concern warrants the need for a special meeting.

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

- The IACUC 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 letter. Reports to OLAW will be in writing and through the IO. Initial 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 IACUC.

- The IACUC makes recommendations in writing (IACUC minutes) to the IO through the R&D (Research & Development) Committee, of which the IO is a member, regarding any aspect of the institution's animal program, facilities, or personnel training.

- The R&D Committee will, in turn, take appropriate action and note this action in the R&D Committee's minutes.

- The Associate Chief of Staff, R&D or his designated alternate, the IACUC Chair or his designated alternate, and the Veterinary Medical Consultant also meet with the IO on a semiannual basis, at which time recommendations are brought forward through the written Table of Deficiencies within the Semiannual Program Review Report.

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:

<u>Submission, Pre-review, & Distribution</u>

- Development of an animal protocol begins through consultation with the Department of Research and the Veterinary Medical Consultant. Investigators are required to complete a protocol and submit it to the Research Office.

- New protocols are submitted electronically to the IACUC Administrator.

- A pre-review is conducted by the IACUC Administrator for any administrative revisions needed.

- Members are notified of protocols for review within the written agenda electronically forwarded to them prior to convened meetings. Annual renewals and amendments, with the exception of amendments that undergo the VVC process, are electronically distributed to the IACUC members in order to determine whether FCR is required.

IACUC Review

- 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. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian;

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

g. Methods of euthanasia used will be consistent with the current American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, unless a deviation is justified for scientific reasons in writing by the investigator.

- 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 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)

- Prior to the review, each IACUC member will be provided with a written description of activities (protocols) that involve the care and use of animals.

- Protocols are electronically distributed to the members when the email informs them of the next meeting.

- The IACUC holds face to face meetings for the review of all new protocols and triennial reviews. Teleconferencing occurs only in rare instances when a member is unable to be on site.

- There are no special attendance requirements for the meetings other than obtaining a quorum.

- Consistent parliamentary procedures must be used to conduct business during IACUC meetings. The parliamentary system used needs to allow for discussion of each item, motions, seconds to motions, and official votes tallied by yeas, nays, and abstentions. To protect anonymity, the identity of the members making a motion, seconding a motion, and voting yea, nay, or abstain is not recorded. A motion must be seconded for a vote to occur. For a motion to pass, a majority of the quorum present must vote affirmatively.

- Investigators may attend the review of their animal protocol to provide immediate clarification and/or discuss desired changes. However, the voting is done in the absence of the submitting investigator.

- The possible outcomes of FCR are as follows:

  a. Approval;
  b. Modification(s) required to secure approval, that is, approvable pending submission, review, and approval of the required clarification and/or changes (modifications); or
  c. Approval withheld

- Review and Approval 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 - All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous agreement to use designated member review subsequent to full committee review 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 full committee review of the protocol. The investigator provides the needed information to the IACUC Administrator, who then communicates the information to the designated reviewers until concurrence for approval has been reached. If decisions are not unanimous, the protocol is referred back for FCR.

If DMR is used, the approval date is the date that the final revised protocol is approved by the designated reviewer.

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

Designated-Member Review

- In instances of DMR, the item will be distributed to IACUC members to allow all members the opportunity to call for FCR.

- Records of polling of members to obtain concurrence to use DMR and approval of items by 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 full committee review is not requested for an annual review or amendment, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review the items and have the authority to approve, require modifications in (to secure approval) or request FCR.

- 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 DMR method may not be conditional.

- After all required modifications are made, a final revised protocol renewal or amendment 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.

- The possible outcomes of DMR are as follows:
  a. Approval,
  b. Require modifications of the protocol to secure approval, or
  c. Request full-committee review.

Special or Expedited Reviews

- There are no alternative processes for special or expedited reviews.

Required Additional Approvals

- The IACUC's final decisions are forwarded to the R&D Committee for use in their final deliberation on a new proposal. The R&D Committee cannot approve an animal study unless it has been approved by the IACUC.

- An approved Animal Component of Research Protocol (ACORP) bears the signature of the investigator, the consulting veterinarian, the chairperson of the IACUC, and other officials as applicable, e.g., biosafety, radiation, human patient care areas/equipment, and explosive agents. The decision of the R&D Committee is recorded in their meeting minutes.

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 below and in IACUC approved policies, review and approval of proposed significant changes will comply with the same requirements as review and approval of new protocols under PHS Policy IV.C. See Part III.D.6. above.

- Examples of changes considered to be significant include, but are not limited to, the following:

  a. in the objectives of a study;
  b. from nonsurvival to survival surgery;
  c. resulting in greater pain, distress or degree of invasiveness;
  d. in housing or use of animals in locations not overseen by the IACUC;
  e. in species;
  f. in Principal Investigator and
  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, 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 and approval of items h. – j. may also be handled administratively in consultation with the VAMC Syracuse veterinarian who is 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.

- 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 written policies related to veterinary verification and consultation and administrative review will be adopted [reviewed and approved] by formal action of 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.

- Further, changes approved administratively using VVC are subject to the following: Review and approval of significant changes within the below categories may be administratively approved utilizing the VVC method, providing they meet defined criteria and do not violate any of the above restrictions preventing administrative review. The categories and conditions under which changes may be administratively approved by the consulting veterinarian are:

    a. Anesthesia, Analgesia, Sedation, or Experimental Substances
        i. Changes in anesthesia, analgesia and sedation are only to agents and dosages listed on the currently approved *Formulary for Laboratory Animals, Third Edition;*
        ii. Changes in experimental substance administration are only to substitute equivalent agents at established safe dosages for that species;

b. Euthanasia - The proposed new method of euthanasia is approved by the AVMA Guidelines for the Euthanasia of Animals;

c. Experimental Procedures - Changes in the duration, frequency, type, or number of experimental procedures are only to substitute procedures that should be equivalent to approved procedures and/or improve animal well-being and/or improve the value of the data collected. These changes do not include:
   i. from non-survival to survival surgery;
   ii. resulting in greater pain, distress, or degree of invasiveness;
   iii. in species;
   iv. in study objectives;

d. Additional Animals
   i. The species involved is not regulated by the USDA;
   ii. The increase does not constitute greater than 10% of the original number approved;
   iii. The increase would not constitute greater than 30% of the original number approved when added to previous requests;

e. Housing Location - Requests to house animals (> 12 hours) in facilities other than the Veterinary Medical Unit (VMU) does not involve a species regulated by the USDA and the space meets the minimum requirements for the species as described in the *Guide*. This only includes laboratories that are already overseen by the IACUC.

- VVC Administrative Review Process:

a. The IACUC Administrator will route the addendum form to the consulting veterinarian who will determine if the proposed change meets the criteria for administrative review;
b. If the consulting veterinarian determines that the addendum does not meet the criteria for administrative review, it will be processed for review according to IACUC-approved policies;
c. If the consulting veterinarian determines that the addendum meets the criteria for administrative review, the consulting veterinarian will interact directly with the PI to resolve any questions or concerns;
d. When all questions/concerns have been resolved, the consulting veterinarian will route the approved addendum to the IACUC Administrator for final processing;
e. The IACUC Administrator will verify personnel training for any added procedures;
f. The IACUC Administrator will notify the PI of approval.

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:

- If the new protocol has been approved, investigators are notified electronically by correspondence from or on behalf of the IACUC Chair and the ACOS, R&D.

- Principal Investigators are notified electronically by correspondence from or on behalf of the IACUC Chair, if modifications have been requested or approval is withheld.

- The written correspondence will delineate modifications required to secure approval.

- 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. If the investigator decides to resubmit, then the revised protocol will then be submitted for full IACUC review.

- The Institutional Official is notified by review of the IACUC meeting minutes at R&D Committee meetings.

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 and by the IACUC during semiannual inspections.

   - The Research Compliance Officer (RCO) is charged with the responsibility of auditing protocols every three years at a minimum. RCO recommendations and/or remedial actions resulting from audits are reviewed by the IACUC.

   - The IACUC provides continuing review of all animal use protocols and performs unannounced semiannual inspections during which laboratory personnel may be interviewed and/or observed.

   Continuing / Periodic Protocol Review

   - USDA Covered Species – Protocols are reviewed at least once every twelve months by a voting member or members of the IACUC.

   - Non-USDA Covered Species – Protocols are reviewed at least once every three years by a voting member or members of the IACUC.

   - Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the IACUC and the R&D 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 and other regulatory bodies as appropriate. Initial/preliminary reports to OLAW may be made verbally.

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

1. Administration/Management

- The Subcommittee on Research Safety and Security (SRSS) is responsible for developing and implementing an OHSP for personal hygiene, protective safety measures, safe use of hazardous materials, and preventive medicine for personnel engaged in the care and use of research animals or are otherwise occupationally exposed.

- The Occupational Health professionals (OHPs) must ensure that all personnel are given the opportunity to participate in the OHSP.

- The OHPs facilitate this program and monitor all personnel who have contact with or exposure to animals or unfixed animal tissues or fluids.

2. Scope

- The OHSP covers all personnel involved in animal care and/or use or are otherwise occupationally exposed.

- All personnel are given the opportunity to either participate in the program, participate in a similar program provided by an affiliate or other institution, or sign a waiver declining to participate. Following completion of an individual health and job related risk assessment, personnel may decline to receive services not required by the VA facility to protect the health of the animals or other personnel (e.g., vaccinations, respiratory protection). Personnel who decline optional services are considered to be enrolled in the OHSP as long as the VA facility documents that they were given the opportunity to receive these services.

- The waiver is to make it clear that non-participation in the OHSP could result in adverse health effects and may place restrictions on access to certain areas. An OHP would be involved in discussing the waiver with the individual.

- As a condition of employment, employees performing specific animal-related duties are required to have immunizations or tests.

- New personnel are enrolled in the program upon hire.

- A written release is provided from the Occupational Health Office before access to the VMU is granted.

3. Health Histories and Evaluations

- A Report of Health/Medical History must be completed upon hire and annually thereafter. This questionnaire is submitted by the employee either directly to the Occupational Health Office or in a sealed envelope to Research Administration. The intent is to help identify any potential increased health risks by evaluation of work exposure to animals and/or tissues and the personal health history. This information remains confidential between the individual and the OHP. Upon initial review, the OHP evaluates the questionnaire and signs and dates the form. An annual review of this form is also completed to ensure there have been no changes to the employee's health over the past year that may increase the risks from exposure to animals.

- All new employees will have animal contact receive pre-exposure tuberculin testing, tetanus immunization, Hepatitis B (optional), a physical, and any other vaccinations available for protection from exposure to research-specific infectious diseases.

- Tuberculosis skin testing or a medical questionnaire are required (and provided) annually, with the exception of personnel who work in the Biosafety Level III facilities, where it is required semiannually.

- OHPs are always available for employees to discuss any health issues which might be job related.

4. Hazard Identification and Risk Assessment

- The OHSP is based upon hazard identification and risk assessment and is the primary responsibility of the SRSS. These responsibilities include inspections, training, investigation, documentation, and safety program review.

- A safety protocol must be reviewed and approved by the SRSS before any activities involving hazardous agents may commence. The SRSS and the IACUC interact effectively to ensure that adequate safety measures are mandated to protect personnel who work in the animal research facility when biological, chemical, or radiological agents are in use.

5. Procedures in Place to Alleviate Hazards and Minimize Risks

- All new employees who will have exposure or contact with animals are provided with documentation explaining zoonotic diseases, hazards, and risk assessments.

- All proposed studies, whether involving hazardous or potentially hazardous agents, are evaluated, approved, and monitored by the Research & Development

Committee and the Subcommittee on Research Safety and Security. These committees provide critical evaluation of each project to assure protection of staff personnel and adequate safety measures.

- Training is provided in accordance with the safety program established by the VAMC and the Subcommittee on Research Safety and Security. Annual training in various subjects such as blood-borne pathogens, infectious disease control, universal precautions, etc. is provided. All personnel who work with animals exposed to hazardous agents are trained in proper procedures to work with the animals and related waste and equipment.

- The VMU facility contains one Animal Biosafety Level 3 (ABSL3) facility. Hazardous agents are contained in the study area and animal housing area by containment at the level of the primary enclosure, disinfection of the materials prior to their transport, negative airflows, and the removal of personal protective equipment prior to leaving the area. The ABSL3 facility contains an anteroom that comprises twenty square feet and is equipped with a separate filtered exhaust, fire sprinkler, and an emergency egress button. This room contains a separate hepa-filter unit which pre-filters the exhaust prior to entering the main exhaust system. The room is also equipped with an emergency battery backup flood light and a type II biological safety cabinet which is certified semiannually. Mice in this room are housed in micro isolator cages. It is mandatory that all manipulations are accomplished under the biological safety cabinet located within the room. All waste, dirty cages with soiled bedding, water bottles, feeders, lids and environmental enrichment devices are double bagged in biohazard bags and disinfected with approved disinfectant. Sufficient contact time is allowed prior to exiting the room. Items are then strapped to a dedicated cart and taken to the autoclave located within the VMU for sterilization. The autoclaved bedding is dumped into double red bags in a polyethylene barrel and disposed of in the regulated medical waste stream. Laboratory areas other than the ABSL3 facility are equipped with fume hoods and laminar flow hoods, as needed.

- All employees exposed to anesthetic gases and/or paraformaldehyde are monitored by the Respiratory Protection Program Administrator by the use of personal monitoring devices. All employees also have access to OSHA hazard notices and Safety Data Sheets. PPE within BSL2 areas includes scrubs, disposable gown or lab coat, mask (if desired), and gloves.

- For BSL3 areas, a wraparound disposable gown, a powered air purifier respirator (PAPR), disposable shoe covers, and gloves are worn. The disposable items are removed and discarded when exiting the biohazardous area. Power air purifying respirators are disinfected prior to exiting the room.

6. Immunizations

- Tetanus immunizations are provided and mandated for all persons working with animals.

- Employees are encouraged to participate in the Hepatitis B series vaccination program provided free of charge by the VAMC.

7. Precautions taken during pregnancy, illness or decreased immunocompetence

- A completed Report of Medical Health/History questionnaire is reviewed by Occupational Health Officials upon hire and annually thereafter. This document helps identify any potential increased health risks that may result from the combination of work exposure to animals and/or tissues and the individual's personal health history. The questionnaire indicates certain medical conditions that may result in increased risks which could be minimized with proper equipment or procedures. A completed questionnaire indicating an increased health risk is addressed by the OHP on an individual basis. This interaction will include the potential risks and precautions to be taken. Women who are pregnant and work with animals need to make their physician and the OHP aware of the pregnancy as early as possible so potential risks can be identified. In addition, personnel are provided printed material regarding the Occupational Health and Safety Program upon hire, which includes physical hazards, allergies, zoonotic diseases, illness, risks during pregnancy, and hazardous agents. Allergens are also addressed in the mandated web-based training and is part of the preventative medicine program, as outlined in the medical questionnaire. All research personnel who have animal contact are trained to be responsible for reducing their exposure to allergens, pathogens, and chemicals through safe work practices.

- The frequency of interaction with Occupational Health Officials required for each person will vary with the risks and durations of exposure to animals and/or unfixed animal tissues. Personnel with higher risk may need annual or more frequent interaction, while personnel with limited risk may need less frequent interaction. If warranted, work restrictions and accommodations will be coordinated among the individual, their supervisor, Occupational Health Officials, and VA Human Resources.

- Pregnant women and/or individuals with illness or decreased immunocompetence should discuss these conditions with their physician and VA Occupational Health Officials as early as possible so the potential risks can be identified and relayed to the employee.

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

- Personnel who are exposed on a routine limited basis must complete the initial and annual Report of Medical/Health History. The Occupational Health Office provides services to these types of personnel.

- All visitors and outside contractors who may be exposed to hazards are provided with an information sheet indicating the potential risk for exposure to hazards upon entrance into Research Service. Signage indicating a potential risk for allergen exposure is posted on entrance to the VMU. Work performed within laboratories must be coordinated with laboratory staff members. These staff members accompany outside personnel, provide information specific to their laboratory and any PPE required. Contractors for autoclave and cagewasher maintenance (the only VMU equipment not maintained by VA personnel) have been provided with the necessary information and are escorted by VMU staff.

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

- All illnesses, injuries, animal bites, animal scratches, and cuts sustained in the animal research facility or research laboratory must be reported promptly to the employee's supervisor and/or the Administrative Officer, R&D. The employee is escorted by their supervisor (if available) to the Occupational Health Office for evaluation.

- First-aid kits are available in the hallway on each floor of Research Service. The Subcommittee on Research Safety and Security and Research Administration are responsible for the maintenance of these kits.

- The Occupational Health Office and/or the VA Emergency Department is responsible for emergency treatment of all job-related injuries. Staff are trained to call for an immediate response to a medical emergency by dialing 55555.

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

- All injuries and illnesses must be submitted into the portal for Employee's Compensation Operations and Management. The OHP also maintains an electronic medical record that tracks workplace incidents.

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

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

1. IACUC Members

- Each IACUC member is informed of the availability of the following reference documents:

  a. The *PHS Policy for the Humane Care and Use of Laboratory Animals;*
  b. The *National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;*
  c. The *ARENA/OLAW IACUC Guidebook*, and local guidance materials;
  d. The AVMA Guidelines on Euthanasia;
  e. A copy of this Assurance.

- A copy of the institution's current PHS Assurance is provided to every member as a component of the IACUC introductory materials.

- All members are required to accomplish the VA web-based training "Essentials for IACUC Members". This will be done initially and then at least once every 36 months. This web-based training includes research and testing methods to minimize animal numbers required to obtain valid results and limit pain and distress.

- Attendance at an IACUC 101, 202, Advanced, or similar course is offered and may be substituted for any refresher IACUC training session.

- Documentation of all IACUC training will be maintained for at least 3 years.

2. Animal Care and Use Personnel

- The Assurance is reflective of the AAALAC Program Description which is reviewed semiannually by the IACUC. All research personnel who use animals are trained on the laws and regulations which ensure that they are aware of the existence of the Assurance and on all applicable aspects of the program which are consistent with the Assurance. Any research personnel can request to see the Assurance at any time through the Research Administration Office.

- The IACUC verifies personnel have adequate training and are qualified to perform their duties. Procedures by which this is accomplished are the following:

Prior to approving any protocol, the IACUC ensures that all staff listed on the protocol have been adequately trained. The experience of all personnel performing procedures is listed on the animal protocol that the IACUC reviews. When new staff is added to an existing protocol, either designated reviewers or the IACUC Chair review training documentation prior to the new person starting work. New employee documentation includes a training sign-off sheet that is placed in their HR file. A training summary sheet is also provided by all those who work with animals. This summary sheet is reviewed initially and in conjunction with the annual and triennial review, if there have been changes to the training summary over the review period. A spreadsheet is maintained by Research Administration, tracking all training that is required in an ongoing basis and any delinquencies are listed on the R&D Committee agenda for required action. The effectiveness of training programs is based on performance that is evaluated by the VMC and/or the employee's supervisor and any serious issues are reported to the IACUC.

- All personnel involved with animal studies are required to accomplish web-based training "Working with the IACUC" and a species-specific web course that covers the species proposed for use before the start of any work utilizing animals and then at least once every 36 months. This web-based training includes research and testing methods to minimize animal numbers required to obtain valid results and limit pain and distress. This training is documented with certificates and entry into an education database.

- Several other VA training modules are available for personnel involved with animal studies. These courses include topics such as alternatives, avoiding unnecessary duplication, USDA pain/distress categories, psychological enrichment, etc. More detailed training is handled through information available in the VMU and training in the laboratory of each investigator. Methods of handling, restraint, proper injection techniques, and general lab animal husbandry are some of the elements which are covered.

- VA on-line training is also provided to cover areas such as infectious diseases and blood-borne pathogens.

- In addition to the above, all new VMU animal care personnel undergo an initial training period directly supervised by the VMU Supervisor. Their training covers the facility layout, equipment operation, animal husbandry, and standard operating

procedures. All VMU animal care personnel are advised to strive towards AALAS certification. Continuing education classes in husbandry are available through AALAS.

- The training includes instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). 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.

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 6 months and will be re-evaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to 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 3 years:

1. A copy of this Assurance and any modifications made to it, as approved by the PHS;

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld;

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Acting Medical Center 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 3 years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked);

2. Any change in the description of the Institution's program for animal care and use as described in this Assurance;

3. Any change in the IACUC membership;

4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, the Acting Medical Center 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. Authorized Institutional Official	
Name: Mr. Chris Frani	
Title: Acting Medical Center Director	
Name of Institution: Syracuse Department of Veterans Affairs Medical Center	
Address: *(street, city, state, country, postal code)* 800 Irving Avenue Syracuse, N.Y. 13210	
Phone: (315) 425-4400 ext (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 support and encourage the humane care and use of animals as specified above.	
Signature (b)(6)	Date: 7/26/2021

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

Name/Title:
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500
Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)
Phone: +1 (301) 496-7163
Fax: +1 (301) 915-9465

(b)(6)

Signature:

Date:

Assurance Number: D16-00275 (A3436)

Effective Date: 7/21/2020

Expiration Date: 7/31/2024

VIII. Membership of the IACUC

Date: April 2020			
Name of Institution: Syracuse Department of Veterans Affairs Medical Center			
Assurance Number: A3436-01			
IACUC Chairperson			
Name*: (b)(6)			
Title*: Research Physiologist		Degree/Credentials*: Ph.D. Scientist	
Address*: *(street, city, state, zip code)* 800 Irving Avenue Syracuse, NY 13210			
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)	D.V.M., DACLAM	Veterinary Medical Consultant, Dir. LAM, SUNYUMU	Veterinarian
(b)(6)	B.S.	Retired Section Sales Operations Manager from Philip Morris	Non-affiliated Member & Nonscientist
(b)(6)	N/A	Ph.D. candidate in the Department of Religion at Syracuse University	Nonscientist
(b)(6)	L.V.T.	VMU Supervisor	N/A

* 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.

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

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: (b)(6)	
Title: IACUC Administrator	
Phone: (b)(6)	E-mail: (b)(6) @va.gov
Contact #2	
Name: (b)(6)	
Title: Administrative Officer, R&D	
Phone: (b)(6)	E-mail: (b)(6) @va.gov

X. Facility and Species Inventory

Date: April 2020			
Name of Institution: Syracuse VAMC			
Assurance Number: A3436-01			
Laboratory, Unit, or Building* *All rooms are located within the Research Service D Wing of Building 1*	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
DG08 BSL3 Housing & Procedures	285	Mouse	85
DG06 Housing & Procedures	285	Mouse	19
DG05 Housing	140	Rat	3
DG04 Housing	190	Mouse	149
DG03 Housing	150	Mouse	2
DG19 Housing	104	Mouse	3
Corridors	697		
Elevator	47		
DG02 Cage Wash	190		
DG01 Dump Station	110		
DG41 Waste Storage	60		
DG07 Shared Procedures	120		
DG14 Cooler	108		
DG19 Clean Bedding Storage	104		
CG26a Clean Storage	180		
Autoclave	50		
CG26a, CG75, CG76 Long Term Storage	562		

Note: Unless otherwise indicated, mice and rats means mice of the genus *Mus* and rats of the genus *Rattus* that are purposely bred for research.