Animal Welfare Assurance for Domestic Institutions

I, James A. Dias, as named Institutional Official for animal care and use at the State University of New York – University at Albany, 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, DHHS, NSF and/or NASA (if applicable). This Assurance covers only those facilities and components listed below.

In this assurance, "Institution" refers to the University at Albany, State University of New York, and includes the major components of the University. These components are physically located on the University at Albany Main Campus in Albany, NY and its Health Sciences Campus in Rensselaer, NY.

[Note: only those entities listed in this section will be entitled to use the Assurance number for grant and contract submissions to PHS agencies.]

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 the PHS Policy are as follows:

The president (CEO) of the University at Albany has delegated authority to the Vice President for Research (VPR) to serve as the Institutional Official (IO). The IO reports directly to the president. The IO is the official responsible for signing the Assurance and any Assurance amendments and
annual reports to the Office of Laboratory Animal Welfare and the U.S. Department of Agriculture.

The University has a Consulting veterinarian who reports directly to the IO.

This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The Chair of the IACUC reports directly to the IO on all matters pertaining to the animal care and use program and works with the Office of Regulatory and Research Compliance (ORRC) for ensuring the proper execution of the responsibilities of the Committee. The Assistant Vice President for Research (AVPR) is also the University at Albany Research Compliance Officer and Director of ORRC and Laboratory Animal Resources (LAR). The AVPR reports directly to the IO. The AVPR is responsible for coordinating the activities of the IACUC and overseeing ORRC and LAR administration.

An organizational chart is provided below:

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

1) Name: Douglas Cohn, DVM

   Douglas Cohn, DVM, is a graduate of the New York State College of Veterinary Medicine, Cornell University, Ithaca, NY. Board certification: Diplomate, American College of Laboratory Animal Medicine. Dr. Cohn is serves as the University at Albany Consulting Veterinarian.

   Dr. Cohn, as the University's Consulting Veterinarian (CV) is a member of the Institutional Animal Care and Use Committee. The CV, as needed, and at least bi-monthly, inspects the animal facilities to assess the animals’ health and welfare. The CV consults with university
investigators and their lab personnel regarding proper handling, immobilization, anesthesia, analgesia, surgery, post-surgical care, and euthanasia of animals.

The CV also consults with the Laboratory Animal Facilities Manager (Facilities Manager) and Laboratory Animal Technicians regarding methods to prevent, control, diagnose, and treat diseases and injuries; consults with the Office of Regulatory and Research Compliance, Office of Environmental Health and Safety, the IACUC, and the IO in the development and administration of training programs.

Dr. Cohn’s time contributed is approximately six hours monthly. When Dr. Cohn is not physically on-site, he is available electronically (e.g., telephone, email, etc.) for consultation and emergency coverage.

2) Name: Karen E. Krause, DVM,

The University also contracts with a clinical veterinarian, Dr. Karen Krause, who serves on an on-call/back-up basis, as necessary and in the event that Dr. Cohn is not available, to consult with the Lab animal facilities staff, Investigators, the IACUC, and the IO.

Dr. Krause is a 1990 graduate of the University of Illinois Urbana-Champaign College of Veterinary Medicine Champaign, IL. Dr. Krause has 30 years’ experience as an Attending Veterinarian, Clinical Veterinarian, and as a Relief/Back-up Veterinarian. Her experience includes, serving as a member of Animal Care and Use Committees, assisting Investigators with planning and writing animal care and use protocols, performing physical examinations, surgeries and necropsies on laboratory animal species (mice, rats, rabbits, etc.) and providing weekend, holiday and after-hours emergency veterinary care.

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

D. 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 will review at least once every six months the institution’s program for humane care and use of animals, the Institution’s animal facilities, including satellite facilities and study areas using the Guide, Public Health Service (PHS) Policy, and the United States Department of Agriculture (USDA) regulations as a basis for review and evaluation.

The program review encompasses animal care and use program, PHS Policy, the Guide, Animal welfare Assurance, disaster planning and emergency preparedness, IACUC standard operating procedures, IACUC membership and functions, IACUC animal use protocol review, special considerations, IACUC animal use training programs, IACUC records and reporting requirements, veterinary care (clinical care and management, animal procurement and transportation/preventive medicine, surgery, pain, distress, anesthesia, and analgesia, euthanasia, and drug storage and control), occupational health and safety of personnel, personnel security, and investigating and reporting animal welfare concerns.

The facility review is a physical inspection of all buildings, rooms, areas, enclosures, and vehicles (including satellite facilities) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.

The IACUC procedures for conducting semiannual program reviews are as follows:
Once every 6 months (semi-annually), the IACUC performs laboratory and facility inspections and a review of the overall institutional animal care and use program. During facility and laboratory inspections, committee members may identify issues of a programmatic nature.

During the Semi-Annual Self-Assessment, the IACUC Chair will appoint a Semi-Annual Program Review Subcommittee (SAPRS) to conduct a Semi-Annual Program Review. The subcommittee will consist of at least 3 members, including the Consulting Veterinarian and at least one scientific member of the committee. No IACUC member wishing to participate in any review or inspection shall be excluded.

The SAPRS will use the following documents to identify potential areas for reviewing and improving the overall animal care and use program:

1. A draft summary of the laboratory and facility inspection findings for the Semi-Annual Self-Assessment in progress.
2. The most current version of OLAW’s “Sample Semiannual Program Review Checklist” ([http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm](http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm)).
3. The current "University at Albany (D16-00376 - A3621-01) Animal Welfare Assurance in accordance with the PHS Policy for Human Care and Use of Laboratory Animals."
4. A sample of IACUC Policies and Procedures such that all Policies and Procedures will be re-reviewed at least once every three years.

The SAPRS will present its findings and recommendations for improvement at a subsequent convened meeting of the IACUC. Deficiencies will be identified as “minor” or “significant” and a deadline for correction established. All deficiencies and a summary of accepted recommendations will be included in the Semi-Annual Report to the Institutional Official, which is reviewed and signed by a majority of the IACUC members and must include any minority views.

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](http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm) as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

All University animal facilities are inspected. Areas inspected include, but are not limited to, cage wash; aseptic surgery; procedure areas; labs, necropsy; supplies and inventory storage; controlled substance storage and records; surgical suites; and recovery areas.

The IACUC Chair and IACUC Administrator create a semiannual inspection itinerary and will schedule inspection visits to laboratories and housing areas. The inspection team will consist of a minimum of two voting members of the IACUC. No IACUC member wishing to participate in any review or inspection shall be excluded. The IACUC Administrator escorts the inspection team and drafts the written report. The report will distinguish between significant and minor deficiencies and will be provided to the Facilities Manager, IACUC, IO and AVPR as prepared. The Facilities Manager will respond to listed deficiencies in writing to the IACUC with a reasonable and specific plan and schedule for each deficiency for correction. The responses will subsequently be reviewed by the IACUC.

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:

Every six months, the AVPR prepares a written report on behalf of the IACUC. The report describes the University’s adherence to the [Guide](http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm) and the Animal Welfare Act. All IACUC semiannual reports will include a description of the nature and extent of this institution’s adherence to the [Guide](http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm).

All departures from the [Guide](http://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm) (including those approved by the IACUC) will be identified specifically and reasons for each departure will be stated. Departures will be reported for each six month reporting period during which an IACUC approved departure is in place.
All deficiencies will be stated, and the report 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. Any failure to adhere to the plan and correction schedule that results in a significant deficiency remaining uncorrected shall be reported by the IACUC through the IO to OLAW within 30 days and, as appropriate, to the Animal and Plant Health Inspection Service (APHIS). If the activity is federally funded, the relevant agency shall also be informed by the IO or (in his/her absence) the AVPR.

The draft semiannual report is distributed to all members of the IACUC for review and discussion at a convened meeting where a quorum is present. The report must be signed by a majority of the members of the IACUC. All minority views, if any, are included in the report.

The signed final semiannual report is submitted to the IO and copies are maintained by ORRC and the LAR. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

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

Concerns about any aspect of animal care and use at the University at Albany may be made to any member of the IACUC, LAR, ORRC, IO, or via anonymous hotline. Anyone that desires to express a complaint regarding the treatment of animals under the university's care is encouraged to contact the IO, CV, IACUC Chair, or the AVPR. Detailed contact information and instructions for submitting concerns (including via anonymous email form) are provided at http://www.albany.edu/orrc/report-concern.php. Information is also prominently posted in the LAR facilities. The IACUC and ORRC will investigate any animal care and use concern, even if submitted anonymously. No adverse action will be taken against anyone making a good-faith report. No employee, committee member, student, or other person shall be discriminated against or be subject to any reprisal for reporting, in good faith, concerns or violations of regulations or standards under the Animal Welfare Act.

All complaints or concerns are communicated immediately to the IO by the IACUC Chair, CV, or AVPR. Following receipt of a complaint or concern, the IACUC Chair, CV, or AVPR will meet with the individual(s) against whom a complaint or concern is lodged. The purpose of this discussion is to allow the individual an opportunity to respond to the claim and to clarify any misunderstanding. If the claim is found to have merit, an inquiry will be conducted by a subcommittee of IACUC members. ORRC participates in the fact-finding, to facilitate documentation and to ensure that the rights and reputation of the accused individuals are protected. In every case, ORRC maintains a record of the concern, the investigator, resulting recommendation and resolution, and the report to the IO and to appropriate federal agencies.

Actions undertaken in response to a complaint or concern will be completed in a timely manner, based on the circumstances or seriousness of the noncompliance. Under federal regulations, the IACUC has the authority to temporarily or permanently suspend approval of an activity that is not being conducted in accordance with IACUC policies or federal requirements, or that has been associated with unexpected serious harm to animal health and safety. The IACUC Chair, CV, or IO may temporarily stop any activity involving the use of animals and impose sanctions and/or secure critical documents at any time during or following an inquiry or investigation, if necessary, to ensure animal health and safety. The IO will assure that the necessary resources are available to conduct a thorough and timely review of all allegations of noncompliance.

Suspension of a protocol may only be approved by the IACUC at a convened meeting. Any suspension of an activity involving animals shall be immediately reported by the IO (or, in his/her absence, by the AVPR) to the Office of Laboratory Animal Welfare and, as appropriate, to APHIS and the federal agency funding the activity.
5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The IO attends semiannual program review meetings of the IACUC and is well informed regarding committee activities. Recommendations are presented and deliberated during committee meetings, and the IO is apprised of such discussions. When a formal action is addressed, a motion is made and seconded, and then the majority vote rules. Such action is communicated to the IO by letter, prepared by the AVPR on behalf of the IACUC and signed by the IACUC Chair. The IACUC also utilizes the Semiannual Report to the IO for formally communicating recommendations; this document is signed by a majority of committee members.

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:

   a. Investigator initiates the animal use protocol submission
      • The Investigator obtains current forms from the ORRC, IACUC website.
      • Investigator completes all appropriate forms and submits them with all required, supporting documents and attachments to ORRC via email to: IACUCSubmissions@albany.edu.

   b. Administrative & Veterinary Pre-Review
      • The animal use protocol undergoes an administrative pre-review for general quality assurance. This pre-review is to determine completeness of application sections, inclusion of documents and attachments, verification of required approvals and clearances (e.g., biosafety committee, etc.) and training requirements.
      • The study also will receive veterinary pre-review at this stage to ensure that descriptions of procedures, endpoint criteria, appropriateness of drugs, and plan for pain intervention have been adequately addressed.
      • Submission will not move forwarded or be “accepted for IACUC review” until outstanding information/revision is provided/completed/addressed.

   c. Application/Submission Accepted for Review
      Once a protocol is accepted for IACUC review, it is given a submission number, logged into a submission tracking database, and begins to move through the review process as described below.

   d. Conflicts of Interest
      Federal regulations do not permit an Institutional Animal Care and Use Committee (IACUC) member to participate in the review of research in which he/she has a conflicting interest, except to provide information requested by the IACUC. This requirement helps to ensure that financial or other personal interests do not compromise the welfare of animals used in research or the objectivity of the IACUC review process.

      Conflicts of interest may be financial or non-financial, such as when an IACUC member is asked to review research in which he/she is also participating as a member of the research team. Other “personal or professional” conflicting interests include any of the following:
IACUC member (or member of his/her immediate family) is related to a member of the research team or advisory committee involved in the design, conduct, or reporting of the research

A conflicting interest that appears to preclude objective assessment of an animal use activity governed by the IACUC. Examples may include:

- Investigator of the research is the IACUC member’s immediate supervisor or the supervisor of the member’s immediate family member;
- IACUC member (or member of his/her immediate family) has an interest in competing research or is competing directly for resources such as funding or sponsorship;

IACUC member personal biases may interfere with an impartial judgement. An Investigator submitting an animal use protocol may request that a member be excluded from review if the Investigator believes the IACUC member has a potential conflict.

An IACUC member may opt out of a review for any reason, including a conflicting interest not specifically described as above. Departmental or unit affiliation is not automatically considered to be a conflicting interest. Veterinary consultation would not be considered a conflicting interest.

When a conflict of interest is identified, an IACUC member may not participate in any type of review of the research conducted by the IACUC, including initial or continuing reviews, review of amendments, or other reviews (e.g., event reports, potential noncompliance). This requirement applies to reviews conducted by the convened IACUC and those performed by designated member procedures. Any member with an identified conflict of interest at a convened meeting will be asked to leave the room during the discussion and voting, unless asked to be present to answer questions or provide information to the IACUC.

e. Pursuant to the IACUC’s “streaming” process, some animal use protocol submissions are automatically referred to the Full Committee Review (FCR). The determination is made by the Chair. One of three conditions will result in a submission being referred automatically to FCR (vs DMR before FCR):

1. The submission is for use of mammals other than rats or mice (i.e., AWA covered species, such as hamsters, gerbils, etc.);
2. The submission involves major survival surgery in any species; or
3. The submission involves the withholding of pain relief (USDA pain category E) in any species.

The IACUC Administrator will notify the Chair of any animal use protocol submissions that may meet the above criteria and the Chair will make the final determination. If the Chair determines that FCR is not automatically required (per the criteria listed above) the submission will follow DMR procedures.

f. Announcing Protocols

- Twice monthly, the IACUC Administrator will issue a “Designated Member Election” notice via email to the entire IACUC membership. The email contains: a full list of each newly submitted animal use protocol request along with a nontechnical summary of each request. The members are instructed to
access the complete application and materials via the secure IACUC Members-only Intranet site.

**g. Designated Member Review:**
- Members have three (3) business days from date of the “Designated Member Election” notice to indicate if any of the application(s) should be referred to the full committee to review (FCR.)

- For each submission, if none of the IACUC members refers it to Full Committee Review, it will then be assigned by the Chair to one or more for review under “Designated Member Review” (DMR). Process.

- The DMR will complete the review(s) for the application(s) to which they have been assigned.

- The IACUC Administrator transmits email notice to the DMR with instructions for accessing the application materials at the secure IACUC Members-only Intranet site.

- The DMR will communicate any comments, requests for modifications, or clarifications to the Investigator via through the IACUC Administrator. The Investigator will respond to the comments, requests for modifications, or clarifications via the IACUC Administrator. This can be an iterative process and may require more than round of back-and-forth communications until the review is complete and all items have been completed/addressed and the DMR has rendered the review determination to the IACUC Administrator.

- **PHS Policy** and the NIH Grants Policy Statement (**NIH GPS, chapter 4.1.1.2**) require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. For all animal use protocols associated with an externally funded grant/contract, the IACUC administrator will verify that the information that the IACUC reviews and approves is congruent with what is in the application/proposal.

- If the application is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They will review identical versions of the application and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

- The DMR has/have the authority to:
  - Approve the application,
  - Require modifications (to secure approval), or
  - Refer to the full committee
    - The only action that DMR cannot take is to disapprove an application/withhold approval

- The IACUC Administrator will assemble the approved and final version of the animal use application, related documentation, review notes/correspondence, and verify that all required additional documents/clearances have been submitted/obtained (e.g., safety review by the University Environmental Health and Safety Office,
training certifications and Occupational Health and Safety assessment/clearance for all personnel listed.)

- All review requirements being complete, the IACUC Administrator will prepare the IACUC approval letter, which is transmitted via email to the Investigator.

- If the application was referred to Full Committee Review either via the “Streaming Process” or by way of referral by an IACUC member or the DMR, the IACUC Administrator will inform the Investigator and the Chair, and the animal use application is placed on the agenda of the next scheduled fully convened IACUC meeting and FCR procedures are followed.

**h. Full Committee Review (FCR)**

- At least 2 weeks (10 business days) before the next scheduled fully convened IACUC meeting, the IACUC Administrator will poll entire IACUC membership via email confirming their planned attendance in order to ensure a quorum will be met and also send an Outlook calendar meeting invitation.

- At least one IACUC member will be assigned by the Chair to review each study. The assigned reviewer is always a scientific representative of the Committee.

- At least five (7) business days before the IACUC meeting, the IACUC Administrator will transmit the following information to the IACUC members via email: the draft meeting agenda and instructions for accessing all of the meeting materials/documents at the secure IACUC Members-only Intranet site. Members are also asked to indicate if any of them would like to place additional item(s) on the meeting agenda.

- The IACUC meeting begins when the Chair calls the meeting to order and indicates whether a quorum of the membership is present. If a quorum is not present, the meeting will be rescheduled. If at any time during the meeting a quorum is lost (e.g. because a member has recused themselves due to a conflict of interest, etc.) the meeting will be adjourned and remaining agenda items will be tabled until the next meeting.

- The Chair shall ask the assigned reviewer(s) to present the animal use protocol under review. The reviewer(s) is/are responsible for presenting a summary of the animal use protocol and articulate any concerns, raise any questions, or identify any aspects of the animal use protocol requiring further clarification. If a secondary reviewer has been assigned, they will add any additional concerns, questions, etc. Comments and assessment is elicited from the veterinarian.

- The IACUC may invite the Investigator (or his/her designated representative) to speak with the Committee before it makes a final determination. If the Investigator opts to do so, they are invited into the meeting at this point solely to provide IACUC members with information about pertinent items related to the submission and must leave the meeting before the IACUC begins deliberations thereon.
Following the summary, review and (when applicable) discussion with the Investigator, the Chair will solicit additional discussion about the item from the entire committee, and will ensure that all opinions are heard as part of the deliberation. Once a consensus is apparent or a clear division in opinions is present, the Chair will ask for a motion.

Acceptable motions for study protocol applications are:

- Approve,
- Require modification to secure approval, or
- Withhold approval

Motions made on animal use protocols will include the review determination and path that will follow the determination.

Once a motion has been made, it must be seconded by another voting member to remain active.

If the motion is not seconded, then the Chair will ask for further discussion. The member who made the motion may alter the motion if further discussion prompts a change. If the motion is altered, it must receive another second to be valid.

The Chair will then ask for a vote on the motion as indicated by a show of hands or by asking for "aye" or "nay" verbal votes.

For the motion to pass, a majority of the quorum present must vote to approve. If the motion does not pass, the Chair will declare the motion dead or in some circumstances recommend further information be gathered and circulated to the IACUC for future consideration of the motion.

The Chair will then ask if any member wishes to submit a minority opinion for inclusion in the minutes. If no requests are made, the Chair will follow the agenda and announce each item of business in order.

Acceptable motions for business items (such as IACUC minutes, etc.) are: approve, approve with changes, disapprove, and table.

If the motion passes, the Chair will ask the IACUC Administrator to record the number of votes made to "approve", "disapprove" or "abstain" and note that a quorum was present for that item of business, as well as any members who recused themselves due to conflict(s) of interest.

The Chair will refer to each item of business and ask if any members need to recuse themselves before deliberation begins.

When all business has been completed, the Chair will adjourn the meeting.

All members’ votes are recorded in the minutes of the meeting. An approval memo or a request for further clarification will be sent this to the Investigator.
A final letter of approval will NOT be issued until all required documentation that is needed is submitted (e.g. EHS, OHS, Training, etc.)

If the IACUC has voted to APPROVE the protocol, the IACUC Administrator prepares the letter of approval that and send to the Investigator. Note: A final letter of approval will NOT be issued until all required documentation that is needed is submitted (e.g. EH&S, OHSP, Training, etc.)

If the IACUC has voted to REQUIRE MODIFICATION TO SECURE APPROVAL, the IACUC Administrator will prepare a letter detailing the required modifications and/or clarifications required and will transmit this via email to the Investigator.

• If the IACUC has voted to REQUIRE MODIFICATION TO SECURE APPROVAL, Note the following:
  • If all members of the IACUC are present at the meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for FCR at a convened meeting.
  • If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:
    o All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when the IACUC has voted to require modification 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.

  Annually, at the beginning of each academic year, all University at Albany IACUC members sign a proxy agreeing that the members present at a convened meeting may vote to allow DMR subsequent to FCR when modification is required to secure approval. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

  When the IACUC uses DMR subsequent to FCR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as serious noncompliance with the PHS Policy.

• If the IACUC votes to WITHHOLD APPROVAL, the IACUC Administrator will prepare a letter detailing the reasons that led to this decision and send this to the Investigator.

7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC
procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Significant amendments must be reviewed and approved by one of the valid IACUC review and approval methods described above; that is, FCR or DMR and minor modifications/amendments may be reviewed and approved via "Administrative Review" by IACUC Administrator. Please see table, below.

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<thead>
<tr>
<th>REVIEW OF IACUC AMENDMENT REQUESTS</th>
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<tbody>
<tr>
<td>MINOR AMENDMENT</td>
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<tr>
<td>Add, delete, or change a title of a study</td>
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<tr>
<td>Add, delete, or change personnel other than Principal Investigator</td>
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<tr>
<td>Add and/or delete location(s)</td>
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<tr>
<td>Add and/or delete animals of species (mice and rats only) approved to be used on the protocol when the increase is no greater than 10% of the approved number of animals</td>
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<tr>
<td>Add, delete, or change a funding source</td>
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<tr>
<td>Correction of typographical errors, or grammar</td>
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<tr>
<td>SIGNIFICANT AMENDMENT</td>
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<tr>
<td>Changes in anesthesia, analgesia, sedation, or experimental substances</td>
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<tr>
<td>Changes in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals</td>
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<tr>
<td>Changes in duration, frequency, type, or number of procedures performed on an animal</td>
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<tr>
<td>New procedure</td>
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<tr>
<td>Increase in number of animals over approved number (for rats or mice, request for increase greater than 10%)</td>
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<tr>
<td>Change in Principal Investigator</td>
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<tr>
<td>Change in study objectives</td>
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<td>Change resulting in greater pain, distress, or degree of invasiveness</td>
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<tr>
<td>Change in housing and/or use of animals in location that is not part of the animal program overseen by IACUC</td>
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<tr>
<td>Change in species, additional of new species, or change in strain</td>
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<tr>
<td>Duration, frequency, or number of procedures performed on an animal</td>
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<tr>
<th>SIGNIFICANT AMENDMENT</th>
<th>DMR or FCR Review</th>
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<tbody>
<tr>
<td>Anesthesia, analgesia, sedation or withholding of analgesics</td>
<td>X</td>
</tr>
<tr>
<td>Significant food/water restriction (not routine fasting)</td>
<td>X</td>
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<tr>
<td>Change from non-survival to survival surgery</td>
<td>X</td>
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<tr>
<td>Change from survival to non-survival surgery</td>
<td>X</td>
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<tr>
<td>Changes in dose volume or route of experimental materials</td>
<td>X</td>
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<tr>
<td>Changes in euthanasia or euthanasia method</td>
<td>X</td>
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<tr>
<td>Change that would require animals to be fed, housed or cared for in any way that is not standard for that species, or does not meet that species' minimum requirements</td>
<td>X</td>
</tr>
<tr>
<td>Changes that would impact personnel safety</td>
<td>X</td>
</tr>
</tbody>
</table>

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 described above within IACUC procedures for protocol review section 6.

9) The USDA, Department of Defense (DoD), and the Veteran’s Administration (VA), require annual review of animal protocols by the IACUC. The PHS Policy at IV.C.5. states “the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three years (3)”. The University at Albany IACUC combines these continuing review procedures by conducting continuing review of approved animal use protocols on an annual basis rather than triennially, eliminating the dual tracking system for the one- and three-year cycles. The IACUC may also decide that a project should be reviewed more often than annually.

For annual continuing review of animal use protocols, the IACUC uses a standard form containing basic protocol information provided by the Investigator. Information concerning the current status of the project is provided by the investigator to the IACUC. This information will include:

- verification of active status
- verify that completed activities were conducted in accordance with the approved protocol
- funding status,
- number of animals used,
- proposed amendments,
- a brief report updating the IACUC on the progress being made on achieving the specific aims of the protocol, and
- information about activities projected for the upcoming year.

The method of performing continuing review is done by DMR or FCR as described above within IACUC procedures for protocol review section 6.

As per the Animal Welfare Act and the NIH Office of Laboratory Animal Welfare (OLAW), animal use protocols may be approved by the IACUC for a maximum of three (3) years. A "de novo" review of complete, current information about the animal activity is done every three years (triennial review) and is done via DMR or FCR as described previously.

Animal use described in the protocol may not continue if annual continuing or triennial review has not been approved by the expiration date.
10) 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 is authorized to suspend an ongoing activity that is not being conducted in accordance with the Guide, Animal Welfare Act, PHS policy, New York State law, University at Albany Assurance, requirements of funding agency, or that has been associated with unexpected serious harm to animals subjects.

The IACUC may suspend an activity only after review of the matter at a convened meeting of the IACUC, and with the affirmative vote of a majority of the quorum present. If the IACUC suspends an activity, the Committee shall document the action, describing the reasons for the IACUC’s action.

In such an event, the AVPR will promptly notify the investigator in writing of the Committee’s decision to suspend approval of any given activity related to the care and use of animals.

The AVPR will have the additional responsibility of notifying, in writing, the CV, LAR, IO, appropriate oversight agencies, and other appropriate university offices (e.g., Awards Management Services, etc.), and include the reasons for the suspension, any applicable corrective action(s) and any further action(s) anticipated. In such an event, the AVPR is to seek follow-up confirmation that the suspension has been specifically noted by each of the administrative officials listed.

Investigators will have fifteen (15) business days from receipt of the suspension or termination statement to submit a written appeal to the IACUC. The appeal will not act to stay the decision to suspend or terminate the activity. If no appeal is made, the decision will stand as final. The IO or his/her designee, in consultation with the IACUC, will take the following actions:

- review the reasons for suspension,
- take appropriate remedial action and
- report the corrective action to any sponsor funding that activity.

A full committee review will be held within fifteen (15) business days of all appeal requests. The investigator will have the opportunity to meet with the committee and individuals with expertise on the subject or outside consultants may be called to aid in the appeal decision. The committee will issue a final decision within fifteen business days.

A written report will be presented to the IO within one week of such a meeting, and a copy of this report will be forwarded to OLAW. The IO will forward a full explanation of the incident and resulting action to OLAW, other funding agencies and the USDA as required.

**Exception:** The CV has the authority to immediately halt an ongoing activity that does not follow the Guide, Animal Welfare Act, PHS policy, New York State law, University at Albany Assurance, or requirements of funding agency.

The CV sits as a voting member of the IACUC. The CV is additionally charged to make his/her own unannounced inspections of our facilities, husbandry procedures and other animal-related activities. The CV has the authority to immediately halt an ongoing activity that s/he deems unacceptable based on animal welfare considerations. In the event that the CV exercises this separate authority to halt any given activity, s/he will immediately notify the Investigator via a written notification of the halt.

The CV will also notify all of the following individuals: the investigator, the IACUC Chair, the IACUC, the LAR Facilities Manager, the IO, and the AVPR and will follow up with a written report within 24 hours. The CV is to seek follow-up confirmation that the halt has been specifically noted by each of the university personnel listed above.

The IACUC Chair will convene a meeting of the full IACUC membership within 7 business days of any such halt by the AV. At this meeting, the IACUC membership will review the matter, hearing from all concerned parties, and then determine whether the animal-use
protocol in question will be permitted to resume or if IACUC suspension is warranted. The IACUC will vote to permit activity to resume or for suspension of the activity only after review of the matter at a convened meeting and with the affirmative vote of a majority of the quorum present. The IACUC shall document the action taken, describing the reasons for the IACUC’s action and documenting any dissenting opinions.

A written report will be presented to the IO within one week of such a meeting, and a copy of this report will be forwarded to OLAW. The IO will forward a full explanation of the incident and resulting action to OLAW, other funding agencies and the USDA as required.

E. The OHSP is a regulatory requirement, enrollment is mandatory not only for laboratory animal care workers, Investigators, laboratory technicians and students but also facilities and maintenance personnel, custodial staff, full-time, part-time, or temporary employees, students, and visitors who will have contact, in terms of physical proximity to, or handling of animals in the course of their employment for research, teaching or testing purposes.

The extent and level of participation of individuals in the Occupational Health and Safety Program (OHSP) will be based on the hazard exposure of each individual engaging in animal use in research or teaching. Program participants will fall into one of three categories, Risk Level 1, Risk Level 2 or Risk Level 3.

1- The following provides procedures and program requirements for individuals assigned Risk Level 1, 2 and 3.

a- **Risk Level 1: (Participants considered to have moderate to high levels of exposure to animals based on their frequency and duration of tasks conducted with animals)**
   - Animal care technicians.
   - Faculty, staff and students involved in animal use protocols.
   - University employees who provide custodial or facility support services in areas where animals are housed and are subject to direct aerosol exposure to animal based allergens for greater than 5% of their total work time (i.e. greater than 2 hours/week for full-time 40 hour/week employees)

**Risk Level 1 - Individuals assigned to Risk Level 1 must:**

1. Have documented proof of all immunizations required by IACUC to handle the laboratory/wild animal(s) in use.

2. Complete Online training provided through the American Association for Laboratory Animal Science (AALAS) Learning Library. The University at Albany AALAS Occupational Health and Safety Course for Research Animal Users covers topics such as:
   - Animal Welfare Regulations;
   - Physical, chemical, and protocol-related hazards;
   - Allergens;
   - Zoonosis;
   - Safe work practices.
   - Special areas of concern, such as pregnancy, illness, or compromised immune status

   Each lesson must be completed and the final exam passed in order to satisfy this part of the OHSP training requirement.

3. Personnel who have moderate to high levels of exposure to animals (Risk Level 1) must complete an Animal Users Health and Safety Questionnaire.
4. Personnel are notified that they may not begin lab or field work involving animals until the Animal Users Health and Safety Questionnaire has been received and evaluated by Community Care Physicians (CCP).

5. The questionnaire is submitted electronically, via secure transmission to CCP for medical evaluation.

6. The CCP representative will inform the personnel and the ORRC, IACUC Administrator when evaluation of the risk assessment form is complete and if any work restrictions or personal protective equipment is recommended. Initiation of lab or field work will be on hold until the ORRC, IACUC Office confirms unrestricted access is allowed and recommended PPE is provided.

7. Individuals who require additional follow-up will be referred to their own physician/medical professional. CCP will notify the ORRC, IACUC Administrator when the employee has been cleared to work with animals.

8. Personnel involved in ongoing animal work will be required to complete a health questionnaire at least once every 3 years (the maximum duration of an animal use protocol).

9. For personnel already enrolled in the OHSP, but involved in more than one animal care protocol, or submitting a new protocol, the IACUC will determine if it is significantly different (different species, location, etc.) and would require that the individual would need to complete a new questionnaire.

10. The Investigator, or other qualified personnel as indicated in the animal care protocol, must provide training on all hazards associated with the tasks being performed.

11. Investigators and any individuals which they supervise must meet the training requirements as instructed by the EH&S to ensure safety of individuals working with specific hazards such as, chemicals, controlled substances, infectious material, or radioactives.

12. Individuals assigned to Risk Level 1 will be provided appropriate PPE by LAR, EH&S, PI, or a physician.

b- Risk Level 2 Participants:

- Investigators who do not have direct contact with animals
- University employees who provide custodial or facility support services in areas where animals are housed and spend less than 5% of their time directly exposed to animal based allergens.
- IACUC members (including non-affiliated member, non-scientist) spending less than 5% of their time directly exposed to animal based allergens.

Risk Level 2 - Individuals assigned to Risk Level 2 must:

1. Students, employees, and IACUC members who spend less than 5% of their time directly exposed to animal based allergens will be provided with Lab Animal Safety Sheets that include potential risks associated with exposure to each animal species.

2. Lab Animal Safety Sheets will also include information on mechanisms to report concerns on the care and use of animals.

3. The PI/instructor will provide any additional safety instruction to students.

4. PI’s will provide any additional safety information to those who provide custodial and facility support services.
5. Individuals assigned to Risk Level 2 will be provided appropriate PPE by the LAR, EH&S, or PI.

c- Risk Level 3 Participants (non-UA employees, unaffiliated individuals)

- Casual visitors
- Outside contractors who will be working in the animal facilities for greater than 5% of their total work time (i.e., greater than 2 hours/week for full-time 40 hour/week employees).

Risk Level 3 - Individuals assigned to Risk Level 2 must:

1. Visitors are permitted only indirect contact with the animals and will be accompanied by the animal facility manager or designee at all times while in the animal facility.

2. Individuals will be advised that, if they have any medical conditions that may increase their risk (being immunocompromised, pregnant, or having allergies, etc.) they should contact their personal health care provider prior to entering an animal facility.

3. Individuals assigned to Risk Level 3 will be provided appropriate PPE by the LAR, EH&S, or PI.
   1. Outside contractors are responsible for providing any necessary personal protective equipment required to reduce occupational exposure for contractors’ employees.

2- LAR staff provide additional, in-person, hands-on training for animal users working in the University at Albany laboratory animal labs on campus. The program includes training on personal protective equipment (PPE), safety eyewash usage, minimizing injuries, bite wounds, control and prevention strategies, hazard identification and risk assessment, facilities equipment and monitoring, disaster planning, and other safety topics. Animal users, as appropriate, are also instructed on proper animal care and use, handling and restraint, injections, and blood extraction techniques. These training courses will be performed by the LAR Facilities Manager or other trained animal care personnel.

3- The University at Albany Office of Environmental Health and Safety (EH&S) is the University office responsible for providing the expertise, advice, guidelines and current standards of professional practice, to ensure the safety and well-being of students, faculty, staff and visitors. The goal is to prevent injury, illness, and environmental damage through the recognition, evaluation, and control of potential hazards arising from University activities, and to comply with federal, state and local safety and environmental regulations.

   a. EH&S has a representative on the IACUC who reviews every animal use protocol. This representative provides recommendations regarding hazards for each protocol with the intent of meeting the objectives of the OHSP.

   b. The Investigator is responsible for following all EH&S health and safety recommendations and ensuring they provide accurate description of the proposed tasks and processes to be conducted. The Investigator must keep a copy of these recommendations and provide it to their personnel.

   c. EH&S will provide training in blood borne pathogens training, chemical safety, sharps, hazardous waste disposal, fire safety, and lab safety, specific to the animal use protocol.

   d. Injuries, such as bites and scratches are managed by EH&S. The individual is instructed to complete and submit an accident report to EH&S, their supervisor, and (when applicable) the Human Resources Office. The individual is encouraged to seek
medical attention immediately at urgent care, or in the case of students, Student Health Services.

4- The University does not use non-human primates currently and does not have plans to use or house them in the future.

5- Program costs charges for the CCP health evaluation are borne by the University at Albany.

6- Records of OHSP health clearances issued for OHSP participants will be maintained in a database by the Office of Regulatory & Research Compliance.

7- Medical evaluation/personal health information collected is considered confidential information and maintained by CCP in accordance with all federal, state, and local HIPAA regulations for personal health confidentiality.

8- The IACUC Compliance Administrator will verify that all animal users listed on a protocol meet the OHSP requirement before IACUC approval is granted.

9- The ORRC, IACUC, LAR, and EH&S participate and coordinate in monitoring of the UA OHSP.

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 attached Species Inventory table.

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

The University at Albany has mandatory education in the ethical principles and guidelines for the use of animals in research. The educational requirement applies to all University at Albany researchers and key personnel involved in research using animals, whether the research is funded or unfunded. IACUC members, LAR staff, and ORRC staff are also required to complete the training. The University at Albany offers the Collaborative Institutional Training Initiative (CITI Program) Laboratory Animal Welfare Courses to fulfill the University’s Laboratory Animal Welfare education requirement. Training and reference materials are also accessible through the University’s AAALAS Learning Library account.

In order to be able to conduct research involving use of laboratory animals, all personnel must have:

- Current successful completion of CITI or AALAS training certification (or equivalent);
- Current successful completion of the Occupational Health and Safety Program;
- Successful completion of LAR, EH&S lab orientation and training;
- Successful demonstrated proficiency in the handling and care of laboratory animals;
- Technical education is based upon individual need and species used including:
  - proper handling and care;
  - resources available for animal users provided by the University;
  - pre-and post-surgical care;
  - proper use of anesthetics, tranquilizers and pain relieving drugs;
  - aseptic surgical procedures.

In addition, training sessions may be offered periodically on various topics such as:

1) State and federal regulations, principles, policies and laws related to animal use and welfare;
2) Public interest issues including humane treatment of animals and the ethics of animal use in research and education;
3) Institutional responsibilities in animal use including the function of the IACUC;
4) Responsibilities of individual investigators, educators, laboratory technicians, animal care personnel and students assuring proper animal care and welfare;
5) How and to whom animal care deficiencies and concerns can and should be reported;
6) Research and testing methods that minimize the number of animals required to obtain valid results and limit animal pain or distress.
7) Resources available for reducing the number of animals used;
8) Resources available for further training at the University of Albany;
9) Such items as the IACUC shall deem necessary.

Investigators and key personnel must provide sufficient proof of qualifications for animal use to the IACUC, the LAR Facilities Manager, or the Consulting Veterinarian (for invasive procedures) prior to beginning animal use. Any investigator lacking sufficient qualifications will be provided with appropriate training from any of the following:

- the LAR Facilities Manager;
- the Consulting Veterinarian;
- the LAR animal care technicians;
- the IACUC Administrator;
- the Research Compliance Officer.

All animal care staff, IACUC/ORRC staff, and animal users are encouraged to seek continuing education throughout their employment at the University at Albany. Training opportunities, when offered, (e.g., offerings by PRIM&R, AAALAS, etc.) are made available by the University. Documentation of all individuals trained for animal use is maintained with the IACUC records.

Upon appointment to the committee, IACUC members are provided with an orientation, background materials, resources and training. Members are provided with a copy of the PHS Policy, the Guide, the Arena/OLAW IACUC Guidebook, and a copy of the University at Albany approved Animal Welfare Assurance. Training opportunities, when offered, (e.g., offerings by PRIM&R, AAALAS, etc.) are made available by the University.

### IV. Institutional Program Evaluation and Accreditation

All of this Institution’s programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC’s evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category 2 — not 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. The report of the most recent evaluations (program review and facility inspection) is attached.
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, James A. Dias, Vice President for Research of the University at Albany.
   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, James A. Dias, Vice President for Research of the University at Albany.
   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: James A. Diaz
Title: VP for Research
Name of Institution: State University of New York - University at Albany
Address: (street, city, state, country, postal code)
1400 Washington Ave, UNH 307
Albany, NY 12222
Phone: 518-956-8170
Fax: 518 956-8175
E-mail: jbias@albany.edu

Acting officially in an authorized capacity on behalf of this institution and with an understanding of the institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature: [Signature]
Date: 7/2/2020

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

Venita B. Thornton, DVM, MPH
Senior Assurance Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500 -MSC 6910
Bethesda, Maryland 20892
Email: thortonv@od.nih.gov
Phone: (301) 451-4208
Fax: (301) 480-3421

Signature: [Signature]
Date: August 6, 2020

Assurance Number: D16-00376 (A3621-01)
Effective Date: August 6, 2020
Expiration Date: July 31, 2024

Digitally signed by Venita B. Thornton
Date: 2020.08.06 17:43:33 -04'00'