

## Charlton, Patricia

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**From:** SVPRESEARCH  
**Sent:** Friday, July 26, 2019 3:59 PM  
**To:** olawdco@mail.nih.gov  
**Cc:** Charlton, Patricia; Diamond, Michael; Harris, Ruth; Walden, Dora  
**Subject:** Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197  
**Attachments:** AU Adverse event 7\_24\_19.pdf

Dear Dr. Morse:

Augusta University would like to report an incident at our University, as well as our response to that incident. A summary of the incident is attached, co-assigned by our new IACUC Chair Ruth Harris, Ph.D., Professor of Physiology, and myself as AU's Institutional Official.

Sincerely,

Michael P. Diamond, M.D., Institutional Official  
Professor and Chair, Department of Obstetrics and Gynecology  
William H. Brooks, M.D., Distinguished Chair  
Associate Dean for Research, Medical College of Georgia  
Senior Vice President for Research



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20892-7982  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

July 31, 2019

Re: Animal Welfare Assurance  
A3307-01 [OLAW Case U]

Dr. Michael Diamond  
Senior Vice President for Research Administration  
Augusta University  
1120 Fifteen Street  
Augusta, GA 30912

Dear Dr. Diamond,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 26, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University. According to the information provided, OLAW understands that on July 24, 2019 a research investigator was observed performing an unapproved physical "stunning" procedure on a mouse in advance of cervical dislocation. It was not specified if the activity to which the mouse was assigned was funded by the PHS or NSF.

After the IACUC review of the case, corrective actions included notifying the PI and retraining of the research investigator.

The prompt consideration of this matter by Augusta University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

*Brent C. Morse, DVM*  
for  
Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

## Charlton, Patricia

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**From:** SVPRESEARCH  
**Sent:** Thursday, August 08, 2019 1:37 PM  
**To:** OLAW Division of Assurances (NIH/OD)  
**Cc:** Diamond, Michael; Charlton, Patricia; Terry, Alvin; Harris, Ruth  
**Subject:** Augusta University's revised Animal Welfare Assurance document and response to Assurance Clarification letter (A3307-01/D16-00197)  
**Attachments:** Augusta University Response to Clarification request.docx; AU OLAW Assurance 2019 with responses.docx

Attached please find Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197), along with a separate document detailing responses to OLAW's Assurance Clarification letter, which I am sending on behalf of Dr. Michael P. Diamond, Augusta University's Senior Vice President for Research and Institutional Official.

Please do not hesitate to contact us with any questions or needed points of clarification.

Respectfully submitted,

Dora

### Dora Walden

Research Training Coordinator  
ClinicalTrials.gov PRS Administrator  
Augusta University | Office of the Senior Vice President for Research  
1120 15th Street, CJ-1031  
Augusta, GA 30912  
O: 706-721-6900 |  
dwalden@augusta.edu



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## Augusta University

### Itemized Description of Response to Assurance Clarification Letter D16-00197 (A3307-01)

Changes to the Assurance are in red font.

**Part I.** The language in the Applicability section of the Assurance has changed since your last renewal to include HHS and/or NSF. Please update the Applicability section to the following statement:

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

This section has been modified as requested

#### **Part I.B.**

- This Assurance lists Jinfiniti Biosciences (tenant in the Life Sciences Incubator) as a covered component of Augusta University. As such, all program components described in the Assurance apply to this Jinfiniti Biosciences. Please clarify that all the programs in the Assurance, including veterinary care, occupational health and safety, and training are applicable to Jinfiniti Biosciences. Please describe the differences, if any exist.

Jinfiniti Biosciences has been removed from the Assurance as they no longer conduct animal research at Augusta University and are no longer a covered component of Augusta University.

A new company, Gerologix, has initiated work at Augusta University and is now a covered component. The Assurance has been edited to confirm that all programs in the Assurance are applicable to Gerologix.

- Please verify the removal of Luminomics, Inc. as a covered component of Augusta University.

We confirm that Luminomics, Inc. is no longer conducting animal research at Augusta University and has been removed as a covered component of Augusta University.

#### **Part III.A.**

- The description of lines of authority depict what appears to be an indirect line of communication between the Institutional Official (IO) and the IACUC with the IACUC Chair mediating between these two entities. The PHS Policy requires an open and direct line of communication between the Institutional Animal Care and Use Committee (IACUC) and the Institutional Official. Please describe or depict this relationship.

Additional information has been included to clarify that all members of IACUC have direct access to the IO, Dr. Diamond. This section has also been modified to reflect the change in IACUC Chair

### **Part III.D.1. and III.D.2.**

- Please clarify in the Assurance if the semi-annual program review and facility inspection occur at least once every six months.

Additional wording has been added to these sections to clarify that the semi-annual program review and the facility inspections occur at least once every 6 months.

### **Part III.D.3.**

- This Assurance states, “Departures from the PHS Policy and the Guide are identified during protocol review, with justification being reviewed and discussed by the IACUC prior to approval.” The PHS Policy requires that any departures from the *Guide* be identified specifically and reasons for each departure will be stated and reported to the IO. Please clarify in the Assurance document that the IACUC approved departures from the PHS Policy and the Guide **are included in the semiannual report** with the reasons for each.

This section has been modified to clarify that IACUC approved departures from PHS Policy and the Guide, together with reasons for each departure, are included in the semiannual report that is submitted to the IO.

### **Part III.D.6.**

- This Assurance describes an expedited review process in which a “protocol is assigned to all members at once for review and comment prior to the meeting,” and that, “a quorum of members must be available.” Is this FCR with a majority vote of a convened quorum of members? What are the protocol review outcomes of the expedited process?

Additional information has been added to this section to clarify the process and outcome of expedited review

- The statement regarding fee for expedited review is not a necessary component of the Animal Welfare Assurance and can be removed from the Assurance document.

The statement has been removed

- This Assurance describes a protocol review outcome of “Approved with modifications” that is then reviewed by DMR, such that a “Designated Member or subcommittee is assigned to review specific requested modifications and approve the protocol once appropriately revised.” Please describe the process for designated member review (DMR) at your institution. Are the possible outcomes of DMR to approve, to require modifications (to secure approval), or to refer to the full committee for review? Designated review may not result in withholding of approval. If more than one DMR is appointed and there are additional modifications required to secure approval, does each DMR review identical copies of the protocol? Is the DMR’s outcome to approve unanimous? Is the approval date of a protocol reviewed by DMR the date that all modifications required to secure approval are agreed to unanimously by all designated members?

More information on the process and potential outcomes of Designated Member or Subcommittee review have been provided. It is made clear that if DMR requires further revision, the revised

protocol is reviewed by all members of the subcommittee. Unanimous approval is required for protocol approval and the date of protocol approval is the date on which the DMR or all members of the subcommittee vote to approve the final version of the protocol.

- Please explain in your Assurance what occurs when the outcome of protocol review is “Tabled” or “Withdrawal from Review”, to include any mechanisms of communication from the IACUC to the PI, resubmission and re-review. How are these outcomes different from “Not Approved”?

Additional information has been provided on the process for communication between the IACUC and PI and for the review process of protocols that are “Tabled” or “Withdrawn from Review”. The reason process for Not approved has been expanded to clarify how this decision is different from that of “Tabled” or “Withdrawn from Review”.

#### **Part III.D.10.**

- Please clarify in the Assurance that a protocol suspension is only official after a majority vote of the quorum of members present at a meeting.

Additional information has been added to this section to clarify that a protocol is only suspended if there is a majority vote of a quorum of IACUC members at a meeting.

#### **Part VII.**

- Please note that OLAW has a new mailing address. Please update the address in the PHS Approving Official block before submitting a final version with signature.

The mailing address for OLAW has been updated. In addition, the contact information for the IACUC Chair has been changed to reflect the appointment of Dr. Harris as Chair of the IACUC

## **Augusta University (AU)**

Assurance number: A3307-01/D16-00197

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

I, Michael P. Diamond as named Institutional Official for animal care and use at Augusta University provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

#### **I. Applicability of Assurance**

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

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
  - None
- B. The following are other institution(s), or branches and components of another institution:
  - Gerologix (tenant in the Life Sciences Incubator)All the programs in the Assurance, including veterinary care, occupational health and safety, and training are applicable to Gerologix. There are no differences between the programs that apply to the Institution and to Gerologix.

#### **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 University President, Brooks A. Keel, Ph.D., delegates authority to the Institutional Official, Senior VP for Research, Michael P. Diamond, M.D.
  - The IACUC Chair, Ruth Harris, Ph.D., reports directly to the Institutional Official.
  - The Director of Veterinary Services, Patricia Charlton, D.V.M., serves as IACUC Attending Veterinarian and reports to the Associate VP for Basic Science Research, Alvin Terry, Ph.D. as well as directly to the Institutional Official.
  - The IACUC reports to the IO through the Chair of the IACUC. The IO has an "open-door" policy and is available to any member of the IACUC should the member have concerns, questions, or opinions regarding the animal care and use program. The IO occasionally attends IACUC meetings which provides an additional opportunity for access by IACUC members.
- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Patricia Charlton, D.V.M., MS

Qualifications

- Degrees:
  - D.V.M., Virginia Maryland Regional College of Veterinary Medicine, 1992
  - M.S. in Veterinary Science, University of Minnesota, 1997
  - B.S. in Animal Science, Virginia Polytechnic Institute and State University, 1985
- Training or experience in laboratory animal medicine or in the use of the species at the Institution:
  - Residency - Large Animal Internal Medicine, University of Minnesota College of Veterinary Medicine, 1996
  - Clinical Laboratory Animal Veterinarian since 1997, including positions at Fort Dodge Animal Health, University of Minnesota Research Animal Resources, and Pfizer Global Research and Development.
  - Clinical Veterinarian, Augusta University, July 2007- present.
  - Research experience includes rodents, rabbits, cats, dogs, non-human primates, pigs, cows, sheep, goats and horses.

Authority: Dr. Charlton has direct clinical program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

- Full time employee with 100% of time contributed to the animal care and use program, including serving on the IACUC as Attending Veterinarian.

2) Name: [REDACTED]

Qualifications

- Degrees:
  - Medico Veterinario, Universidad de La Salle (Bogota, Colombia), 2001
- Training or experience in laboratory animal medicine or in the use of the species at the Institution:
  - Nonhuman Primate Medicine and Management Internship, 2006.
  - Mannheimer Foundation (Homestead, Fl.), Staff Veterinarian 2004-2013.
  - Clinical Veterinarian, Augusta University, 2013-present.

Responsibilities:

Works under authority delegated by the Director of Veterinary Services, Dr. Patricia Charlton. See Veterinarian Responsibilities below.



Time contributed to program:

Full time employee with 100% of time contributed to the animal care and use program.

3) Name: [REDACTED]

**Qualifications**

- Degrees:
  - D.V.M., Virginia Maryland Regional College of Veterinary Medicine, 2011
  - B.S., Drexel University, 2007
- Training or experience in laboratory animal medicine or in the use of the species at the Institution:
  - Residency – Laboratory Animal Medicine, UC - San Diego, 2014 - 2017
  - Clinical Veterinarian, Augusta University, 2017 – present.

**Responsibilities:**

Works under authority delegated by the Director of Veterinary Services, Dr. Patricia Charlton. See Veterinarian Responsibilities below.

Time contributed to program:

Full time employee with 100% of time contributed to the animal care and use program.

**Veterinarian Responsibilities:**

The clinical veterinarian(s) and/or their designated staff for the program are responsible for handling day-to-day concerns of all animal colonies and provide consultation services and training on various aspects of laboratory animal research. They have responsibility and may delegate authority in the following areas:

- Clinical Direction of the central administrative unit of Augusta University that provides veterinary medical care, husbandry, nutrition, and sanitation programs.
- Monitor the occupational health of Laboratory Animal Services (LAS) Staff, zoonosis control, and hazard containment programs within the laboratory animal facilities.
- Review all animal use protocols and proposals with respect to veterinary care, animal husbandry and animal welfare.
- Render advice on animal model and vendor selection; serving as advisor to all animal users regarding anesthesia, analgesia, tranquilization, immobilization and euthanasia including drugs, dosages, routes and methods.
- Observe all animals daily, receiving and reviewing written and electronic daily reports on all animals to assess their health and welfare. Taking immediate corrective action in those cases where an animal may be inappropriately treated or exhibiting pain.
- Provide a health program for all animals. Ensure incoming animals are appropriately screened to determine their health status, appropriate preventative measures such as vaccinations are used, an appropriate quarantine and isolation program, separation by species or vendor source, and stabilization programs are in effect.
- Monitor the surgery and post-surgical care programs; providing appropriate post-surgical care.
- Act on reported animal care and use concerns by investigating relevant issues followed by immediate action whenever the welfare of any animal is the issue.

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 five 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 the Institution's program for humane care and use of animals at least once every 6 months, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
  - The Semiannual Program Review Checklist section of the [OLAW Checklist](#) is the template for the semiannual review, and all aspects of the program listed in the Checklist are reviewed at least once every 6 months.
  - Sections of the OLAW Checklist are divided up and assigned to subcommittees of at least 2 IACUC members per subcommittee. All IACUC members are invited to participate. They complete the review of their assigned sections and submit the completed Checklist section and relevant notes and data to the IACUC Coordinator for compilation.
  - The full IACUC reviews and discusses all of the subcommittee section checklists and related notes and data at its regular monthly meeting. Action items and final IACUC decision are compiled and prepared for member signatures. The report is submitted to the IO.
- 2) Inspect all of the Institution's animal facilities, including satellite facilities and animal surgical sites, at least once every 6 months using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
  - All IACUC members are invited by the IACUC Coordinator to participate in the semiannual facility inspections.
  - At least two voting members, guided by the OLAW Checklist, perform the evaluation of each section or area. Inspectors are escorted by a LAS staff member when inspecting animal facilities.
  - All animal facilities on the Health Sciences, Summerville and Gracewood campuses are inspected. All PI Labs are inspected at least once every 6 months throughout the year on a rotation established by the IACUC Coordinator.
  - All aspects of the program listed in the Semiannual Facility Inspection Checklist section of the [OLAW Checklist](#) are reviewed.
  - The IACUC Coordinator compiles checklist entries and notes for presentation to the Committee. Inspection data are then presented and discussed at a convened meeting of 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:
  - The IACUC Coordinator develops semiannual reports based on the [OLAW semiannual report to the Institutional Official template](#), using meeting minutes, and program review, facility and lab inspection checklists to complete each report section. Reports are distributed to IACUC members for review and comment and a signature page is circulated. The final document is submitted to the IO by the IACUC Chair.
  - Departures from PHS Policy and the Guide are identified during protocol review, with justification being reviewed and approved by the IACUC. Each departure from PHS Policy and the Guide, together with the reason for each departure, is included in the semi-annual report that is submitted to the IO.
  - Deficiencies are identified on appropriate review/ inspection checklists as minor or major, and documented in the report to the IO, including expected remediation dates. Outstanding deficiencies are carried on the IACUC meeting agenda where progress is reviewed monthly until complete.
  - All sections on the [OLAW semiannual report to the Institutional Official template](#), including any Minority Views from meeting minutes are included in reports.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
  - Instructions on animal welfare incident reporting are posted near all vivarium exits and on both the IACUC and LAS web pages. Reports may be made anonymously.
  - The Institution has a policy in place for protection against reprisal for good faith disclosures.

- Reports are made via a web form that sends email notices to the IACUC office, IACUC Chair, LAS Office and Attending Veterinarian. Urgent items may also be reported by phone to LAS. The reporting individual has the option of remaining anonymous or identifying themselves. The Attending Veterinarian and IACUC Chair may take immediate action (including placing a temporary hold on animal work) when necessary to ensure animal welfare.
  - All reports are presented for discussion and resolution at the following IACUC meeting and remain on the agenda and in the meeting minutes until remediation is completed. Meeting minutes are provided to the IO, IACUC and LAS representatives.
  - Those who choose not to report anonymously are notified by the IACUC Chair of the incident resolution.
- 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:
- Program recommendations are made as a matter of course at weekly Animal Care and Use Leadership meetings that include the IO, IACUC and LAS representatives.
  - Written recommendations are made to the IO in the Semiannual Reports of the Program Review and Facility Inspection.
  - Recommendations involving critical animal welfare issues may also be made via email between or among the IO, IACUC Chair, and Attending Veterinarian when necessary.
  - Recommendations may also be made as part of annual budget planning.
- 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:
- Protocols are created, submitted, reviewed, modified, renewed and stored, electronically via the eSirius 3G Protocol Management module.
  - A dashboard displays role-based alerts and deadlines for documents that require attention by the PI, IACUC office, or reviewers. The software also notifies reviewers and PIs via email when a task is assigned to them.
  - To avoid conflicts of interest, those listed as personnel on any given protocol are not included in its review, are excused from the meeting during discussion of the protocol, are not counted toward a quorum for its review, and do not cast a vote on the protocol.
  - New Protocols and 3-year (*de novo*) renewals follow the same protocol preparation, submission, and review process in eSirius.
  - All IACUC members agree in writing, in advance, to allow Designated Member Review (DMR) to be assigned subsequent to a Full Committee Review (FCR), when modifications are required.
  - Review Process:
    - i. The PI submits a protocol to the IACUC for review via eSirius by the posted meeting deadline.
    - ii. A pre-review for completeness is conducted by the IACUC Office.
    - iii. The protocol is assigned to the Attending Veterinarian, Community Members, and Consultants (including Environmental Health and Safety (EH&S) personnel) for review, and then returned to the IACUC Office.
    - iv. The protocol is assigned to a Lead Science IACUC Member for review and consolidation of comments, and then returned to the IACUC Office.
    - v. The protocol is returned to the PI for any necessary modifications, after which it is returned by the PI to the IACUC Office.
    - vi. The revised protocol is distributed via email as a pdf to all Committee Members prior to the IACUC meeting.
    - vii. The assigned Lead Science IACUC Member presents the protocol to the full Committee for discussion at a convened meeting of the IACUC with a quorum of voting members present.
    - viii. As each protocol is discussed, it is classified by acclamation as:
      - Approved

- Approved with modifications followed by Designated Member Review (DMR). A designated committee member or subcommittee are authorized by the IACUC Chair to review specific modifications requested by the full committee if the modifications are not considered significant enough to require a second FCR. The outcomes of a DMR are to approve a protocol, require modifications to secure approval or to refer the protocol back to FCR. DMR cannot result in withhold approval. The process for DMR is that the protocol is returned to the PI by the IACUC Office with a request to make the changes. The resubmitted protocol is reviewed by the DMR or subcommittee. If the review is by a subcommittee, then the revised protocol is reviewed by all members of the subcommittee and there has to be a unanimous vote to approve. Any member of the subcommittee can request the protocol be returned to the PI for further minor revision or can recommend the protocol be referred for FCR. Minor modifications are reviewed and approved by all members of the subcommittee. If the protocol is approved, then the date of approval is the date of unanimous DMR approval of the final revisions to the protocol.  
The Augusta University Designated Member Review Policy is included as part of the "IACUC Animal Use Protocol Submission and Review Policy". All IACUC members agree **in advance in writing** (form w/signatures on file in the IACUC office) that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. Designation of a protocol to DMR is reported in the minutes of the meeting that involved FCR of the protocol. The minutes of the subsequent meeting(s) record the outcome of the DMR review and the date of protocol approval.
- Tabled if a protocol requires changes that can only be approved by FCR. The protocol is returned to the PI by the IACUC Office with a request for revision. The PI is informed that the revised protocol will be brought to the committee for review at the next convened meeting of a quorum of voting members of the IACUC.
- Not approved if a protocol includes procedures that are not approved by a majority of a quorum of voting IACUC members. The IACUC Office informs the PI that the protocol is not approved and the PI is advised to meet with the Attending Veterinarian and/or IACUC Chair to identify changes in procedure that meet both the needs of the PI and that could be approved by the IACUC. The revised protocol is resubmitted for FCR at the next convened meeting of a quorum of voting members of the IACUC.
- ix. Withdrawal from Review if a PI fails to respond to requests from the IACUC for protocol revisions after two consecutive IACUC meetings. The IACUC Office informs the PI that the protocol has been withdrawn from review. The PI can submit a new protocol for FCR.
- x. As review of each agenda section is completed (e.g., New Protocols, Major Amendments), any minority views are noted and a vote is taken to affirm the classifications assigned to all documents in that section.
- A PI may request a protocol be reviewed ahead of the normal review process. The IACUC will make every effort to promote a protocol ahead of the normal review process and convene a special meeting exclusively for review of that protocol. The protocol is assigned to all committee members at once for review and comment prior to the meeting. Any member can request revisions and the revised protocol is sent out to all committee members for review. FCR of the protocol is performed at a meeting of a quorum of voting members. The committee votes to approve or not approve the protocol. If the protocol is not approved, then it is sent to the PI for further revision followed by a second FCR by a quorum of voting members of the IACUC.

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:

- Proposed changes are submitted, routed, and reviewed electronically in the eSirus 3G Protocol Management module.
- **Administrative Review.** The following are not considered "significant" changes, and are subject only to administrative review and approval:
  - Changes in funding source
  - Changes/updates to non-key personnel
  - Changes in LAS-maintained vivarium space
  - Contact information updates
  - Increase in animal numbers of not more than 10% of the originally approved allocation in pain categories C and D
  - Changes in strain of a previously-approved species, including genetically-modified strains
- **Veterinary Verification and Consultation Review (VVC)**  
Specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animal activity in this circumstance. **(NOT-OD-14-126)**

The VVC process is a streamlined mechanism for approving specific significant changes.

The following significant changes are subject to veterinary review and approval only:

- Changes in anesthesia, analgesia, sedation or experimental substances including new drugs of the same class (purpose), change of duration, frequency, route of administration or dosage as long as the proposed changes are consistent with standard veterinary care.
- Change in euthanasia method, provided it is approved in the 2013 AVMA Guidelines for Euthanasia
- Changes to approved blood collection procedures in accordance with IACUC Guidelines.
- Changes between acceptable methods for collection of tissue for genetic analysis as defined in the IACUC policy/guidelines on (tail tip excision, ear punch, peripheral blood collection, distal toe clipping).
- Minor changes to duration, frequency, type or number of procedures performed on an animal if, in the professional opinion of the veterinarian, the change will not increase the potential for pain, distress or discomfort.

#### **Role of the VVC Veterinarian**

Any veterinarian approved by the IACUC may conduct VVC; this includes all staff Veterinarians. The responsibilities of the Vet are as follows:

- Ensure that the requested change is eligible for VVC
- Verify that the requested change is addressed by existing IACUC policy
- Determine if the change is appropriate under the specific circumstances. If so the change may be authorized. If not the following actions are appropriate under VVC
  - Recommend revision to the existing request if it is within the scope of the policy and is appropriate for the conditions of the experiment
  - Defer the request to DMR or FCR

### **Procedure for VVC**

The following process must be followed in regard to conduct and subsequent documentation of the VVC process. The VVC mechanism may be applied under Standard and Expedited amendment circumstances:

#### **Standard response amendment**

- ✓ Amendment is submitted by the PI or their designee through the standard electronic submission process.
- ✓ IACUC Coordinator determines if it is eligible for VVC.
- ✓ A VVC-Vet will be assigned to the amendment for review, and the review will be conducted as described under "Role of the VVC Veterinarian" above.
- ✓ Amendments approved through VVC will be listed for IACUC review and approval along with the other protocol actions in the agenda for the regular monthly meeting.

#### **Rapid response amendment**

- ✓ In emergency situations or when a PI determines that rapid changes to experimental conditions are necessary, the PI may contact the IACUC office to inquire about rapid amendment approval.
- ✓ If the request appears to meet the specific conditions listed above, it must be documented in an e-mail to the VVC-Vet for review as described under "Role of the VVC Veterinarian" above.
- ✓ If the amendment is authorized by the VVC-Vet, the PI is required to submit the amendment, verbatim from the e-mail, through the standard electronic submission process.
- ✓ VVC-approved amendments will be listed for IACUC review and approval along with the other protocol actions in the agenda for the regular monthly meeting.

- **Designated Member Review.** The following significant changes may be reviewed by a subcommittee consisting of at least two voting members of the IACUC, designated by the IACUC Chair, if no member of the IACUC calls for an elevation of the modification request to full committee during a 5-day electronic polling period (review of a written description of the request by all committee members via email).
  - Additional experiments that fit within the scope/rationale of the originally approved protocol
  - Additional animals up to 25% of the originally approved allocation of research animals (categories C and D only; increases in category E require full committee review)
  - Change in Lead Researcher
  - Changes that may have an impact on the safety of research personnelNote: A modification submitted for Designated Member Review may be elevated to Full Committee Review at the request of any single voting member of the IACUC.
- **Full Committee Review.** All other significant changes follow the same review process as a new protocol.

- 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:



- Approved: The IACUC Office updates the status of approved protocols and amendments in eSirius. The software then notifies the PI via email.
  - Require modifications (to secure approval): The IACUC office notifies the PI that changes are still required and that they should look for further reviewer questions (or answer those waiting) in eSirius.
  - Not approved: The IACUC Chair informs the PI via email and/ or phone and attempts to assist the PI in making changes that would be acceptable.
  - The IO is provided a copy of IACUC minutes as notification.
- 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 has 2 primary elements:
    - The LAS Post Approval Monitoring Specialist (PAM) conducts scheduled, unscheduled, and for cause reviews of current protocols with PIs and their staff. Critical welfare issues are reported immediately to the IACUC. Reports for all PAM reviews are filed with the IACUC monthly, with any necessary follow up designated to the IACUC or the PAM based on the nature of PAM recommendations.
    - The IACUC Coordinator organizes unscheduled (unannounced) lab inspections on a rotating basis by 2-person teams of IACUC members. These also serve as lab inspections for a given semi-annual review.
  - A flag for "Three-year Renewal due" appears on the PI's dashboard in eSirius 3G in advance of the third-year approval anniversary. The software also sends an email notice. Additional email reminders are sent by the IACUC Office. Continuing review follows the same process as that for a new protocol. A protocol will expire on its expiration date if a three-year renewal application has not been reviewed and approved by the IACUC. During the lapse in approval, animals are placed on the holding protocol and are off limits to investigators and research personnel. No experimental use or observation of animals may take place during a protocol lapse period – failure to act in accordance with this restriction will be handled as regulatory noncompliance.
  - A flag for "Annual Review due" appears on the PI's dashboard in eSirius 3G in advance of the first and second approval anniversary. The software also sends an email notice. Additional email reminders are sent by the IACUC Office. A progress report is submitted to the IACUC Office via eSirius 3G. Annual reviews of protocols that use USDA-covered species are discussed at the IACUC full committee meetings. All other annual reviews (non USDA-covered species) are processed and approved administratively.
- 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, IV.C.I.a.g. of the PHS Policy, the Guide, or the Institution's Assurance. The suspension of a protocol is only official after a majority vote at a meeting of a quorum of voting members of the IACUC.
  - If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW and as appropriate for covered species, to APHIS.
- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
- All personnel (including Environmental Health & Safety, Environmental Services, IACUC, Information Technology, LAS, Physical Plant, and Contract staff and students) who enter areas where animals may be present must complete a comprehensive electronic occupational health screening questionnaire that evaluates their risks based on their personal health and potential exposure levels to animals and hazards.

- When exposure risks from the assessment indicate, medical evaluations are required and scheduled by the IACUC Occupational Health Coordinator. Medical evaluations include vaccinations, annual respirator fittings for inhalant risks and/ or annual tuberculosis screenings for Nonhuman Primate exposure when indicated.
  - All personnel are notified via email by the IACUC Occupational Health Coordinator when regular renewal risk assessments are due, typically every one to three years.
  - Training includes procedures for reporting injuries, immediate care, and receiving treatment. Specific additional training is provided regarding Nonhuman Primate exposure and Macacine herpesvirus 1 when appropriate.
  - Mechanical and hearing safety signs are posted where appropriate (e.g. cage wash) and monitored by the IACUC.
  - Biological, Chemical, Environmental, Fire, and Radiation Safety are evaluated by EH&S. Signs are posted where appropriate and monitored by that office. Protocols are reviewed by the appropriate EH&S Committee to ensure safety compliance.
  - Appropriate risk based personal protection training is provided online and in person.
  - Personal Protective Equipment is provided to all personnel, which may include shoe covers, rubber boots, gowns, nitrile gloves, masks, respirators, face shields, hair bonnets and scrubs as appropriate to a particular animal facility. Scrubs are laundered on-site.
  - Showers, sinks, and locker rooms are located in all animal facilities.
  - Animal exposure injuries are monitored, followed, and reported by Employee Health and Wellness.
  - Current occupational health clearance is required for badge access into vivarium space.
- 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 are provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
- **Non-research personnel** (including contractors) who might be exposed to animals or enter animal areas must view the Facility Hazards and Protections video and successfully complete the accompanying quiz. This training covers basic information about PPE, allergies, hazards, bites, scratches, zoonosis, reporting injuries, immediate care and getting medical treatment. Practical, in person training is also provided by the LAS Training coordinator which stresses proper PPE, Zoonosis, and exposure treatment based on the vivarium access requested.
  - **Veterinarian Supervised** trainees must be accompanied by a veterinarian at all times in animal areas and complete online LATA training modules on:
    - i. Occupational Health and Safety
    - ii. Laboratory Animal Allergies and Asthma
  - **Research Personnel** (including all PIs – even if they have no animal contact) must complete:
    - i. Online LATA training on:
      1. Occupational Health & Safety
      2. Humane Care & Use of Laboratory Animals
      3. Principles of Replacement, Reduction & Refinement
      4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
      5. Laboratory Animal Allergies & Asthma
      6. IACUC 101
      7. A species-specific module for working with each species covered in the protocol
      8. Zoonotic disease and transmission (only required for NHP users)
    - ii. Online Vivarium Practices and Policies Training
    - iii. In person practical training with the LAS Training Coordinator.
    - iv. Additional training is provided by the LAS Training Coordinator as indicated (e.g., ABSL-2 Access, Aseptic Surgery, etc.)
  - **IACUC Personnel** must complete:
    - i. Online LATA training on:
      1. Occupational Health & Safety

2. Humane Care & Use of Laboratory Animals
  3. Principles of Replacement, Reduction & Refinement
  4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
  5. Laboratory Animal Allergies & Asthma
  6. IACUC 101
  - ii. Online Vivarium Practices and Policies Training
  - iii. Online Surgery training
  - iv. In person eSirus Reviewer training
  - v. Attend IACUC 101 Series 101 Program as soon as possible.
  - vi. Attend continuing IACUC conferences, typically every 1 to 3 years
- Links (if not hard copies) are provided to the Animal Welfare Act, the Guide, and PHS Policy.

- **LAS Personnel** must complete:

- i. Online LATA training on:
  1. Occupational Health & Safety
  2. Humane Care & Use of Laboratory Animals
  3. Principles of Replacement, Reduction & Refinement
  4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
  5. Laboratory Animal Allergies & Asthma
  6. IACUC 101
  7. All species-specific modules
  8. Zoonotic disease and transmission
- ii. Online Vivarium Practices and Policies Training
- iii. Read all SOPs
- iv. In person, practical training by the LAS Training Coordinator and their Vivarium Supervisor.
- v. Monthly continuing education seminars by the LAS Training Coordinator or designee.

Additional resources are available in the online AALAS Learning Library. All are encouraged to complete certification exams at no cost. A monetary incentive is provided for each certification. Membership and attendance at AALAS conferences at no charge is encouraged.

- **Wildlife Research** faculty and students must complete:

- i. Faculty and students must complete CITI Wildlife modules. Animal exposure risk information is presented as part of the course.
- ii. EH&S Provides Right to Know chemical safety training to personnel exposed to hazards.
- iii. EH&S provides a hazard course tailored specifically to LAS personnel.

**Completion of assigned Training modules are required for badge access into vivarium space.**

#### **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 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 to OLAW 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, Dr. Michael P. Diamond.
  - 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, Dr. Michael P. Diamond.
  - 5. Any minority views filed by members of the IACUC.If there are no changes to report, a written notification that there are no changes will be provided.
- 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: Michael P. Diamond, M.D.

Title: Institutional Official,  
Senior VP for Research

Name of Institution: Augusta University

Address: (street, city, state, country, postal code)

1120 15<sup>th</sup> Street, CJ 1036

Augusta, GA 30912

Phone: 706-721- 9771

Fax: 706- 446-0289

E-mail: MIDIAMOND@augusta.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:

Date:

8/28/19

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

Name/Title: Paula Knapp, Animal Welfare Policy Scientist

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health

6700B Rockledge Drive

Suite 2500, MSC 6910

Bethesda, MD USA 20892-6910

Phone: +1 (301) 496-7163

Fax: +1 (301) 451-5672

Signature:

Paula E.

Knapp -S

Digitally signed by  
Paula E. Knapp -S  
Date: 2019.09.03  
08:02:45 -04'00'

Date: August 29, 2019

Assurance Number: D16-00197 (A3307-01)

Effective Date: August 29, 2019

Expiration Date: August 31, 2023

## VIII. Membership of the IACUC

[illegible]



## IX. Other Key Contacts (optional)

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

<b>Contact #1</b>	
Name: Alvin V. Terry, Jr., Ph.D.	
Title: Associate VP for Basic Science Research	
Phone: 706-721-9462	E-mail: <a href="mailto:aterry@augusta.edu">aterry@augusta.edu</a>
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

## X. Facility and Species Inventory

Date: 3/1/2019

Name of Institution: Augusta University

**Assurance Number:** A3307-01/D16-00197

[illegible]



August 14, 2019

Dr. Michael Diamond, Institutional Official  
Augusta University

Dear Dr. Diamond,

This memo acknowledges that Gerologix Inc agrees to be added as a covered component under the Assurance of Augusta University. Gerologix agrees to follow the guidance of the National Institutes of Health (NIH), Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

Gerologix also agrees to follow the guidance of Augusta University's Institutional Animal Care and Use Committee (IACUC) and Institutional Official, Dr. Michael Diamond; as well as the humane care and use of animals involved.

A handwritten signature in blue ink, appearing to read "Mark W. Hamrick", followed by a horizontal line.

Mark W. Hamrick, President & Co-Founder, Gerologix Inc.  
Entity Administrator  
706-414-1732  
721 Michaels Crk  
Evans, GA 30809  
hamrickmwh@gmail.com

**Charlton, Patricia**

---

**From:** Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>  
**Sent:** Wednesday, August 14, 2019 1:21 PM  
**To:** Walden, Dora  
**Cc:** Diamond, Michael; Charlton, Patricia; Terry, Alvin; Harris, Ruth  
**Subject:** [EXTERNAL] RE: Augusta University's revised Animal Welfare Assurance document and response to Assurance Clarification letter (A3307-01/D16-00197)  
**Attachments:** CC Addition Letter Template.docx

## CAUTION: EXTERNAL SENDER

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Dear Ms. Walden,

Thank you for the response letter and revised Assurance document in response to my clarification request letter dated July 15, 2019. Most items have been adequately addressed. There are however some additional clarifications needed regarding the use of designated member review at your institution. Please review my questions below and submit a revised Assurance document directly to me for a more expedited review. My email is [pknapp@nih.gov](mailto:pknapp@nih.gov). Please also feel free to give me a call at 301-451-4206 if you wish to discuss before resubmitting. Additionally, I must apologize for relaying incorrect information regarding the need for a letter from Gerologix to be added as a covered component to Augusta University's Animal Welfare Assurance. After consulting with colleagues, I learned that OLAW does need an official letter on file from Gerologix, signed by the Gerologix Institutional Official, agreeing to follow NIH and PHS guidelines, the guidance of Augusta University's IACUC, as well as the human care and use of animals involved. Please see the attached general template that may be used for reference. I was able to confirm that we do not need additional documentation to remove Jinfiniti Biosciences and Luminomics.

1. The description in IIID6 of DMR subsequent to FCR when modifications are required to secure approval, this Assurance explains that a designated committee member or subcommittee is authorized to review modifications required to secure approval. The PHS Policy states that the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Please clarify in the Assurance that the qualified designated member reviewer(s) are appointed by the Chair.

2. This Assurance describes a process of DMR subsequent to FCR when modifications are required to secure approval. Please review the guidance below from [OLAW FAQ D3](#) and clarify in the Assurance the following:

- Does your IACUC have such a policy?
- If not, please describe how all IACUC members, even those not present at the meeting, have the protocol available to them and have the opportunity to call for FCR.
- If so, are new members informed of the policy and is it reviewed regularly?
- Are the outcomes of DMR to approve, require modifications to secure approval, or refer to FCR? DMR may not result in withhold approval.
- Is the method of protocol review documented?

Again, please don't hesitate to contact me if you have questions. Otherwise, I look forward to hearing back from you soon.

Best,  
Paula

Paula Knapp  
Animal Welfare Policy Scientist  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, MD 20892  
301.451.4206



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#### [OLAW FAQ D3](#)

Designated member review may be utilized only after all members have been provided the opportunity to call for full-committee review. If any member requests full committee review then that method must be used. If not, the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Designated review may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. Designated review may not result in withholding of approval. When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

1. If **all** members of the IACUC **are** present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review, or returned for FCR at a convened meeting.
2. 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:
  - a. 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 modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
  - b. In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW. (IACUCs that newly elect to utilize a standard operating procedure for DMR subsequent to FCR should provide information about this program change to OLAW in the next Annual Report.)
3. If all members are not present **and** the IACUC lacks written standard procedures as described above, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted **only** if all members of the committee have had the opportunity to request FCR and none have done so. ([PHS Policy IV.C.2](#))

In response to questions from the community regarding this guidance, OLAW offers the following clarifications:

**Can a quorum of the IACUC decide to establish the DMR subsequent to FCR policy?**

No. A DMR subsequent to FCR policy, along with appropriate implementing procedures, may be established only by unanimous consent of all members of the IACUC. While all members need not be physically present at the meeting where the policy is proposed, each individual must be given the opportunity to provide their input in person or *via* facsimile, email, or memorandum prior to its approval.

**What does “in advance, in writing” mean?**

“In advance” means that the IACUC-approved policy must be in place prior to the first meeting at which it is used. “In writing” means that the policy and procedures must be written down and documented in the IACUC’s permanent records as having been established by unanimous agreement of all Committee members. Members are not required to physically sign the DMR subsequent to FCR policy.

**Does there have to be a written statement for every meeting?**

No. The IACUC-approved DMR subsequent to FCR policy allows an appropriately constituted Committee, by unanimous consent, to implement the policy, whenever appropriate, to evaluate revised proposals using DMR. The outcomes of DMRs must then be appropriately documented in the IACUC minutes or elsewhere.

**When can the IACUC start using DMR subsequent to FCR?**

As soon as all members agree to the process and the IACUC-approved, written DMR subsequent to FCR policy and procedures are in place. In addition, when an IACUC establishes the new policy and procedures, OLAW must be notified in the next institutional Annual Report, and the policy must be documented in the institution’s Assurance renewal.

**What happens to the DMR subsequent to FCR policy as the membership of the IACUC changes?**

OLAW expects IACUCs to have appropriate standing mechanisms in place to 1) inform new members of *all* its policies and procedures, and 2) review all IACUC policies and procedures regularly.

**From:** OLAW Division of Assurances (NIH/OD) <assurances.olaw@od.nih.gov>

**Sent:** Thursday, August 08, 2019 2:34 PM

**To:** Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>

**Subject:** FW: Augusta University's revised Animal Welfare Assurance document and response to Assurance Clarification letter (A3307-01/D16-00197)

Hi Paula,

Enclosed is the revised assurance for Augusta University.

Thanks, Sue

B-)

**From:** SVPRESEARCH <[SVPRESEARCH@augusta.edu](mailto:SVPRESEARCH@augusta.edu)>

**Sent:** Thursday, August 08, 2019 1:37 PM

**To:** OLAW Division of Assurances (NIH/OD) <[assurances.olaw@od.nih.gov](mailto:assurances.olaw@od.nih.gov)>

**Cc:** Diamond, Michael <[michael.diamond@augusta.edu](mailto:michael.diamond@augusta.edu)>; Charlton, Patricia <[PCHARLTON@augusta.edu](mailto:PCHARLTON@augusta.edu)>; Terry, Alvin <[ATERRY@augusta.edu](mailto:ATERRY@augusta.edu)>; Harris, Ruth <[RUHARRIS@augusta.edu](mailto:RUHARRIS@augusta.edu)>

**Subject:** Augusta University's revised Animal Welfare Assurance document and response to Assurance Clarification letter (A3307-01/D16-00197)



Attached please find Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197), along with a separate document detailing responses to OLAW's Assurance Clarification letter, which I am sending on behalf of Dr. Michael P. Diamond, Augusta University's Senior Vice President for Research and Institutional Official.

Please do not hesitate to contact us with any questions or needed points of clarification.

Respectfully submitted,

Dora

**Dora Walden**

Research Training Coordinator

[ClinicalTrials.gov](#) PRS Administrator

Augusta University | Office of the Senior Vice President for Research

1120 15th Street, CJ-1031

Augusta, GA 30912

O: 706-721-6900 |

[dwalden@augusta.edu](mailto:dwalden@augusta.edu)



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**Itemized Description of Response to Request for Additional Clarification Augusta University D16-00197 (A3307-01)**

*Information added to the Assurance are in blue font*

1. Please clarify in the Assurance that the qualified designated member reviewer(s) are appointed by the Chair.

The Assurance specifies that the designated reviewers are appointed by the IACUC Chair

2. This Assurance describes a process of DMR subsequent to FCR when modifications are required to secure approval. Please review the guidance below from [OLAW FAQ D3](#) and clarify in the Assurance the following:

- Does your IACUC have such a policy?

The Augusta University Designated Member Review Policy is included as part of the "IACUC Animal Use Protocol Submission and Review Policy". All IACUC members agree **in advance in writing** (form w/signatures on file in the IACUC office) that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. This information is now included in the Assurance

- If not, please describe how all IACUC members, even those not present at the meeting, have the protocol available to them and have the opportunity to call for FCR.

All protocols scheduled for review at a convened meeting of the IACUC are emailed in pdf format to all members of the IACUC prior to the meeting. The minutes of the meeting are distributed by email to all members of the IACUC with 5 days of the meeting. Therefore, all IACUC members, including those not present at the meeting, have an opportunity to request FCR of a protocol that has been assigned DMR.

- If so, are new members informed of the policy and is it reviewed regularly?

New members of the IACUC are informed of the IACUC Animal Use Protocol Submission and Review Policy and it is reviewed by the full committee as part of the semi-annual review. This information is now included in the Assurance

- Are the outcomes of DMR to approve, require modifications to secure approval, of refer to FCR? DMR may not result in withhold approval.

The outcomes of DMR are to approve a protocol, require modifications to secure approval or to refer the protocol back to FCR. DMR cannot result in withhold approval. This is now explicitly stated in the Assurance.

- Is the method of protocol review documented?

The method of protocol review is documented in the minutes of convened IACUC meetings. The outcome of the review of each protocol, including DMR, is reported in the minutes of the meeting that involved FCR of the protocol. The minutes of the subsequent meeting(s) record the outcome of the DMR review and the date of protocol approval. This information is now included in the Assurance.

COMPANY LETTERHEAD

Date

Addressed to either OLAW or the Assured Institution

This memo acknowledges that [Institutions name to be added as covered component] agrees to be added as a covered component under the Assurance of [Assured Institution]. [Institutions name to be added as covered component] agrees to follow the guidance of the National Institutes of Health (NIH), Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

[Institution's name to be added as covered component] also agrees to follow the guidance of [Assured Institution's name] Institutional Animal Care and Use Committee (IACUC) and Institutional Official, [Name of Assured Institution's IO]; as well as the humane care and use of animals involved.

Signature of Institutional Official of

[Institution's name to be added as covered component]

Title

Email and Phone Number

## **Augusta University (AU)**

Assurance number: A3307-01/D16-00197

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

I, Michael P. Diamond as named Institutional Official for animal care and use at Augusta University provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

#### **I. Applicability of Assurance**

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

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
  - None
- B. The following are other institution(s), or branches and components of another institution:
  - Gerologix (tenant in the Life Sciences Incubator)  
All the programs in the Assurance, including veterinary care, occupational health and safety, and training are applicable to Gerologix. There are no differences between the programs that apply to the Institution and to Gerologix.

#### **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 University President, Brooks A. Keel, Ph.D., delegates authority to the Institutional Official, Senior VP for Research, Michael P. Diamond, M.D.
- The IACUC Chair, Ruth Harris, Ph.D., reports directly to the Institutional Official.
- The Director of Veterinary Services, Patricia Charlton, D.V.M., serves as IACUC Attending Veterinarian and reports to the Associate VP for Basic Science Research, Alvin Terry, Ph.D. as well as directly to the Institutional Official.
- The IACUC reports to the IO through the Chair of the IACUC. The IO has an "open-door" policy and is available to any member of the IACUC should the member have concerns, questions, or opinions regarding the animal care and use program. The IO occasionally attends IACUC meetings which provides an additional opportunity for access by IACUC members.

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

1) Name: Patricia Charlton, D.V.M., MS

Qualifications

- Degrees:
  - D.V.M., Virginia Maryland Regional College of Veterinary Medicine, 1992
  - M.S. in Veterinary Science, University of Minnesota, 1997
  - B.S. in Animal Science, Virginia Polytechnic Institute and State University, 1985
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Residency - Large Animal Internal Medicine, University of Minnesota College of Veterinary Medicine, 1996
  - Clinical Laboratory Animal Veterinarian since 1997, including positions at Fort Dodge Animal Health, University of Minnesota Research Animal Resources, and Pfizer Global Research and Development.
  - Clinical Veterinarian, Augusta University, July 2007- present.
  - Research experience includes rodents, rabbits, cats, dogs, non-human primates, pigs, cows, sheep, goats and horses.

Authority: Dr. Charlton has direct clinical program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

- Full time employee with 100% of time contributed to the animal care and use program, including serving on the IACUC as Attending Veterinarian.

2) Name: [REDACTED]

Qualifications

- Degrees:
  - Medico Veterinario, Universidad de La Salle (Bogota, Colombia), 2001
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Nonhuman Primate Medicine and Management Internship, 2006. Mannheim Foundation (Homestead, FL.), Staff Veterinarian 2004-2013.
  - Clinical Veterinarian, Augusta University, 2013-present.

Responsibilities:

Works under authority delegated by the Director of Veterinary Services, Dr. Patricia Charlton. See Veterinarian Responsibilities below.



Time contributed to program:

Full time employee with 100% of time contributed to the animal care and use program.

3) Name: [REDACTED]

**Qualifications**

- Degrees:
  - D.V.M., Virginia Maryland Regional College of Veterinary Medicine, 2011
  - B.S., Drexel University, 2007
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Residency – Laboratory Animal Medicine, UC - San Diego, 2014 - 2017
  - Clinical Veterinarian, Augusta University, 2017 – present.

**Responsibilities:**

Works under authority delegated by the Director of Veterinary Services, Dr. Patricia Charlton. See Veterinarian Responsibilities below.

Time contributed to program:

Full time employee with 100% of time contributed to the animal care and use program.

**Veterinarian Responsibilities:**

The clinical veterinarian(s) and/or their designated staff for the program are responsible for handling day-to-day concerns of all animal colonies and provide consultation services and training on various aspects of laboratory animal research. They have responsibility and may delegate authority in the following areas:

- Clinical Direction of the central administrative unit of Augusta University that provides veterinary medical care, husbandry, nutrition, and sanitation programs.
- Monitor the occupational health of Laboratory Animal Services (LAS) Staff, zoonosis control, and hazard containment programs within the laboratory animal facilities.
- Review all animal use protocols and proposals with respect to veterinary care, animal husbandry and animal welfare.
- Render advice on animal model and vendor selection; serving as advisor to all animal users regarding anesthesia, analgesia, tranquilization, immobilization and euthanasia including drugs, dosages, routes and methods.
- Observe all animals daily, receiving and reviewing written and electronic daily reports on all animals to assess their health and welfare. Taking immediate corrective action in those cases where an animal may be inappropriately treated or exhibiting pain.
- Provide a health program for all animals. Ensure incoming animals are appropriately screened to determine their health status, appropriate preventative measures such as vaccinations are used, an appropriate quarantine and isolation program, separation by species or vendor source, and stabilization programs are in effect.
- Monitor the surgery and post-surgical care programs; providing appropriate post-surgical care.
- Act on reported animal care and use concerns by investigating relevant issues followed by immediate action whenever the welfare of any animal is the issue.

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 five 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 the Institution's program for humane care and use of animals **at least once every 6 months**, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
  - The Semiannual Program Review Checklist section of the [OLAW Checklist](#) is the template for the semiannual review, and all aspects of the program listed in the Checklist are **reviewed at least once every 6 months**.
  - Sections of the OLAW Checklist are divided up and assigned to subcommittees of at least 2 IACUC members per subcommittee. All IACUC members are invited to participate. They complete the review of their assigned sections and submit the completed Checklist section and relevant notes and data to the IACUC Coordinator for compilation.
  - The full IACUC reviews and discusses all of the subcommittee section checklists and related notes and data at its regular monthly meeting. Action items and final IACUC decision are compiled and prepared for member signatures. The report is submitted to the IO.
- 2) Inspect all of the Institution's animal facilities, including satellite facilities and animal surgical sites, **at least once every 6 months** using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
  - All IACUC members are invited by the IACUC Coordinator to participate in the semiannual facility inspections.
  - At least two voting members, guided by the OLAW Checklist, perform the evaluation of each section or area. Inspectors are escorted by a LAS staff member when inspecting animal facilities.
  - All animal facilities on the Health Sciences, Summerville and Gracewood campuses are inspected. All PI Labs are inspected **at least once every 6 months** throughout the year on a rotation established by the IACUC Coordinator.
  - All aspects of the program listed in the Semiannual Facility Inspection Checklist section of the [OLAW Checklist](#) are reviewed.
  - The IACUC Coordinator compiles checklist entries and notes for presentation to the Committee. Inspection data are then presented and discussed at a convened meeting of 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:
  - The IACUC Coordinator develops semiannual reports based on the [OLAW semiannual report to the Institutional Official template](#), using meeting minutes, and program review, facility and lab inspection checklists to complete each report section. Reports are distributed to IACUC members for review and comment and a signature page is circulated. The final document is submitted to the IO by the IACUC Chair.
  - Departures from PHS Policy and the Guide are identified during protocol review, with justification being reviewed and approved by the IACUC. **Each departure from PHS Policy and the Guide, together with the reason for each departure, is included in the semi-annual report that is submitted to the IO.**
  - Deficiencies are identified on appropriate review/ inspection checklists as minor or major, and documented in the report to the IO, including expected remediation dates. Outstanding deficiencies are carried on the IACUC meeting agenda where progress is reviewed monthly until complete.
  - All sections on the [OLAW semiannual report to the Institutional Official template](#), including any Minority Views from meeting minutes are included in reports.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
  - Instructions on animal welfare incident reporting are posted near all vivarium exits and on both the IACUC and LAS web pages. Reports may be made anonymously.
  - The Institution has a policy in place for protection against reprisal for good faith disclosures.

- Reports are made via a web form that sends email notices to the IACUC office, IACUC Chair, LAS Office and Attending Veterinarian. Urgent items may also be reported by phone to LAS. The reporting individual has the option of remaining anonymous or identifying themselves. The Attending Veterinarian and IACUC Chair may take immediate action (including placing a temporary hold on animal work) when necessary to ensure animal welfare.
  - All reports are presented for discussion and resolution at the following IACUC meeting and remain on the agenda and in the meeting minutes until remediation is completed. Meeting minutes are provided to the IO, IACUC and LAS representatives.
  - Those who choose not to report anonymously are notified by the IACUC Chair of the incident resolution.
- 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:
- Program recommendations are made as a matter of course at weekly Animal Care and Use Leadership meetings that include the IO, IACUC and LAS representatives.
  - Written recommendations are made to the IO in the Semiannual Reports of the Program Review and Facility Inspection.
  - Recommendations involving critical animal welfare issues may also be made via email between or among the IO, IACUC Chair, and Attending Veterinarian when necessary.
  - Recommendations may also be made as part of annual budget planning.
- 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:
- Protocols are created, submitted, reviewed, modified, renewed and stored, electronically via the eSirius 3G Protocol Management module.
  - A dashboard displays role-based alerts and deadlines for documents that require attention by the PI, IACUC office, or reviewers. The software also notifies reviewers and PIs via email when a task is assigned to them.
  - To avoid conflicts of interest, those listed as personnel on any given protocol are not included in its review, are excused from the meeting during discussion of the protocol, are not counted toward a quorum for its review, and do not cast a vote on the protocol.
  - New Protocols and 3-year (*de novo*) renewals follow the same protocol preparation, submission, and review process in eSirius.
  - All IACUC members agree in writing, in advance, to allow Designated Member Review (DMR) to be assigned subsequent to a Full Committee Review (FCR), when modifications are required.
  - Review Process:
    - i. The PI submits a protocol to the IACUC for review via eSirius by the posted meeting deadline.
    - ii. A pre-review for completeness is conducted by the IACUC Office.
    - iii. The protocol is assigned to the Attending Veterinarian, Community Members, and Consultants (including Environmental Health and Safety (EH&S) personnel) for review, and then returned to the IACUC Office.
    - iv. The protocol is assigned to a Lead Science IACUC Member for review and consolidation of comments, and then returned to the IACUC Office.
    - v. The protocol is returned to the PI for any necessary modifications, after which it is returned by the PI to the IACUC Office.
    - vi. The revised protocol is distributed via email as a pdf to all Committee Members prior to the IACUC meeting.
    - vii. The assigned Lead Science IACUC Member presents the protocol to the full Committee for discussion at a convened meeting of the IACUC with a quorum of voting members present.
    - viii. As each protocol is discussed, it is classified by acclamation as:
      - Approved

- Approved with modifications followed by Designated Member Review (DMR). A designated committee member or subcommittee are authorized by the IACUC Chair to review specific modifications requested by the full committee if the modifications are not considered significant enough to require a second FCR. The outcomes of a DMR are to approve a protocol, require modifications to secure approval or to refer the protocol back to FCR. DMR cannot result in withhold approval. The process for DMR is that the protocol is returned to the PI by the IACUC Office with a request to make the changes. The resubmitted protocol is reviewed by the DMR or subcommittee. If the review is by a subcommittee, then the revised protocol is reviewed by all members of the subcommittee and there has to be a unanimous vote to approve. Any member of the subcommittee can request the protocol be returned to the PI for further minor revision or can recommend the protocol be referred for FCR. Minor modifications are reviewed and approved by all members of the subcommittee. If the protocol is approved, then the date of approval is the date of unanimous DMR approval of the final revisions to the protocol.

The Augusta University Designated Member Review Policy is included as part of the "IACUC Animal Use Protocol Submission and Review Policy". All IACUC members agree **in advance in writing** (form w/signatures on file in the IACUC office) that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. Designation of a protocol to DMR is reported in the minutes of the meeting that involved FCR of the protocol. The minutes of the subsequent meeting(s) record the outcome of the DMR review and the date of protocol approval.

- Tabled if a protocol requires changes that can only be approved by FCR. The protocol is returned to the PI by the IACUC Office with a request for revision. The PI is informed that the revised protocol will be brought to the committee for review at the next convened meeting of a quorum of voting members of the IACUC.
- Not approved if a protocol includes procedures that are not approved by a majority of a quorum of voting IACUC members. The IACUC Office informs the PI that the protocol is not approved and the PI is advised to meet with the Attending Veterinarian and/or IACUC Chair to identify changes in procedure that meet both the needs of the PI and that could be approved by the IACUC. The revised protocol is resubmitted for FCR at the next convened meeting of a quorum of voting members of the IACUC.
- ix. Withdrawal from Review if a PI fails to respond to requests from the IACUC for protocol revisions after two consecutive IACUC meetings. The IACUC Office informs the PI that the protocol has been withdrawn from review. The PI can submit a new protocol for FCR.
- x. As review of each agenda section is completed (e.g., New Protocols, Major Amendments), any minority views are noted and a vote is taken to affirm the classifications assigned to all documents in that section.
- A PI may request a protocol be reviewed ahead of the normal review process. The IACUC will make every effort to promote a protocol ahead of the normal review process and convene a special meeting exclusively for review of that protocol. The protocol is assigned to all committee members at once for review and comment prior to the meeting. Any member can request revisions and the revised protocol is sent out to all committee members for review. FCR of the protocol is performed at a meeting of a quorum of voting members. The committee votes to approve or not approve the protocol. If the protocol is not approved, then it is sent to the PI for further revision followed by a second FCR by a quorum of voting members of the IACUC.

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:

- Proposed changes are submitted, routed, and reviewed electronically in the eSirius 3G Protocol Management module.
- **Administrative Review.** The following are not considered "significant" changes, and are subject only to administrative review and approval:
  - Changes in funding source
  - Changes/updates to non-key personnel
  - Changes in LAS-maintained vivarium space
  - Contact information updates
  - Increase in animal numbers of not more than 10% of the originally approved allocation in pain categories C and D
  - Changes in strain of a previously-approved species, including genetically-modified strains

- **Veterinary Verification and Consultation Review (VVC)**

Specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animal activity in this circumstance. (**NOT-OD-14-126**)

The VVC process is a streamlined mechanism for approving specific significant changes.

The following significant changes are subject to veterinary review and approval only:

- Changes in anesthesia, analgesia, sedation or experimental substances including new drugs of the same class (purpose), change of duration, frequency, route of administration or dosage as long as the proposed changes are consistent with standard veterinary care.
- Change in euthanasia method, provided it is approved in the 2013 AVMA Guidelines for Euthanasia
- Changes to approved blood collection procedures in accordance with IACUC Guidelines.
- Changes between acceptable methods for collection of tissue for genetic analysis as defined in the IACUC policy/guidelines on (tail tip excision, ear punch, peripheral blood collection, distal toe clipping).
- Minor changes to duration, frequency, type or number of procedures performed on an animal if, in the professional opinion of the veterinarian, the change will not increase the potential for pain, distress or discomfort.

#### **Role of the VVC Veterinarian**

Any veterinarian approved by the IACUC may conduct VVC; this includes all staff Veterinarians. The responsibilities of the Vet are as follows:

- Ensure that the requested change is eligible for VVC
- Verify that the requested change is addressed by existing IACUC policy
- Determine if the change is appropriate under the specific circumstances. If so the change may be authorized. If not the following actions are appropriate under VVC
  - Recommend revision to the existing request if it is within the scope of the policy and is appropriate for the conditions of the experiment
  - Defer the request to DMR or FCR



### **Procedure for VVC**

The following process must be followed in regard to conduct and subsequent documentation of the VVC process. The VVC mechanism may be applied under Standard and Expedited amendment circumstances:

#### **Standard response amendment**

- ✓ Amendment is submitted by the PI or their designee through the standard electronic submission process.
- ✓ IACUC Coordinator determines if it is eligible for VVC.
- ✓ A VVC-Vet will be assigned to the amendment for review, and the review will be conducted as described under "Role of the VVC Veterinarian" above.
- ✓ Amendments approved through VVC will be listed for IACUC review and approval along with the other protocol actions in the agenda for the regular monthly meeting.

#### **Rapid response amendment**

- ✓ In emergency situations or when a PI determines that rapid changes to experimental conditions are necessary, the PI may contact the IACUC office to inquire about rapid amendment approval.
  - ✓ If the request appears to meet the specific conditions listed above, it must be documented in an e-mail to the VVC-Vet for review as described under "Role of the VVC Veterinarian" above.
  - ✓ If the amendment is authorized by the VVC-Vet, the PI is required to submit the amendment, verbatim from the e-mail, through the standard electronic submission process.
  - ✓ VVC-approved amendments will be listed for IACUC review and approval along with the other protocol actions in the agenda for the regular monthly meeting.
- **Designated Member Review.** The following significant changes may be reviewed by a subcommittee consisting of at least two voting members of the IACUC, designated by the IACUC Chair, if no member of the IACUC calls for an elevation of the modification request to full committee during a 5-day electronic polling period (review of a written description of the request by all committee members via email).
    - Additional experiments that fit within the scope/rationale of the originally approved protocol
    - Additional animals up to 25% of the originally approved allocation of research animals (categories C and D only; increases in category E require full committee review)
    - Change in Lead Researcher
    - Changes that may have an impact on the safety of research personnelNote: A modification submitted for Designated Member Review may be elevated to Full Committee Review at the request of any single voting member of the IACUC.
  - **Full Committee Review.** All other significant changes follow the same review process as a new protocol.
- 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:

- Approved: The IACUC Office updates the status of approved protocols and amendments in eSirius. The software then notifies the PI via email.
  - Require modifications (to secure approval): The IACUC office notifies the PI that changes are still required and that they should look for further reviewer questions (or answer those waiting) in eSirius.
  - Not approved: The IACUC Chair informs the PI via email and/ or phone and attempts to assist the PI in making changes that would be acceptable.
  - The IO is provided a copy of IACUC minutes as notification.
- 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 has 2 primary elements:
    - The LAS Post Approval Monitoring Specialist (PAM) conducts scheduled, unscheduled, and for cause reviews of current protocols with PIs and their staff. Critical welfare issues are reported immediately to the IACUC. Reports for all PAM reviews are filed with the IACUC monthly, with any necessary follow up designated to the IACUC or the PAM based on the nature of PAM recommendations.
    - The IACUC Coordinator organizes unscheduled (unannounced) lab inspections on a rotating basis by 2-person teams of IACUC members. These also serve as lab inspections for a given semi-annual review.
  - A flag for "Three-year Renewal due" appears on the PI's dashboard in eSirius 3G in advance of the third-year approval anniversary. The software also sends an email notice. Additional email reminders are sent by the IACUC Office. Continuing review follows the same process as that for a new protocol. A protocol will expire on its expiration date if a three-year renewal application has not been reviewed and approved by the IACUC. During the lapse in approval, animals are placed on the holding protocol and are off limits to investigators and research personnel. No experimental use or observation of animals may take place during a protocol lapse period – failure to act in accordance with this restriction will be handled as regulatory noncompliance.
  - A flag for "Annual Review due" appears on the PI's dashboard in eSirius 3G in advance of the first and second approval anniversary. The software also sends an email notice. Additional email reminders are sent by the IACUC Office. A progress report is submitted to the IACUC Office via eSirius 3G. Annual reviews of protocols that use USDA-covered species are discussed at the IACUC full committee meetings. All other annual reviews (non USDA-covered species) are processed and approved administratively.
- 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, IV.C.I.a.g. of the PHS Policy, the Guide, or the Institution's Assurance. **The suspension of a protocol is only official after a majority vote at a meeting of a quorum of voting members of the IACUC.**
  - If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW and as appropriate for covered species, to APHIS.
- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
- All personnel (including Environmental Health & Safety, Environmental Services, IACUC, Information Technology, LAS, Physical Plant, and Contract staff and students) who enter areas where animals may be present must complete a comprehensive electronic occupational health screening questionnaire that evaluates their risks based on their personal health and potential exposure levels to animals and hazards.

- When exposure risks from the assessment indicate, medical evaluations are required and scheduled by the IACUC Occupational Health Coordinator. Medical evaluations include vaccinations, annual respirator fittings for inhalant risks and/ or annual tuberculosis screenings for Nonhuman Primate exposure when indicated.
  - All personnel are notified via email by the IACUC Occupational Health Coordinator when regular renewal risk assessments are due, typically every one to three years.
  - Training includes procedures for reporting injuries, immediate care, and receiving treatment. Specific additional training is provided regarding Nonhuman Primate exposure and Macacine herpesvirus 1 when appropriate.
  - Mechanical and hearing safety signs are posted where appropriate (e.g. cage wash) and monitored by the IACUC.
  - Biological, Chemical, Environmental, Fire, and Radiation Safety are evaluated by EH&S. Signs are posted where appropriate and monitored by that office. Protocols are reviewed by the appropriate EH&S Committee to ensure safety compliance.
  - Appropriate risk based personal protection training is provided online and in person.
  - Personal Protective Equipment is provided to all personnel, which may include shoe covers, rubber boots, gowns, nitrile gloves, masks, respirators, face shields, hair bonnets and scrubs as appropriate to a particular animal facility. Scrubs are laundered on-site.
  - Showers, sinks, and locker rooms are located in all animal facilities.
  - Animal exposure injuries are monitored, followed, and reported by Employee Health and Wellness.
  - Current occupational health clearance is required for badge access into vivarium space.
- 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 are provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
- **Non-research personnel** (including contractors) who might be exposed to animals or enter animal areas must view the Facility Hazards and Protections video and successfully complete the accompanying quiz. This training covers basic information about PPE, allergies, hazards, bites, scratches, zoonosis, reporting injuries, immediate care and getting medical treatment. Practical, in person training is also provided by the LAS Training coordinator which stresses proper PPE, Zoonosis, and exposure treatment based on the vivarium access requested.
  - **Veterinarian Supervised** trainees must be accompanied by a veterinarian at all times in animal areas and complete online LATA training modules on:
    - i. Occupational Health and Safety
    - ii. Laboratory Animal Allergies and Asthma
  - **Research Personnel** (including all PIs – even if they have no animal contact) must complete:
    - i. Online LATA training on:
      1. Occupational Health & Safety
      2. Humane Care & Use of Laboratory Animals
      3. Principles of Replacement, Reduction & Refinement
      4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
      5. Laboratory Animal Allergies & Asthma
      6. IACUC 101
      7. A species-specific module for working with each species covered in the protocol
      8. Zoonotic disease and transmission (only required for NHP users)
    - ii. Online Vivarium Practices and Policies Training
    - iii. In person practical training with the LAS Training Coordinator.
    - iv. Additional training is provided by the LAS Training Coordinator as indicated (e.g., ABSL-2 Access, Aseptic Surgery, etc.)
  - **IACUC Personnel** must complete:
    - i. Online LATA training on:
      1. Occupational Health & Safety

2. Humane Care & Use of Laboratory Animals
  3. Principles of Replacement, Reduction & Refinement
  4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
  5. Laboratory Animal Allergies & Asthma
  6. IACUC 101
  - ii. Online Vivarium Practices and Policies Training
  - iii. Online Surgery training
  - iv. In person eSirius Reviewer training
  - v. Attend IACUC 101 Series 101 Program as soon as possible.
  - vi. Attend continuing IACUC conferences, typically every 1 to 3 years
- Links (if not hard copies) are provided to the Animal Welfare Act, the Guide, and PHS Policy.
- **LAS Personnel** must complete:
    - i. Online LATA training on:
      1. Occupational Health & Safety
      2. Humane Care & Use of Laboratory Animals
      3. Principles of Replacement, Reduction & Refinement
      4. Principles of Minimizing Pain & Distress & Developing Humane Endpoints
      5. Laboratory Animal Allergies & Asthma
      6. IACUC 101
      7. All species-specific modules
      8. Zoonotic disease and transmission
    - ii. Online Vivarium Practices and Policies Training
    - iii. Read all SOPs
    - iv. In person, practical training by the LAS Training Coordinator and their Vivarium Supervisor.
    - v. Monthly continuing education seminars by the LAS Training Coordinator or designee.
- Additional resources are available in the online AALAS Learning Library. All are encouraged to complete certification exams at no cost. A monetary incentive is provided for each certification. Membership and attendance at AALAS conferences at no charge is encouraged.
- **Wildlife Research** faculty and students must complete:
    - i. Faculty and students must complete CITI Wildlife modules. Animal exposure risk information is presented as part of the course.
    - ii. EH&S Provides Right to Know chemical safety training to personnel exposed to hazards.
    - iii. EH&S provides a hazard course tailored specifically to LAS personnel.

**Completion of assigned Training modules are required for badge access into vivarium space.**

#### **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 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 to OLAW 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, Dr. Michael P. Diamond.
  - 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, Dr. Michael P. Diamond.
  - 5. Any minority views filed by members of the IACUC.If there are no changes to report, a written notification that there are no changes will be provided.
- 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

<b>A. Authorized Institutional Official</b>	
Name: Michael P, Diamond, M.D.	
Title: Institutional Official, Senior VP for Research	
Name of Institution: Augusta University	
Address: (street, city, state, country, postal code) 1120 15 <sup>th</sup> Street, CJ 1036 Augusta, GA 30912	
Phone: 706-721- 9771	Fax: 706- 446-0289
E-mail: MIDIAMOND@augusta.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:	Date:

<b>B. PHS Approving Official</b> (to be completed by OLAW)	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

## VIII. Membership of the IACUC

Date: March 1, 2019			
Name of Institution: Augusta University			
Assurance Number: A3307-01			
<b>IACUC Chairperson</b>			
Name*: Dr. Ruth Harris			
Title*: Professor of Physiology and IACUC Chair			Degree/Credentials*: Ph.D.
Address*: (street, city, state, zip code) 1120 15 <sup>th</sup> Street. CA 1018 Augusta, GA 30912			
E-mail*: ruharris@augusta.edu			
Phone*: 706-721-4479		Fax*: 706-721-7299	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Ruth Harris	Ph.D.	Professor	Scientist & IACUC Chair
Patricia Charlton	D.V.M.	Veterinarian	Attending Veterinarian
Member 1	Ph.D.	Associate Professor	Scientist & IACUC Vice Chair
Member 2	Ph.D.	Retired Professor	Scientist
Member 3		Vacant	Nonaffiliated
Member 4	Ph.D.	Associate Professor	Scientist
Member 5	Ph.D.	Professor	Scientist
Member 6	Ph.D.	Professor	Scientist
Member 7	Ph.D.	Associate Professor	Scientist
Member 8		Retired Retail Manager	Nonaffiliated
Member 9		AU Business Manager	Nonscientist

## IX. Other Key Contacts (optional)

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

<b>Contact #1</b>	
Name: Alvin V. Terry, Jr., Ph.D.	
Title: Associate VP for Basic Science Research	
Phone: 706-721-9462	E-mail: <a href="mailto:aterry@augusta.edu">aterry@augusta.edu</a>
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

## X. Facility and Species Inventory

[illegible]



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910

Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163

August 28, 2019

Reference: Assurance **D16-00197** (A3307-01)

**Approval of Assurance**

Michael Diamond, M.D.  
Senior Vice President for Research Administration  
Augusta University  
1120 15th Street, CJ 1036  
Augusta, GA 30912

Dear Dr. Diamond,

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance (Assurance) that was submitted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised 2015.

Your Assurance, identification number **D16-00197 (A3307-01)**, became effective on **August 28, 2019** and will expire on **August 31, 2023**. Please include the Assurance number on all correspondence to OLAW. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document in defining the relationship of your Institution with the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that an Annual Report to OLAW is required at least once every 12 months. Annual Reports for the previous calendar year are due by January 31<sup>st</sup>.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

Paula E. Knapp -S

Digitally signed by  
Paula E. Knapp -S  
Date: 2019.09.03  
08:40:29 -04'00'

Animal Welfare Policy Scientist, OLAW  
National Institutes of Health

cc: IACUC Chair  
POC



**Charlton, Patricia**

---

**From:** Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>  
**Sent:** Wednesday, August 28, 2019 12:05 PM  
**To:** SVPRESEARCH  
**Cc:** Diamond, Michael; Charlton, Patricia; Terry, Alvin; Harris, Ruth  
**Subject:** [EXTERNAL] RE: Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197)

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Hi Dora,

I was just heading out of the office for the weekend, returning on Tuesday, when I received your email. I will countersign the final Assurance and have an approval letter generated when I return. Please know that although it will be past the 8/31/19 renewal date when I can enter the approval into our system, it will not have a negative impact on the status of your Assurance or on your institution's ability to draw funds. Your institution name will remain as an actively Assured organization on all sources to the public and any funding agencies. I hope you have a nice holiday!

Thank you,  
Paula

Paula Knapp  
Animal Welfare Policy Scientist  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, MD 20892  
301.451.4206



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**From:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Sent:** Wednesday, August 28, 2019 11:05 AM  
**To:** Knapp, Paula (NIH/OD) [E] <pknapp@od.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; Charlton, Patricia <PCHARLTON@augusta.edu>; Terry, Alvin

<ATERRY@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>

**Subject:** RE: Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197)

Attached please find a clean pdf version with an updated IO signature of Augusta University's Animal Welfare Assurance document (A3307-01/D16-00197) which I am sending on behalf of Dr. Michael P. Diamond, Augusta University's Senior Vice President for Research and Institutional Official.

Thanks again. If you should have any questions, please do not hesitate to contact us.

Respectfully submitted,

*Dora*

**Dora Walden**

Research Training Coordinator

[ClinicalTrials.gov](https://clinicaltrials.gov) PRS Administrator

Augusta University | Office of the Senior Vice President for Research

1120 15th Street, CJ-1031

Augusta, GA 30912

O: 706-721-6900 |

[dwalden@augusta.edu](mailto:dwalden@augusta.edu)



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**From:** Knapp, Paula (NIH/OD) [E] <[pknapp@od.nih.gov](mailto:pknapp@od.nih.gov)>

**Sent:** Monday, August 26, 2019 10:16 AM

**To:** Walden, Dora <[DWALDEN@augusta.edu](mailto:DWALDEN@augusta.edu)>

**Cc:** Diamond, Michael <[michael.diamond@augusta.edu](mailto:michael.diamond@augusta.edu)>; Terry, Alvin <[ATERRY@augusta.edu](mailto:ATERRY@augusta.edu)>; Charlton, Patricia <[PCHARLTON@augusta.edu](mailto:PCHARLTON@augusta.edu)>; Harris, Ruth <[RUHARRIS@augusta.edu](mailto:RUHARRIS@augusta.edu)>

**Subject:** [EXTERNAL] RE: Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197)

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Hi Dora,

Thank you for your patience as I reviewed your revised Assurance and letter from Gerologix. The Assurance is ready for approval. At your convenience, please submit a clean pdf version (no highlights or mark-ups) with an updated IO signature. I will then countersign and send back along with an official OLAW approval letter. It has been a pleasure

working with you to renew your institution's Animal Welfare Assurance. Please do not hesitate to reach out to me directly if you have any questions or concerns about your animal program or Assurance.

Kindly,  
Paula

Paula Knapp  
Animal Welfare Policy Scientist  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500 MSC 6910  
Bethesda, MD 20892  
301.451.4206



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**From:** Walden, Dora <[DWALDEN@augusta.edu](mailto:DWALDEN@augusta.edu)>  
**Sent:** Friday, August 16, 2019 3:43 PM  
**To:** Knapp, Paula (NIH/OD) [E] <[pknapp@od.nih.gov](mailto:pknapp@od.nih.gov)>  
**Cc:** Diamond, Michael <[michael.diamond@augusta.edu](mailto:michael.diamond@augusta.edu)>; Terry, Alvin <[ATERRY@augusta.edu](mailto:ATERRY@augusta.edu)>; Charlton, Patricia <[PCHARLTON@augusta.edu](mailto:PCHARLTON@augusta.edu)>; Harris, Ruth <[RUHARRIS@augusta.edu](mailto:RUHARRIS@augusta.edu)>  
**Subject:** Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197)

Ms. Knapp –

We appreciate your offer to preview our resubmission to OLAW. Attached please find the Augusta University's revised Animal Welfare Assurance document (A3307-01/D16-00197), along with a separate document detailing responses to OLAW's Assurance Clarification letter, and the official letter from Georologix which I am sending on behalf of Dr. Michael P. Diamond, Augusta University's Senior Vice President for Research and Institutional Official.

Thanks again. If you should have any questions, please do not hesitate to contact us.

Respectfully submitted,

*Dora*

**Dora Walden**  
Research Training Coordinator  
[ClinicalTrials.gov](https://clinicaltrials.gov) PRS Administrator  
Augusta University | Office of the Senior Vice President for Research  
1120 15th Street, CJ-1031  
Augusta, GA 30912  
O: 706-721-6900 |  
[dwalden@augusta.edu](mailto:dwalden@augusta.edu)



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## Charlton, Patricia

---

**From:** SVPRESEARCH  
**Sent:** Friday, August 30, 2019 4:21 PM  
**To:** olawdco@mail.nih.gov  
**Cc:** Diamond, Michael; Harris, Ruth; Charlton, Patricia; Terry, Alvin  
**Subject:** Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197  
**Attachments:** AU Adverse event 8-29-19.docx

Dear Dr. Morse:

I am writing to inform you of an adverse event that occurred at Augusta University yesterday, the acute response, and corrective action plans. Details are provided in the attached letter from our IACUC Chair Ruth Harris, PhD. Please do not hesitate to contact us with any questions.

Sincerely,

Michael P. Diamond, M.D., Institutional Official  
Professor and Chair, Department of Obstetrics and Gynecology  
William H. Brooks, M.D., Distinguished Chair  
Associate Dean for Research, Medical College of Georgia  
Senior Vice President for Research



**Charlton, Patricia**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Tuesday, September 03, 2019 7:41 AM  
**To:** SVPRESEARCH; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Diamond, Michael; Harris, Ruth; Charlton, Patricia; Terry, Alvin  
**Subject:** [EXTERNAL] RE: Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197

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---

Thank you for providing this final report Dr. Diamond. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** SVPRESEARCH [<mailto:SVPRESEARCH@augusta.edu>]  
**Sent:** Friday, August 30, 2019 4:21 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diamond, Michael <[michael.diamond@augusta.edu](mailto:michael.diamond@augusta.edu)>; Harris, Ruth <[RUHARRIS@augusta.edu](mailto:RUHARRIS@augusta.edu)>; Charlton, Patricia <[PCHARLTON@augusta.edu](mailto:PCHARLTON@augusta.edu)>; Terry, Alvin <[ATERRY@augusta.edu](mailto:ATERRY@augusta.edu)>  
**Subject:** Augusta University unexpected adverse event report - Assurance number: A3307-01/D16-00197

Dear Dr. Morse:

I am writing to inform you of an adverse event that occurred at Augusta University yesterday, the acute response, and corrective action plans. Details are provided in the attached letter from our IACUC Chair Ruth Harris, PhD. Please do not hesitate to contact us with any questions.

Sincerely,

Michael P. Diamond, M.D., Institutional Official

Professor and Chair, Department of Obstetrics and Gynecology  
William H. Brooks, M.D., Distinguished Chair  
Associate Dean for Research, Medical College of Georgia  
Senior Vice President for Research



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6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

September 9, 2019

Re: Animal Welfare Assurance  
A3307-01 [OLAW Case V]

Dr. Michael P. Diamond  
Professor of Obstetrics and Gynecology  
Leon Henri Charbonnier Endowed Chair  
Associate Dean for Research  
Senior Vice President for Research  
Georgia Regents University  
1120 Fifteen Street  
Augusta, GA 30912

Dear Dr. Diamond:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 30, 2019 letter describing a noncompliance at your institution, which was not preceded by a preliminary report to OLAW. According to the information provided, our office understands that on August 29, 2019 two cages of mice were found with no water. One cage has two dead animals. The investigator had removed the mice from the vivarium for euthanasia but was not able to complete the euthanasia in a timely manner and failed to provide the animals with food and water. It appears the animals were housed in the laboratory overnight, but while the area was approved by the IACUC for surgeries, it was not approved for overnight housing of animals.

Immediate corrective measures included care of the surviving mice until they were able to be humanely euthanized. Vivarium access for the responsible individual was removed until retraining is completed. In addition, a group training session for all laboratory members is planned.

OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please contact our office if the corrective actions are not carried out as described. In addition, please ensure that no charges are made to the PHS grant for any unauthorized activities. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely;

*Nicolette Petervary, M.D.*

*Nicolette*  
Nicolette Petervary, VMD, DACAW  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Chair