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The Honorable J. Chapman Petersen
Chair, Senate Committee on Agriculture, Conservation, and Natural Resources

The Honorable David W. Marsden
Chair, Senate Subcommittee on Companion Animals

Dear Senators Petersen and Marsden,

In response to your letter dated February 1, 2023, requesting additional information regarding our recent Animal Welfare Act (AWA) citations and our actions taken to correct the issues, please find below Virginia Tech's commitment to ensuring animal welfare, a summary of the 12 citations received in 2021 and 2022, and in an effort of full disclosure, a summary of a recent 2023 inspection.

Virginia Tech's animal care program strives to ensure the highest standards of animal care and use across our broad and varied research and teaching activities. We monitor over 600 active projects each year across seven of our 10 colleges, many of which are aimed directly at improving human and animal health.

The recent citations and our responses to them drive us to continue to improve our program so that we can maintain and promote the research excellence for which Virginia Tech is known. We take this feedback seriously and our goal is always to achieve complete compliance with all AWA regulations.

The following addresses the request for information detailing how Virginia Tech plans to ensure ongoing and consistent compliance with federal laws and regulations for animal welfare through two mechanisms.

1. The Institutional Animal Care and Use Committee (IACUC), required by regulations to ensure the humane use of animals and oversight of the animal use program, is committed to the task of this assurance of animal well-being and use. The below items represent a few of the mandated regulatory requirements and initiatives to go beyond the requirements.
 - a. Mandated review of animal use through submitted protocols by ensuring use of the animals is humane, in accordance with regulations, literature reviewed for unnecessary

- duplication, appropriate harm/benefit analysis, and appropriate alternatives to painful or distressful procedures have been considered;
- b. Mandated semi-annual evaluation of compliance and areas for improvement in all aspects of the animal program, including veterinary care, IACUC functions, disaster planning, personnel training, record requirements, occupational health and safety, security, and investigating and reporting animal welfare concerns. It is through this process that the IACUC identified the need for additional training on the literature search portion of the protocol, as well as several of the other citations;
 - c. Initiated Progress Review meetings yearly with Investigators in which a selection of 3-8% of active protocols are selected for review by meeting with the Investigator to discuss progress of the animal work, review experiment documents, answer questions, and present the meeting at the next IACUC convened meeting for discussion and consideration of current work as “Met Compliance”, “Requires Educational Reminder” or “Compliance issue”;
 - d. Mandated Investigation of all reported and anonymous animal welfare concerns and report unexpected events to ensure animal welfare, compliance with approved procedures, and make determinations on corrective actions when appropriate;
 - e. Initiated the formation of a subcommittee to review each citation and present potential initiatives to prevent future citations. The first initiatives were presented at the April 2023 IACUC meeting, the following two initiatives were approved (below), the subcommittee continues to meet and additional initiatives will be brought to the IACUC for consideration.
 - i. Require all new animal users, including researchers, graduate students, and lab managers to meet with the Animal Care and Use Program (ACUP) office before submitting protocols or at time of initial submission to discuss the Virginia Tech IACUC’s requirements and expectations for animal use, review the research plan, answer questions, and establish a supportive relationship with new stakeholders;
 - ii. Require both ACUP and veterinary personnel be present throughout USDA facility inspections to provide necessary information at time of inspection, and for awareness of concerns before the conclusion of the inspection.
2. The Office of Research and Innovation (ORI) is taking multiple institutional efforts to enhance our animal care programs. These approaches strive for increased training, transparency, oversight, monitoring, and communication throughout the university, and include:
- a. Detailed discussion of citations with the Board of Visitors, President, and Provost;
 - b. Notification of all citations to the principal investigator and their department head, associate dean for research, and dean so that the entire chain of command is aware of any noncompliance and can work together to improve compliance of all animal research activities;

- c. Perform internal, unannounced spot inspections of animal research laboratories to ensure compliance, confirm best practices, provide project-specific guidance, and address any concerns presented by researchers;
- d. Provide educational opportunities to all animal users, support staff, and the IACUC through ORI sponsored industry and regulatory agency webinars and conferences;
- e. Semi-annual Animal Care Town Halls to regularly remind researchers of the various crucial aspects of compliance, including the necessity to adhere strictly to approved protocols.
- f. All noncompliance with laws, regulations, and university animal care policies are reviewed by the IACUC. Further internal investigation or disciplinary actions may be initiated depending on the severity of the violation and issues/concerns described in the citation. Per university policies, consequences for researchers involved may include temporary or permanent suspension of the activity or loss of the privilege to work with animals.

Below, please find the requested information for the cause, resolution, reporting, and prevention of future violations of the AWA violations over the past two years (2021-2023), including USDA inspections on June 29, 2021, February 1, 2022, July 26, 2022, and a recent inspection on January 9, 2023.

Citations Received in 2021

Citation: 2.31(d)(1)(ii):

Cause: Investigators are required to perform a literature search for procedures causing more than slight pain and distress to animal research subjects. The literature searches for three protocols were either not robust or did not include all procedures that may include more than slight pain or distress procedures.

Accountability: The IACUC alerted the Investigator of the citation, educated them on an appropriate literature search, and, if the protocol was active, an amendment was required updating the literature search.

Funding sources: Henry Jackson Foundation (federal flow through from Army Medical Research and Materiel Command (AMRMC)) and National Institutes of Health (NIH).

Report to funding agency: Reported to Henry Jackson Foundation; reporting not required to NIH per OLAW reporting requirements.

Action taken on publishing data: N/A

Actions to prevent future violations: The IACUC and Animal Care and Use Program (ACUP) had previously identified literature searches as a weak point for some investigators and reviewers. Before the citation occurred the IACUC Administrator had worked with USDA's AWIC to schedule a literature review training for IACUC members/reviewers and the training occurred the week after the citation. Following the training, ACUP created new tutorials to assist investigators with completion of the literature searches.

Citation: 2.31(e)(3):

Cause: An adverse event report indicated that three Gottingen pigs unexpectedly died during study procedures. The investigator attempted to troubleshoot the problem in real time and made several ad hoc changes to the study procedures. These changes were not included in the IACUC approved protocol, leading to a citation for off-protocol procedures.

Accountability: The IACUC sent a letter to the PI requesting in the future: 1. Contact the Office of the University Veterinarian if unexpected health events occur and 2. Submit an amendment and receive approval before initiating any changes to the experiment.

Funding source: Henry Jackson Foundation (federal flow through from Army Medical Research and Materiel Command (AMRMC)).

Report to funding agency: Reported to Henry Jackson Foundation.

Action taken on publishing data: Only data collected from the approved revised protocol will be used for publication.

Actions to prevent future violations: In this study of potential brain trauma, the sponsor had specifically asked for an increase in the exposure level. Neither the investigator nor the sponsor anticipated that this would result in death. Immediately after the event, the protocol was closed until the data were reviewed and discussion with the funding agency occurred to determine how to proceed. The investigator was sent an educational letter reminding to send an amendment to the protocol to update procedures before initiating. Additionally, the investigator was required to meet with ACUP and a staff veterinarian before a new protocol was submitted. The investigator has since reviewed the data, met with the funding agency, and submitted a new protocol. The ACUP director, two ACUP protocol coordinators, and a senior research veterinarian met to discuss the new submission, gain a better understanding of the experiments, and assist in adding appropriate flexibilities to the protocol while ensuring the welfare of the animals. All humane endpoints and monitoring plans were reviewed. After administrative and veterinary questions were sent to the investigator and responses were received, the protocol was reviewed by the convened IACUC, which recommended review by the designated member reviewer mechanism. The revised protocol was approved.

Citation: 2.38(f)(1):

Cause: Part 1: A dairy cow was found in distress during the USDA facility inspection. The cow was assessed by a College of Veterinary Medicine (CVM) veterinarian and resolved without issue. The veterinarian noted that the day, though not overly hot, had excessive humidity which compounded the issue. Part 2: This citation was the result of the study listed in the preceding citation, which was cited for both off-protocol procedures (2.31(e)(3)) and animal handling (this citation).

Accountability: Part 1: No disciplinary action required by the IACUC, see Actions to prevent future violations below. Part 2: The IACUC sent an educational letter to the PI requesting in the future: 1. Contact the Office of the University Veterinarian if unexpected health events occur and 2. Submit an amendment and receive approval before initiating any changes to the experiment.

Funding source: Part 1: N/A. Part 2: Henry Jackson Foundation (federal flow through from Army Medical Research and Materiel Command (AMRMC)).

Report to funding agency: Part 1: N/A. Part 2: Reported to Henry Jackson Foundation.

Action taken on publishing data: Part 1: N/A. Part 2: Only data collected from the approved revised protocol will be used for publication. The data from the cohort of animals in the event will not be used for publication.

Actions to prevent future violations: Part 1: While a shaded area was available to the animal at the time, an additional shade area was opened to allow for access to two shade areas. Part 2: The protocol was closed until the data were reviewed and discussion with the funding agency occurred to determine how to proceed. The investigator was sent an educational letter reminding to send an amendment to the protocol to update procedures before initiating. Additionally, the investigator was required to meet with ACUP and a staff veterinarian before a new protocol was submitted. The investigator has since reviewed the data, met with the funding agency, and submitted a new protocol. The ACUP director, two ACUP protocol coordinators, and a senior research veterinarian met to discuss the new submission, gain a better understanding of the experiments, and assist in adding appropriate flexibilities to the protocol while ensuring the welfare of the animals. All humane endpoints and monitoring plans were reviewed. After administrative and veterinary questions were sent to the investigator and responses were received, the protocol was reviewed by the convened IACUC, which recommended review by the designated member reviewer mechanism. The revised protocol was approved.

Citation: 3.125(a):

Cause: Several facility deficits were noted in the swine housing facilities including cracks in concrete flooring and cinder block walls, as well as exposed metal due to lack of upkeep and repair.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: Animals were moved out of spaces with potential injury concerns. Three pens were designated for AWA-regulated animals and were repaired and inspected by the IACUC. Additionally, all spaces were either repaired or decommissioned until repairs could occur depending on repair requirements. The IACUC continues the semiannual inspections of this facility, and the manager has prioritized facilitating repairs as noted.

Citation: 3.127(a):

Cause: Multiple sheep and beef cattle pastures do not have shade provided for heat and weather relief.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: With the advice from the USDA Veterinary Medical Officer (VMO), the CVM teaching college moved use of agriculture animals to a veterinary client-patient relationship. Due to this change of relationship, these areas are no longer regulated under AWA and therefore no longer inspected by the USDA. The IACUC, however, required both the beef and sheep center to create mitigation plans for all pastures without access to shade or shelter during weather events with potential to cause heat or cold stress. The 8-page plans detailed managerial strategies for potential cold- and heat-stress weather events. Mitigation strategies included monitoring, movement, shelter, and additional procedures to eliminate negative weather impact on the welfare of the animals. The plans were approved by the IACUC, which required all individuals working at the facilities to review them.

Citation: 3.127(c):

Cause: Pool of standing water noted at the sheep center.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: The building underwent extensive repairs to prevent water leakage and the excess water has been eliminated.

Citations Received in 2022

Citation: 2.31(b)(3)(ii):

Cause: The citation stated that the IACUC was not fully constituted by nature of lacking an unaffiliated member. However, the IACUC was fully constituted at the time of the inspection with a long-standing unaffiliated member and a new unaffiliated member appointed the same month of the inspection. The concern was the lack of recent attendance of the long-standing member at meetings. This was an unusual event for the member due to the pandemic, but the regulations do not specify the number of meetings a member must attend. The USDA inspector acknowledged that there is no regulation but stated that it is not in the spirit of the regulation.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: The IACUC remains fully constituted with a non-affiliated (a.k.a. community) member and now an alternate. Review of all members' participation occurs each

July before September 1 membership renewals. The July review of the member in question in 2021 showed they had attended 70% of meetings, which is our expectation for members.

Citation: 2.33(b)(1):

Cause: An animal required euthanasia and the designated CVM veterinarian was delayed while out on another call. A university staff veterinarian was able to provide sedation in the interim to relieve suffering until the CVM veterinarian arrived. The citation requested that the university staff veterinarians have access to euthanasia solution.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: No external funding.

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: While the CVM veterinarians responsible for the provision of veterinary care to this animal had access to euthanasia solution, the Animal Resources and Care Division (ARCD) staff veterinarians, who consult and liaise with the CVM veterinarians, applied for and acquired the appropriate licensure, lock boxes, and euthanasia solution as a backup mechanism in case CVM veterinarians are delayed in the future.

Citation: 3.13(a)(1):

Cause: The Virginia Tech Program of Veterinary Care document did not specify the minimum frequency for the attending veterinarian to visit the animal facilities.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: While the Program of Veterinary Care document stated that the Attending Veterinarian would regularly visit the facility, the document was updated to specify that the attending veterinarian would visit the animal facility at least annually.

Citation: 3.137(a)(4):

Cause: The transport enclosures used to transport hibernating Big Brown Bats acquired from out of state to the facility in the fall of 2021 have insufficient ventilation openings.

Accountability: The IACUC alerted the Investigator of the citation, educated them on the transportation requirement and required an amendment to add the appropriate justification for the deviation of the transport enclosure.

Funding source: No external funding.

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: Appropriate ventilation for the bats in torpid (inactive) state, which represented deviation from the AWA regulations, was described and approved in the IACUC protocol, however, scientific justification for the deviation was not included in the initial protocol. In follow-up with the USDA investigator, the IACUC learned that the bat transport did not fall under this regulation due to the species. The original protocol and transport approved was appropriate. However, to address the citation, an amendment with the scientific justification was submitted and approved by the IACUC.

Citation: 2.31(e)(3):

Cause: An investigator administered a substance that was not approved on the IACUC protocol to Syrian hamsters during an experiment.

Accountability: The IACUC sent the Investigator a minor non-compliance letter with a reminder to submit and receive approval of an amendment before initiating procedures.

Funding source: Georgetown University (federal flow through award from NIH).

Report to funding agency: Reported to NIH.

Action taken on publishing data: N/A, not published, with no plans to publish or share the data

Actions to prevent future violations: The investigator received a minor non-compliance letter from the IACUC with a reminder to submit an amendment to update the protocol for this and all future changes to study procedures before implementing them. The amendment was submitted and approved by the IACUC. The investigator was reminded of their responsibility to follow protocols as approved by the IACUC.

Citation: 3.129(a):

Cause: A genetically modified, Cesarean derived piglet undergoing intense veterinary care, observation, and assessment every two hours by qualified individuals failed to receive a sufficient amount of food to maintain proper body condition and health and died.

Accountability: The IACUC reviewed the incidence and found no compliance issue as the pig was under veterinary care and directive throughout the time period.

Funding source: NIH.

Report to funding agency: Reporting not required to NIH per OLAW reporting requirements, as the IACUC determined that the piglet was under appropriate veterinary supervision throughout the experiment.

Action taken on publishing data: No restrictions on publication of data, as this was not an issue related to noncompliance.

Actions to prevent future violations: Following the citation, an IACUC subcommittee was formed to review the current feeding SOPs for these special piglets. After review an updated SOP was submitted to and approved by the IACUC. The SOP includes feeding regimen and timelines along with veterinary consultation and euthanasia parameters and directives in one document. The SOP was reviewed by the USDA VMO, who stated she was pleased with the direction of the SOP and will look forward to seeing the SOP in use in future visits.

Citations Received in 2023

Citation: 2.31(e)(3):

Cause: Part 1: During review of monitoring documents and the approved IACUC protocol, the USDA VMO noted that weight monitoring and blood sampling procedures were incomplete. The VMO also noted that the housing units in use for the animals—while better for the animals’ welfare—did not match the description of the units described in the protocol. Part 2: During review of monitoring documents and the approved IACUC protocol, the USDA inspector noted that facility staff failed to insert an intravenous catheter within the 2-day window stated in the protocol.

Accountability: Part 1: Currently under review by the IACUC. Part 2: The IACUC sent an educational letter to the PI requesting in the future: 1. Submit an amendment and receive approval before initiating any changes to the experiment and 2. Submit an amendment to update the protocol with the new timeline.

Funding source: Part 1: NIH. Part 2: Commercial/industry funding

Report to funding agency: Part 1: Currently under investigation by the IACUC. Investigation findings will be discussed at the May 2023 IACUC meeting where a determination will be made whether the incident is required to be reported to NIH. Part 2: N/A.

Action taken on publishing data: Part 1: Not published, under IACUC review for the May 2023 meeting. Part 2: N/A, proprietary data.

Actions to prevent future violations: Part 1: The protocol was closed and is currently undergoing a post approval monitor review that will be presented at the May 2023 IACUC meeting. The investigator was required to submit a new protocol for the animal work. Before submission the investigator met with individuals from the IACUC, ACUP, and an ARCD veterinarian to discuss the research protocol and formulate a plan to ensure compliance. A new protocol has been approved and ACUP and veterinary care staff will assist in ensuring compliance of the protocol before initiation. Part 2: The IACUC issued an educational letter reminding the investigator about the importance of following IACUC protocols as approved and requesting an amendment for the change in experimental procedures. An amendment has been submitted and approved.

Citation: Initially 2.32(c)(1)(ii); changed by USDA in April to 2.38(f)(1):

Cause: An animal was euthanized by the veterinarian conducting the training following an unexpected injury that occurred during an animal handling training session.

Accountability: The event was reviewed by the IACUC and determined no discipline action required as the training was performed as approved on the protocol, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A, training exercise.

Actions to prevent future violations: This citation was appealed and reclassified by USDA under a different section of the AWA regulations. We will continue to conduct animal handling training to

ensure all individuals are adequately trained to handle the specific species and the nuances of the species.

Citation: 2.36(b):

Cause: Our annual report to USDA of animals used in or held for research inadvertently excluded 24 gerbils that arrived at the laboratory 3 days prior to the reporting cut-off date. Unfortunately, the investigator's designee forgot to include these newly arrived animals.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: We are examining and revising our internal process for ensuring all AWA animals are counted for the annual report, including using both investigator-initiated reports and the university's animal ordering systems.

Citation: 3.13(a)(3):

Cause: The Program of Veterinary Care requires a schedule of vaccinations for dogs from the attending veterinarian. The existing document listed the vaccinations that were provided in accordance with standards and frequency used by the Virginia-Maryland College of Veterinary Medicine (CVM) rather than listing a specific vaccine schedule.

Accountability: No disciplinary action required by the IACUC, see Actions to prevent future violations below.

Funding source: N/A

Report to funding agency: N/A

Action taken on publishing data: N/A

Actions to prevent future violations: The Program of Veterinary Care has been updated to include tables with defined vaccination schedules that are used by the CVM.

Please know that Virginia Tech strives to not only meet the required regulations but to ensure that all animal care and research is carried out at the highest ethical standards. We understand the privilege and responsibility of animal care, and as a result we are fully committed to taking these important steps to prevent future violations of this nature.

We invite you to visit Virginia Tech to tour our animal facilities and receive a briefing from individuals who share your commitment to the care and use of animals. Elizabeth Hooper, Associate Vice President of Government & Community Relations, will be following up with your offices in hopes of identifying potential dates for a visit.

We look forward to having you in Blacksburg and appreciate all that you do on behalf of the Commonwealth of Virginia.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Sui', with a long horizontal flourish extending to the right.

Dr. Daniel Sui, Ph.D.
Senior Vice President for Research & Innovation
Virginia Tech Institutional Official

CC:

Dr. Tim Sands, President, Virginia Tech
Dr. Cyril Clarke, Provost, Virginia Tech
Elizabeth Hooper, Associate Vice President, Government & Community Relations