March 20, 2023

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:

This letter is in response to your inquiry of February 1, 2023, asking for information regarding the cause of our recent (September 2021) AWA violations and subsequent steps that were taken in response to these violations. Please note that the three violations from this inspection were all related to a single research protocol with two of the violations tied to actions of a single individual and one being the result of a policy that has since been changed. In the case of the responsible researcher, ODU took immediate action by suspending his research privileges and requiring extensive retraining prior to allowing continued work under rigorous, in-person supervision.

This blemish on our animal program is not at all reflective of the high standards we strive to maintain. ODU has a long history of compliance with the Animal Welfare Act with our only other violation in the past decade being a non-critical paperwork issue.

**A detailed explanation for the cause of the AWA violations for 2021-2023:**

The violations resulted from a regularly scheduled USDA inspection on September 15, 2021:

**Multiple changes made to a protocol without notifying the IACUC or AV;** This first violation was the direct result of protocol deviations by a postdoctoral researcher on the approved protocol. Upon investigation, it appeared that this individual did not adequately understand the strict requirements set forth by the IACUC and subsequently disregarded the procedures in the approved protocol. Specifically, the following deviations from the approved protocol occurred:

1. Kept inadequate medical records that failed to demonstrate that required post-operative care was provided.
2. Inconsistent administration of antibiotics over a 10-day postoperative period
3. Kept inadequate medical records that failed to provide evidence of intra-operative monitoring of vital signs
4. Altered procedure for preparation of surgical site

**Adequate training and review of personnel qualifications not being performed at a frequency to ensure proper care of animals;** This second violation was also tied to the postdoctoral student referenced in the first violation. Given that this student received retraining and then was responsible for

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another protocol deviation, USDA considered inadequate supervision and training as being linked to the student's lack of understanding.

**Attending veterinarian and adequate vet care relating to lack of access to appropriate drugs;** The third violation was the result of a previous policy that required the principal investigator of a project to have euthanasia drugs on hand for a research project. Appropriate planning for rare worst-case scenarios had not occurred prior to the beginning of the protocol linked to this violation. Prior to this isolated event, the policy of having the PI (DEA license holder) maintain euthanasia drugs had always been sufficient as they had been available on campus any time a drug was needed. In this particular incident, the PI's designee had not yet arrived on campus, causing a delay in obtaining the drugs needed to euthanize an animal in distress (drugs administered 69 minutes after Attending Veterinarian indicated that euthanasia should take place within 60 minutes).

**Information detailing:**

**if and how individuals responsible for these violations were disciplined and/or held accountable for their failures**.

A two-pronged approach was taken to address the first two violations. Education, increased oversight, and restrictions on activities were placed on 1) the laboratory group responsible for the related research project and 2) the individual in that laboratory group who was responsible for the deviations. The following actions were taken:

1. Lab members were allowed to continue to work on approved protocols, however:
    a. *Communication between the research team and the animal care staff is critical.* Animal care staff must be informed by the research team regarding when work is going to occur and know who will be present and conducting the work.
    b. Mouse work was required to be finished by 3:30pm. This allowed the animals to recover from any procedures while animal care staff were still present. A new daily check form was created and used for these projects and posted in the facility. Research team members were required to sign off on this form, and animal care staff also signed off at the end of each day to confirm that the animals were checked by lab staff in accordance with the protocols and to confirm that the animals did not need vet intervention or meet early endpoint criteria.
    c. If rabbit work was to occur, only 2 rabbits could be ordered. Animal care staff MUST be involved in all aspects of the rabbit work (pre-, intra, post op care). The PI was responsible for covering the tech time charges.
        i. After the 2 rabbits, the IACUC reassessed if more may be ordered. *(At the time of writing this letter, the IACUC has approved more rabbits be ordered. All procedures have been under animal care supervision and gone smoothly.)*
    d. If an experimental manipulation or check (weight, assessment, etc.) is to occur on a weekend or holiday, the research team MUST coordinate with animal care staff's weekend schedule to perform this work while an animal care staff member is present. Animal care staff was responsible for signing the daily check confirming someone from the research team came and did what was expected.

2. The individual responsible for the violation had his facility access card revoked.
    a. If present in the facility, he was required to be accompanied and supervised by someone from the research team who was senior to him.
    b. The supervising individual took full responsibility for the accuracy of work that was being done.
    c. If the individual responsible for the violation was conducting the work (under direct supervision from a lab member), he was also subject to frequent observation from the Attending Veterinarian and/or Research Compliance Coordinator.
    d. At no time could the individual responsible for the violation be left unattended in the animal facility. He was required to leave the facility if the supervising person had to step out.
3. Daily checks were mandated for one calendar year. Monthly updates were reported to the IACUC. *(At the time of writing this letter, the IACUC has maintained this requirement and is scheduled to revisit the subject during the April 2023 meeting).*
    a. If any issues arise, animal care staff is required to notify the Compliance Office immediately, and appropriate action will be taken.
    b. At the end of the one year, the IACUC will decide if the daily checks need to continue or be modified. The PI will be advised how the IACUC wishes to proceed at this point.
    c. The individual responsible for the violation will not be allowed to work with USDA species *unsupervised* for at least three years
4. The study PI and the individual responsible for the violation were required to attend a training conference at their own expense.
    a. Suggested: https://www.scaw.com/iacuc-training-workshops.html
5. A Project Implementation Meeting (PIM) was scheduled within the first 30 days of this sanction period to review mouse work being conducted in the facility, and a PIM for the rabbit protocol was required to occur within 60 days of restarting that project.
6. The individual responsible for the violation was required to submit a letter to the IACUC acknowledging the wrongdoing that has occurred, accept responsibility for these issues, and show a willingness to accept retraining.

Regarding the violation related to lack of appropriate drug availability, only a procedural change was implemented. No disciplinary action was implemented, as this was the result of an unforeseen circumstance and the issue was corrected immediately after this isolated incident occurred. Drugs are available for future animals, through the Attending Veterinarian's DEA license, and this correction was noted in the citation from the USDA.

**Whether these violations were associated with protocols for which ODU received public monies, and if so, the source of monies;** Yes, federal funds had been received from NIEHS and NIH for a research protocol tied to the first two violations.

**If the PI or designee reported these violations to the entities funding the research associated with these violations;** The circumstances surrounding these citations were not deemed to be a systemic issue with the protocol or ODUs animal program, but rather with an individual. For this reason, it did not require a stoppage of the study that would have prompted a report to the funding agency. Self-reports of

the incidents are made to our federal oversight agencies and their responses are typically shared with any relevant funding agencies.

**Any action taken by ODU to address the publishing of data from the protocols associated with these violations;** ODU has not taken any action to address the publishing of data from this protocol. No research data could be used from animals impacted by these violations. Further, there was no reason to question the validity of the data collected from any animals not impacted by the violations. No restrictions have been placed on the PI's ability to publish data.

**Actions ODU has taken to prevent such violations from occurring in the future;** Multiple safeguards have been implemented since these issues have occurred. The IACUC has created a new policy, titled Project Implementation Meeting Guideline (PIM), in which the IACUC determines if each new protocol being reviewed should require a meeting between the PI, the Attending Veterinarian, the compliance coordinator, and vivarium management, prior to the protocol starting. In these meetings, the following areas are discussed:

a) Clarify safety procedures for lab and vivarium staff.
b) Identify and review PI's training program for all staff listed on the approved protocol. Identify training that may be needed (procedural, safety, etc.).
c) Review ODU's Animal Recordkeeping Guidelines and review templates and forms the PI will be using.
d) Answer any questions the investigator or lab may have regarding animal use, husbandry, etc.
e) Some protocols may be designated for increased Post-approval Monitoring (PAM). PAMs may be conducted by Compliance staff or vivarium staff.

In addition to the PIM meetings, specific oversight of the individual responsible for the first two violations continues to be a priority, and he continues to have vivarium staff check behind him each day that he is present in the facility using animals. This information was outlined earlier in this letter.

Regarding the availability of euthanasia drugs, a policy change was implemented to require drugs by held under Attending Veterinarian oversight rather than the investigator responsible for the animals on their protocol. Appropriate drugs are now consistently available directly within the animal facility for all species housed, giving direct access to appropriate animal care staff.

**ODUs plan to ensure ongoing and consistent compliance with federal laws and regulations about animal welfare of animals used for experimental purposes.**

ODU has an ongoing quality assurance assessment process in which we are continually evaluating mechanisms to enable compliance and assure the welfare of animals under our care. We maintain our AAALAC accreditation to demonstrate a standard well beyond the floor level of regulatory requirements. ODUs IACUC is very involved and participation in the semi-annual inspections and program review always exceeds the minimal requirement. Our contracted animal care company provides quality assurance audits of the facilities periodically as well.

The particular USDA visit that resulted in these citations was an anomaly for our program. ODU has a long history of clean inspection reports and no citations during USDA inspections. The protocol

deviations on the rabbit protocol were self-reported to USDA prior to the inspection, and ODU will continue to work with our federal oversight agencies and continue to be transparent and self-report any issues of non-compliance. Corrective action plans are implemented within the program as soon as deviations are noted.

Please let me know if you have any additional questions.

Sincerely,

Morris W. Foster
Vice President for Research

Cc: President Brian O. Hemphill, Ph.D., President
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