



Robert M. Gibbens, D.V.M., Director,
Animal Welfare Operations. USDA-APHIS-Animal Care.
Via e-mail: robert.m.gibbens@usda.gov
animalcare@usda.gov

9/22/21

Dr. Gibbens,

I am writing to you today to file an Official Complaint against Sam Houston State University (SHSU) of Huntsville, TX, for what are clear violations of the Animal Welfare Act (AWA) which resulted in the deaths of multiple animals.

As you know, when filing complaints we typically cite the registration number of the facility. However, when we searched the USDA databases for inspection reports and/or annual reports filed by Sam Houston State University of Huntsville (TX) we were unable to locate any documentation which indicates that this institution is currently registered with the USDA. It is entirely possible that an application has been filed, and is in process. However, for the purposes of this complaint, we will work under the assumption that Sam Houston State University has not yet registered with the USDA.

The registration regulation states:

Sec. 2.30 Registration. (a) Requirements and procedures. (1) Each research facility other than a Federal research facility, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the AC Regional Director. The registration form shall be filed with the AC Regional Director for the State in which the research facility has its principal place of business, and shall be updated every 3 years by the completion and filing of a new registration form which will be provided by the AC Regional Director. Except as provided in paragraph (a)(2) of this section, where a school or department of a university or college uses or intends to use live animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary.

SHSU clearly uses animals for teaching purposes. This institution has a program in Animal Science (ANSC) which lists multiple classes involving animals. This link to their catalogue shows many classes that utilize animals: <http://catalog.shsu.edu/undergraduate/course-descriptions/ansc/>

Failure to register with the USDA is, in and of itself, a serious AWA violation. However, a much more serious violation has occurred. According to a report filed with the Office of Laboratory Animal Welfare, ten cows died of dehydration.

The OLAW report, dated 6/21/21, states ***“ten beef bulls died in the field due to no water . . . the IACUC discussed the incidents at several emergency convened meetings where a quorum of the IACUC determined that the PI deviated from the AG guide and his protocol. . . . Ultimately, the IACUC suspended the protocol approval and requested corrective actions from the PI.”***

“On November 13, 2020, the Director of Research Compliance who also serves and the university’s IACUC Administrator received two adverse event reports pertaining to the aforementioned deaths, which occurred between November 9th through November 12th, 2020.”

“The PI expressed regret at the loss of the animals in a letter to the IACUC and took responsibility for the noncompliance. The IACUC determined that this was not an isolated incident and thus a programmatic failure. Based on the IACUC’s determination and because of other factors not connected to IACUC business, the PI was relieved of his duties at SHSU, and a new PI was hired to replace him. Suspension of the protocol approval remained in place until the IACUC reviewed and approved the corrective action plan as submitted by the new PI.”

This horrific situation which allowed ten cows to die of dehydration potentially violates multiple sections of the AWA. The failure to provide adequate water would violate ***Sec. 3.130 watering — If potable water is not accessible to the animals at all times, it must be provided as often as necessary for the health and comfort of the animal. Frequency of watering shall consider age, species, condition, size, and type of the animal. All water receptacles shall be kept clean and sanitary.***

Additionally, the regulation for IACUC is relevant both because the approved protocol was violated, and because when the protocol was suspended, there is no indication that this was reported to the USDA ***Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)***

Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities;

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 APHIS and any Federal agency funding that activity;

There is no indication in the attached OLAW report (such as an indication of cc’ing it to the USDA) that the USDA was notified of this suspension. Therefore, this code section has also been violated.

I know that your office considers AWA violations to be very serious in nature, especially when they kill or seriously injure animals. Since Sam Houston State University has killed at least ten animals, failed to report a suspended protocol, and may also have failed to register with USDA/APHIS/AC, I must insist that you launch a full investigation, and at the conclusion of your investigation, you must take the most severe action allowable under the AWA and immediately begin the process of issuing the maximum fine allowable against Sam Houston State University -- \$10,000 per infraction/per animal.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

Michael A. Budkie, A.H.T.,
Executive Director, SAEN

Attachments: 1 OLAW Non-Compliance Report



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OFFICE OF RESEARCH AND SPONSORED PROGRAMS

June 21, 2021

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

Sam Houston State University, in accordance with Assurance D19-01078 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident in which ten beef bulls died in the field due to no water and approved by the IACUC in a Principal Investigator's (PI) animal colony protocol, entitled "SHSU Gibbs Ranch." This incident was first reported to Dr. Axel Wolff, OLAW, on November 25th, 2020 via a telephone call by Sharla Miles, M.Ed., CIP, Director, Research Compliance in the Office of Research and Sponsored Programs.

On November 13, 2020, the Director of Research Compliance who also serves as the university's IACUC Administrator received two adverse event reports pertaining to the aforementioned animal deaths, which occurred between November 9th through November 12th, 2020. At the time these incidents were reported, the approved colony protocol described procedures for providing animals with water 24/7 via ponds or piped in water fed into tanks.

Following the University's IACUC policy on Alleged Incident of Noncompliance, the IACUC discussed the incidents at several emergency convened meetings where a quorum of the IACUC determined that the PI deviated from the Ag Guide and his protocol. Plus, the committee determined that while the PI met the threshold for the procedures detailed in the Gibbs Ranch Standard Operating Procedure (SOP), an IACUC review of this SOP found that it requires extensive revisions to further protect the animals housed at this facility. Ultimately, the IACUC suspended the protocol approval and requested corrective actions from the PI.

To address the situation, corrective actions were taken including the creation of a husbandry checklist, which included daily checkups for animal welfare, and revisions to the Gibbs Ranch SOP to be more detailed regarding when the veterinarian should be contacted in the event sick animals are identified.

The PI expressed regret at the loss of the animals in a letter to the IACUC and took responsibility for the noncompliance. The IACUC determined that this was not an isolated incident and thus a programmatic failure. Based on the IACUC's determination and because of other factors not connected to IACUC business, the PI was relieved of his duties at SHSU, and a new PI was hired to replace him. Suspension of the protocol approval remained in place

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until the IACUC reviewed and approved the corrective action plan as submitted by the new PI.

The following corrective action plan was implemented after the incident:

1. A protocol amendment was submitted to request approval for replacing the previous PI of the colony protocol with the new PI. Protocol amendment was approved
2. Creation of a husbandry checklist, which will include daily checkups for animal welfare, availability of feed/supplement resources, water availability and etc to the animals. Provide training to personnel on use of the checklist. The checklist must include:
 - a. The check list must be completed daily for wherever animals are present
 - b. A place for personnel assigned to these tasks to initial on the checklist that these inspections have been performed
 - c. A place for the Ranch Manager to sign and date [NOTE: All completed checklists must to be placed into a file to be created by the Ranch Manager and available at all times for inspection.]
3. Revision of the **SHSU Gibbs Ranch Standard operating procedure (SOP)** to be more detailed regarding the section titled *Identification and Treatment of Sick Animals* to include the previously mentioned checklist and a strict timeline for when a veterinarian must be called and consulted. The IACUC requires that the strict timeline begin once an incident has been identified (e.g., within one hour, within a four-hour period, etc.).

At their meeting on December 11, 2020, the IACUC reviewed and accepted the corrective action plan as submitted by the PI, and the committee reinstated the approval of this colony protocol contingent upon the aforementioned corrective plan being implemented immediately.

Sam Houston State University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Marcy Beverly, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Chad Hargrave, PhD
Associate Vice President for Research
Institutional Official
Sam Houston State University

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