



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, 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) 480-3387

February 13, 2020

Re: Animal Welfare Assurance
A3958-01 [OLAW Case E]

Dr. Daniel Scholl
Vice President for Research and Economic Development
South Dakota State University
Division of Research and Economic Development
Morrill Hall (b) (4) Box 2201
Brookings, SD 57007

Dear Dr. Scholl,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 11, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at South Dakota State University. According to the information provided, OLAW understands that a bighorn sheep was found recumbent for four days after which it died. The sheep had not been euthanized when the protocol humane endpoints had been reached.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) questioning the Principal Investigator (PI) who contested the facts but did not provide any medical records for the sheep. The study has ended and there are no more animals on the protocol. The PI and students were retrained on maintaining medical records and the students were retrained on monitoring the health of animals. The incident was cited by the USDA which led the IACUC to improve post-approval monitoring, provide training on record keeping, and training on monitoring clinical signs in animals.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy and recommends that staff also be instructed to promptly contact the veterinarian about any animal concerns.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., Ph.D., USDA-APHIS-AC



SOUTH DAKOTA STATE UNIVERSITY

Division of Research and Economic Development

A3958-E

February 11, 2020

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:

South Dakota State University, in accordance with Assurance A3958-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding failure to euthanize a bighorn sheep according to an IACUC-approved animal study protocol, entitled "Investigating the role of super-shedders in respiratory disease persistence and transmission in bighorn sheep."

On October 8, 2019, the Attending Veterinarian received a necropsy report indicating a bighorn sheep was inactive on the 25th, laying down in the same spot and not rising upon approach on the 28th, and dead on the 29th. The animal was not euthanized per protocol endpoints (sufficiently weak, lethargic, or moribund that it was not able to rise and flee to avoid an approaching researcher).

The IACUC invited the PI to discuss the incident in a convened meeting on October 23, 2019. The PI claimed that his graduate student made an error in filling out the necropsy report and that she would be happy to testify to this fact. He said the sheep was not moribund and he shared photos of the sheep the student had sent him. The PI was asked to produce medical records for the sheep, but he did not.

Given the PI's verbal account and the absence of further records, the IACUC could not determine the accuracy of the submitted necropsy report. Because the project had ended and there were no more animals under the PI's care, animal welfare was no longer a pressing concern. As corrective action, the IACUC Chair advised the PI that his students need to be retrained on how to detect behavioral changes, and that both the students and the PI require further training on how to maintain medical records.

The USDA review of IACUC records and facility paperwork on Jan 29-30, 2020 resulted in a finding of critical noncompliance. The inspection found that the IACUC failed to review, approve, require modifications in, or withhold approval of significant changes regarding the care and use of animals in ongoing activities (Sect. 2.31(c)(7)). The specific instance cited was the unapproved deviation from protocol described above. As corrective action, the IACUC will improve its post-approval monitoring and provide training on record keeping and clinical symptom monitoring.

South Dakota 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 require any

further information, please don't hesitate to contact
(b) (6)

Thank you for your consideration of this matter.

Sincerely,

DocuSigned by:

(b) (6)

877331682210854
Daniel F. Scholl
Institutional Official
Vice President, Research and Economic Development
South Dakota State University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 13, 2020 6:44 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance

Thank you for this report, (b) (6) We will send a response shortly.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Wednesday, February 12, 2020 6:11 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of noncompliance

Dear OLAW,

Please see the attached report of noncompliance related to animal research at South Dakota State University.

Should you require any additional information, please don't hesitate to contact me.

Sincerely,
(b) (6)



www.sdstate.edu



**SOUTH DAKOTA
STATE UNIVERSITY**