



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) 402-7065

November 21, 2018

Re: Animal Welfare Assurance  
A3027-01 [OLAW Case F]

Mary Berry, Ph.D.  
Vice President for Research  
University of South Dakota  
414 East Clark Street  
Vermillion, SD 57069

Dear Dr. Berry,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 25, 2018 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of South Dakota, following up on an initial August 17, 2018 email notification. According to the information provided, OLAW understands that laboratory personnel performed unauthorized injections in the thighs of mice and subsequently failed to euthanize animals whose tumor size had attained the 5 mm endpoint in accordance with the IACUC approved protocol. The performance of all unauthorized procedures were discontinued upon discovery and all animals involved in the unapproved treatments were immediately euthanized by the Attending Veterinarian (AV).

The corrective actions consisted of the following:

- 1) The IACUC approving an amendment to the protocol to include the thigh injections in mice.
- 2) The Principal Investigator (PI) providing written assurance that all animal activities will be performed in accordance with the approved protocols.
- 3) Training of all personnel on protocol compliance, including refresher training of the PI's active protocols.
- 4) Post-approval monitoring of two ongoing approved protocols to ensure compliance.
- 5) Enhancing oversight by the AV of animal procedures performed in the laboratory until January 2019.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

*Page 2 – Dr. Berry  
November 21, 2018  
OLAW Case A3027-F*

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair

(b) (6)

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Cc: William Percy, Ph.D.  
Ruth Bakker, DVM  
 (b) (6)

414 E Clark Street Vermillion, SD 57069-2390  
605-677-6265 / Fax 605-677-6387  
[ehs@usd.edu](mailto:ehs@usd.edu)

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, November 01, 2018 1:46 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of noncompliance

Thank you for providing this final report. 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:** (b) (6)  
**Sent:** Thursday, November 01, 2018 1:03 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** FW: Report of noncompliance

Good afternoon. Attached please find our Final Report concerning a non-compliance issue initially reported to you on August 17, 2018. A signed hard copy is being mailed as well. If you have any questions regarding this matter, please feel free to reach out to us.

Thank you.

(b) (6)

(b) (6)

How are we doing? Please consider giving us suggestions for improvement. <http://www.usd.edu/research/feedback>



**From:** (b) (6)  
**Sent:** Friday, August 17, 2018 4:49 PM  
**To:** 'olawdco@mail.nih.gov' <olawdco@mail.nih.gov>  
**Subject:** Report of noncompliance

Please feel free to call me if you have any questions regarding this report. We will submit a final report when all corrective actions have been implemented.

(b) (6)

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August 17, 2018

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Preliminary Report on Non-Compliance

Dear Sir or Madam,

The University of South Dakota (USD), in accordance with Assurance #D16-00130 (A3207-01) and PHS Policy IV.F.3, provides this report of noncompliance regarding the use of a surgical procedure not included in an approved protocol.

(b) (6) conducts several experiments employing mouse models to study Alzheimer's Disease and Huntington's Disease. (b) (6)'s laboratory has programmed the fibroblast cells derived from Huntington's Disease patients into induced pluripotent stem cells (iPS), and his approved protocol calls for injection of these iPS cells into the testis capsule of 6-week-old immunocompromised mice. After 6 – 8 weeks the animals are sacrificed, or earlier if a tumor reaches 5 mm in size. The Attending Veterinarian discovered that his laboratory had injected some animals in the thigh, rather than the testis capsule, and that some animals had growths in excess of 5 mm.

The Attending Veterinarian immediately suspended this work, and the IACUC met in extraordinary session, and has also conferred with (b) (6). The following Corrective Action Plan was resolved upon:

- (b) (6) will discontinue all procedures not explicitly included in the approved protocol AUP-17-09.
- The Attending Veterinarian will immediately euthanize all animals involved in the unapproved treatment.
- If (b) (6) wishes to include thigh injections of iPS cells in his study, he must submit an amendment to his existing protocol for IACUC consideration.
- (b) (6) must provide a written assurance, stating that all animal research procedures will be conducted as described in the approved protocol, unless and until an amendment has been reviewed and approved.
- (b) (6) must train his staff on the requirements of conducting animal research in strict accordance with approved protocols, and train them on all active protocols.

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orsp@usd.edu • www.usd.edu/research



UNIVERSITY OF  
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- Vice-President for Research Compliance will conduct an audit of all of (b) (6)'s active Animal Use Protocols.
- The IACUC will monitor (b) (6)'s laboratory for 6 months.

We will submit a final report once these corrective actions have been implemented. Should you have any questions regarding this preliminary report, please contact William Percy, PhD, IACUC Chair.

Sincerely,

(b) (6)

Mary Berry, Ph.D.  
Interim Vice President for Research  
Institutional Official

Cc:

Ruth Bakker, DVM  
(b) (6)  
William Percy, Ph.D.  
(b) (6)

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## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 20, 2018 7:19 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of noncompliance

Thank you for this preliminary report. We will open a case file and await further information.

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:** (b) (6)  
**Sent:** Friday, August 17, 2018 5:49 PM.  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Report of noncompliance

Please feel free to call me if you have any questions regarding this report. We will submit a final report when all corrective actions have been implemented.

(b) (6)

How are we doing? Please consider giving us suggestions for improvement. <http://www.usd.edu/research/feedback>



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