



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 20892-7982
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

DATE: January 8, 2019

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (#016-18) - Animal Welfare Assurance
A4149-01 [Case 12R]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2018 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute on Aging (NIA). Your letter supplements the information in the prompt preliminary report filed with OLAW on December 11, 2018. According to the information provided, OLAW understands that the NIA ACUC was informed on December 6, 2018 by a protocol PI that blood had been collected from 5 rats although the blood collection procedure was not included in the approved protocol. One of the animals was subsequently euthanized due to bruising at the collection site. The responsible individual was instructed to refrain from blood collection until the incident could be investigated by the ACUC.

Corrective and preventive actions included the ACUC advising the PI that:

- The responsible individual must complete refresher training offered by the NIH Office of Animal Care and Use;
- The responsible individual must complete a training session on blood collection techniques with the veterinary staff;
- The responsible individual must submit an updated "Training and Experience" form to the ACUC; and
- If blood is to be collected in the future, the PI must submit an amendment adding blood collection to the ASP.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Page 2 – Dr. Gottesman
January 8, 2019
OLAW Case A4149-12R

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Jennifer O'Connell, Ph.D., NIA ACUC Vice Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

December 20, 2018

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance A4149-01 (#016-18)

This correspondence conveys the results of an investigation by the National Institute of Aging (NIA) ACUC, in accordance with Assurance A4149-01 and PHS Policy IV.F.3. The adverse event involved conducting procedures on rats without appropriate IACUC review and approval.

As noted in the attached NIA ACUC memorandum, the event was first reported to the NIH Office of Animal Care and Use by the NIA ACUC Chair on December 11, 2018. Please contact me or Dr. Stephen Denny, Acting Director, Office of Animal Care and Use, if additional information or clarifications are required.

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. O'Connell
Dr. Denny



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Aging
Biomedical Research Center
Baltimore, Maryland 21224

December 18, 2018

To: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

From: Jennifer O'Connell, Ph.D. [REDACTED]
Vice Chair, NIA Animal Care and Use Committee

Subject: National Institute on Aging Animal Welfare Incident – Final Report

Per the requirements of PHS Policy and NIH Policy Manual 3040-2, I am reporting an incident that occurred within the National Institute on Aging (NIA) involving the care and use of animals in biomedical research.

INCIDENT:

It was reported to the ACUC Program Coordinator that blood had been collected from five rats assigned to an Animal Study Proposal (ASP) that was not approved for blood collection. One of the rats was subsequently euthanized due to bruising at the collection site. The responsible individual was instructed to refrain from blood collection until the incident could be investigated by the ACUC.

ACTIONS:

The Animal Care and Use Committee (ACUC) Vice Chair was notified, at which point a subcommittee, composed of the Attending Veterinarian and the ACUC Program Coordinator, was appointed to investigate the incident. The Principal Investigator (PI) was also notified. The responsible individual submitted a written statement to the ACUC accepting full responsibility for the incident, expressing regret, and acknowledging the significance of the noncompliance.

After discussion at a convened meeting, the ACUC concluded that this was a reportable incident of protocol noncompliance.

Subsequent to the meeting, the PI was advised of the following conditions:

- The responsible individual must complete refresher training offered by the NIH Office of Animal Care and Use;
- The responsible individual must complete a training session on blood collection techniques with the veterinary staff;
- The responsible individual must submit an updated "Training and Experience" form to the ACUC; and
- If blood is to be collected in the future, the PI must submit an amendment adding blood collection to the ASP.

The ACUC feels that these actions will prevent the recurrence of a similar incident in the future.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 03, 2019 3:41 PM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 NIH Adverse Animal Incident Report (NIA 016-18)

Thank you for this final report Dr. Denny. 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Denny, Stephen (NIH/OD) [E]
Sent: Thursday, January 03, 2019 3:22 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 NIH Adverse Animal Incident Report (NIA 016-18)

Dear OLAW/DCO,

Final reports from the NIH Institutional Official and the National Institute on Aging ACUC addressing an animal incident reported to this office on December 11th are attached. The adverse event involved conducting biosampling procedures on rats without appropriate IACUC review and approval.

If you have any questions please contact me via email or the phone number listed below. Thanks, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, Office of Animal Care and Use | National Institutes of Health | Bldg 31-Rm B1C37, 9000 Rockville Pike, Bethesda, MD 20982 | Phone: (301) 496-5424 | <http://oacu.od.nih.gov>

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 11, 2018 9:45 AM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 NIH Reportable Event - Initial NIA (016-18)

Thank you for this prompt preliminary report Dr. Denny. We will open a case file and await further information as noted in your email.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Denny, Stephen (NIH/OD) [E]
Sent: Tuesday, December 11, 2018 9:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 NIH Reportable Event - Initial NIA (016-18)

Dear OLAW/DCO –

Today the National Institute for Aging (NIA) ACUC Coordinator informed this office of a reportable animal incident involving the performance of an unapproved blood collection procedure in five rats. The rats were on an ACUC approved study. The incident was reported to the ACUC by the Principal Investigator on December 6.

The NIA ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use | Phone: (301) 496-5424