



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

DATE: September 29, 2022

TO: Nina F. Schor, M.D., Ph.D.  
Deputy Director for Intramural Research, NIH

FROM: Director  
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (ORS-DVR #39-22) - Animal Welfare Assurance  
A4149-01 [Case 17P]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 16, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Office of Research Services/Division of Veterinary Resources. According to the information provided, OLAW understands that on July 20, 2022, retro-orbital blood collection from mice was conducted as part of a training session for veterinary technicians. Animals were under general anesthesia according to the approved animal study proposal (ASP), and the procedure followed the applicable SOP, Survival Bleeding of Rodents. The training ASP specifies that rodents be euthanized after this procedure. In this incident, animals were recovered after retro-orbital bleeds. Animals remained clinically normal and healthy for one week until they were used for a terminal training procedure. It was found that the training staff had not read the entire protocol prior to conducting the training and had followed an established SOP which is referenced within the ASP. In this case the animals recovered without incident.

Corrective and preventive actions: Survival retro-orbital bleeding after initial training may be added to the ASP and will be reviewed by the ACUC. The training group has reviewed the ASP and has conducted training on the ASP for all staff. Trainers will also review the ASP and relevant SOPs prior to each training to ensure the training sessions match these documents.

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,

**Brent C. Morse -S**

Digitally signed by Brent C. Morse

-S

Date: 2022.09.29 15:08:11 -04'00'

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

cc: Dr. Stephen Denny  
Dr. Richard Wyatt  
Dr. Joanne Smith, Chair, ORS ACUC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

September 16, 2022

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 D16-00602 (DVR 39-22)

This correspondence conveys the results of an animal incident investigation by the NIH Office of Research Services Division of Veterinary Medicine (DVR) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure to institute euthanasia procedures in mice as outlined in the ACUC-approved Animal Study Proposal.

The event was first reported to the NIH Office of Animal Care and Use by the DVR ACUC Chair on July 26, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Nina F. Schor -S	Digitally signed by Nina F. Schor -S Date: 2022.09.16 17:45:15 -04'00'
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Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt  
Dr. Denny  
Dr. Smith



**To:** Nina F. Schor, M.D., Ph.D.  
Deputy Director for Intramural Research, NIH

**From:** Joanne Smith  
Chair, ORS Animal Care and Use Committee

**Subject:** NIH DVR Animal Incident Report, Deviation from approved protocol

In accordance with Animal Welfare Assurance # D16-00602 and PHS Policy IV.F.3., the ORS ACUC provides this report of an incident that occurred involving the care and use of animals in biomedical research.

**Incident Summary:**

Date: Wednesday July 20, 2022

Description: Recovery of training mice after retro-orbital bleed, deviation from approved protocol.

The incident was discovered by the facility veterinarian and reported to the PI and ACUC Chair Friday July 22, 2022. It was reported to OACU 7/26/22 by the ACUC Chair. A subcommittee conducted interviews to investigate the incident and corrective actions. These included the following:

- ORS-17 PI on 8/3/2022
- Contract Lead Trainer 8/4/2022
- Contract Manager 8/4/2022

Retro-orbital blood collection from mice was conducted as part of a training session for veterinary technicians on July 20, 2022. Animals were under general anesthesia according to the approved animal study proposal (ASP), ORS 17, and the procedure followed the applicable DVR SOP 215 Survival Bleeding of Rodents. The SOP is written to guide trained personnel, while on the training ASP, the endpoint guideline specifies that rodents be euthanized after this procedure. The training protocol specifies euthanasia due to the inexperience of trainees to avoid inadvertent harm to animals. In this case animals were recovered after retro-orbital bleeds. Animals remained clinically normal and healthy for one week until they were used for a terminal training procedure. The training staff discovered this oversight the next day and reported to the facility veterinarian who in turn reported to the PI and ACUC Chair. It was found that the training staff had not read the entire protocol prior to conducting the training and had followed an established SOP which is referenced within the ASP. In this case the animals recovered without incident.

**ACUC Review:**

The incident was reviewed at the full committee meeting on August 16, 2022. The committee voted that this is reportable to OLAW as a noncompliance for not following procedures in an approved ASP. There was no animal harm in this case.



**Corrective Actions Proposed and Timeline for Implementation:**

The training ASP has been moved to a new PI recently, this incident happened during the time of transition between PIs. As part of this transition the new PI is in the process of submitting amendments. Survival retro-orbital bleeding after initial training may be added to the ASP and will be reviewed by the ACUC. The training group has reviewed the ASP and has conducted training on the ASP for all staff. This training was implemented the second week of August. Trainers will also review the ASP and relevant SOPs prior to each training to ensure the training sessions match these documents.

The ORS ACUC feels these actions will prevent the occurrence of a similar incident in the future.

Sincerely,

Joanne M. Smith -S

Digitally signed by Joanne M.  
Smith -S  
Date: 2022.09.15 08:12:22 -04'00'

Chair, ORS Animal Care and Use Committee

## McCoy, Devora (NIH/OD) [E]

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**From:** Denny, Stephen (NIH/OD) [E]  
**Sent:** Monday, September 19, 2022 8:09 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** D16-00602 NIH Animal Incident Report (DVR 39-22)  
**Attachments:** D16-00602 NIH IO Animal Incident Memo (DVR 39-22).pdf; D16-00602 NIH ACUC Animal Incident Report (DVR 39-22).pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH Office of Research Services-Division of Veterinary Medicine ACUC address an animal incident involving the failure to institute euthanasia procedures in mice as outlined in the ACUC-approved Animal Study Proposal.

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

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |  
Phone: (301) 435-2188 | **NIH . . . Turning Discovery Into Health** |

## McCoy, Devora (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, September 19, 2022 9:15 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (DVR 39-22)

Good morning Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
301-435-2390

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**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Monday, September 19, 2022 8:09 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (DVR 39-22)

Dear OLAW/DCO,

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

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |  
Phone: (301) 435-2188 | *NIH . . . Turning Discovery Into Health* |