



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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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

DATE: August 22, 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 #27-22) - Animal Welfare Assurance  
A4149-01 [Case 17I]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 10, 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 June 21, 2022, the ACUC was notified that on the holiday weekend of June 18-20 three NHPs lacked water for some portion of the long weekend, resulting in one death. Subsequently, it was discovered that for the waterline to the specific quad unit in which the three animals were housed, the male and female portions of the water hookup were together but not fully engaged. The weekend caretaker admitted she in fact had not performed the required lixit check the day before and falsely reported that she had. She is no longer employed at NIH.

Corrective and preventive actions: To address this incident, retraining on caretaker staff on checking of lixits and water lines has been done and several changes of the facility's husbandry log have been made. The changes are: 1) to check the waterlines daily in addition to lixits, 2) to add additional weekly lixit and water line checks, and 3) to have two different teams (the cage change team and the caretaker team) to check the water lines and Lixits immediately following the cage change (Every 14 days). Management is retraining staff on the changes to the SOPs. The department's Quality Control Manager has been tasked to include water line and lixit checks in their periodic facility review. A special meeting was held with the government staff to emphasize the importance of oversight to ensure work is being completed properly.

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: 2022.08.22 12:12:46 -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)

August 10, 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 27-22)

This correspondence conveys the results of an animal incident investigation by the NIH Office of Research Services Division of Veterinary Resources (DVR) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure to monitor the water connection to a nonhuman primate cage in accordance with the nonhuman primate husbandry SOP.

The event was first reported to the NIH Office of Animal Care and Use by the DVR ACUC Chairman on June 21, 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: 2022.08.10  
16:14:45 -04'00'

Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt  
Dr. Denny  
Dr. Smith



**To:** Michael M. Gottesman, MD  
Deputy Director for Intramural Research, NIH

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

**Subject:** NIH DVR Animal Incident Report

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:** June 18-20 (Juneteenth holiday weekend)

**Description:** Three NHPs lacked water for some portion of long weekend, one death

Reported to the ACUC and AV 6/21/22 by the Facility Veterinarian. ACUC Chair reported to OACU on the same day.

ACUC Investigation team conducted interviews 6/28/22 with the Facility Veterinarian who was also the veterinarian on call over the holiday weekend, the Facility Manager, The Veterinary Technician who was on duty over the weekend, Supervisors for the Vet. Technician and for the Caretaker, and the contracting company Contract Lead for the facility. On 7/7/22 they interviewed the investigator for the animals involved.

One rhesus monkey (first patient) was reported Monday 6/20 for acutely not eating. This animal was housed in a quad cage. It and one other were on the top level, and one was on the bottom level. Cages were changed out 5 days earlier. Per facility's SOPs and guidelines, the water Lixits are checked daily to ensure they are functional and when animals are not eating, caretakers should perform additional checks on the water supply. The caretaker on that day initially reported that she had performed the Lixit check. The veterinarian on call was contacted and prescribed treatment for possible dehydration based on description of clinical appearance. The first patient received a standard fluid therapy to which he responded well. The next morning, 7/21, another animal (second patient) immediately adjacent to the first patient was reported with similar but more severe symptoms. Subsequently, it was discovered that for the waterline to this specific quad unit the male and female portions of the water hookup were together but not fully engaged. Despite medical intervention, the second animal did not recover and died on the following day. The animal in the lower level remained healthy. Later, the weekend caretaker admitted she in fact had not performed the Lixit check the day before and falsely reported.



The deceased animal was in the cohort of a novel HIV vaccine study begun in March 2021, and had been nearing study completion, with this event resulting in a loss of data to the study.

**ACUC Review:**

The incident was reviewed at a full committee ACUC meeting on 7/19/22. The committee concluded that the incident is reportable based on guidance to report conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.

**Corrective Actions and Implementation Schedule:**

The weekend caretaker was removed from the service contract and is no longer in employ at NIH. To address this incident, retraining on caretaker staff on checking of Lixits and water lines has been done and several changes of the facility's husbandry log have been made. The changes are: 1) to check the waterlines daily in addition to Lixits, 2) to add additional weekly Lixit and water line checks, and 3) to have two different teams (the cage change team and the caretaker team) to check the water lines and Lixits immediately following the cage change (Every 14 days). Management is retraining staff on the changes to the SOPs. The department's Quality Control Manager has been tasked to include water line and Lixit checks in their periodic facility review. A special meeting was held with the government staff to emphasize the importance of oversight to ensure work is being completed properly.

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: 2022.07.22 13:05:05 -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:** Thursday, August 11, 2022 8:40 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** D16-00602 NIH Animal Incident Report (DVR 27-22))  
**Attachments:** D16-00602 IO Animal Incident Memo (DVR 27-22).pdf; D16-00602 ACUC Animal Incident Report (DVR 27-22).pdf

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

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the ORS-Division of Veterinary Resources (DVR) ACUC address an animal incident involving nonhuman primates. The event was first reported to the NIH Office of Animal Care and Use by the DVR ACUC Chairman on June 21, 20022.

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:** Thursday, August 11, 2022 9:41 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (DVR 27-22))

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

**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Thursday, August 11, 2022 8:40 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (DVR 27-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the ORS-Division of Veterinary Resources (DVR) ACUC address an animal incident involving nonhuman primates. The event was first reported to the NIH Office of Animal Care and Use by the DVR ACUC Chairman on June 21, 20022.

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** |