



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTHFOR 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

October 29, 2019

Re: Animal Welfare Assurance  
#A3002-01 [OLAW Case 1S]

Dr. Steven E. Braverman  
Medical Center Director  
VA Greater Los Angeles Healthcare System  
Department of Veterans Affairs  
11301 Wilshire Boulevard  
Los Angeles, CA 90073

Dear Dr. Braverman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 11, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Veterans Affairs Greater Los Angeles Healthcare System, following up on an initial telephone report on August 28, 2019. According to the information provided, OLAW understands that an implanted minipump in a mouse had shifted location and was causing the animal difficulty in walking. The problem had not been reported to the veterinarian. The other mice on study did not exhibit pain or distress but some also had migrated implants.

The corrective actions consisted of euthanizing the mouse and counseling the research staff to call the veterinarian for any animal health concerns. The technician involved was retrained. The Principal Investigator and staff reviewed the euthanasia guidelines, were retrained on the implantation procedure, were retrained on recognizing adverse clinical signs in mice, and were directed to modify the implant technique to prevent pump migration. The laboratory was placed on enhanced post-approval monitoring and the attending veterinarian and an Institutional Animal Care and Use Committee (IACUC) member will observe the next pump implantation procedure.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

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

cc: IACUC Chair  
Animal Program Compliance Officer

(b)(6)

James Trout, Ph.D., Director, RSAW, ORO, VHA, VA



DEPARTMENT OF VETERANS AFFAIRS  
Greater Los Angeles Healthcare System  
11301 Wilshire Boulevard  
Los Angeles, CA 90073

October 11, 2019

In Reply Refer To: 691/11

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Veterinary Medical Officer, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Gopee:

In accordance with our Public Health Service (PHS) Assurance # D16-00002 and consistent with VA agency policies, we report a case of non-compliance with PHS Policy. This research was funded locally.

On June 28, 2019, a mouse implanted with an a subcutaneous Alzet minipump was found in distress during routine health checks by animal facility staff. The pump had migrated from its original insertion site and was causing difficulty in ambulation. When questioned about the mouse, laboratory personnel indicated that they were aware that the mouse was having difficulty ambulating but did not realize that veterinary staff needed to be called. The mouse was euthanized, and research staff were instructed to contact veterinary staff immediately if any mice had similar difficulty ambulating or showed signs of pain or distress such as hunched posture. No other mice were observed to be in pain or distress.

This issue was discussed at the August 2019 IACUC meeting and an investigative team was named. Remedial actions taken by the committee were:

- The laboratory technician was required to retake the Working with Mice, Working with Rats and Post-Procedure Care in Rodents CITI courses.
- The PI and his laboratory staff must review the criteria for euthanasia as stated in the ACORP to clearly understand the criteria.
- The PI and his laboratory staff must be retrained on the implantation procedure. The manufacturer of the osmotic pump will be contacted for information on the surgical procedure.

The IACUC team observed all the mice with minipump implants and met with the PI and staff to discuss the issue. Some other mice had

West Los Angeles Healthcare Center  
11301 Wilshire Blvd.  
Los Angeles, CA 90073  
(310) 478-3711

Bakersfield Community-Based  
Outpatient Clinic  
1801 Westwind Drive  
Bakersfield, CA 93301  
(661) 632-1800

Los Angeles Ambulatory  
Care Center  
351 East Temple Street  
Los Angeles, CA 90012  
(213) 253-2677

Gardena Community-Based  
Outpatient Clinic  
1149 West 190<sup>th</sup> Street  
Gardena, CA 90248  
(310) 851-4704

San Luis Obispo Community-Based  
Outpatient Clinic  
1288 Morro Street, Suite 200  
San Luis Obispo, CA 93401  
(805) 543-1233

Santa Barbara Community-Based  
Outpatient Clinic  
4440 Calle Real  
Santa Barbara, CA 93110  
(805) 683-1491

Santa Maria Community-Based  
Outpatient Clinic  
1550 East Main Street  
Santa Maria, CA 93454  
(805) 354-6000

Oxnard Community-Based  
Outpatient Clinic  
1690 Universe Circle  
Oxnard, CA 93033  
(805) 204-9135

Lancaster Community-Based  
Outpatient Clinic  
340 East Avenue I  
Lancaster, CA 93535  
(661) 729-8655

East Los Angeles Community-Based  
Outpatient Clinic  
5426 East Olympic Blvd., Suite 150  
Commerce, CA 90040  
(323) 725-7557

Sepulveda Ambulatory Care Center  
16111 Plummer Street  
North Hills, CA 91343  
(818) 891-7711

San Gabriel Valley Community-Based  
Outpatient Clinic  
7 West Foothill Blvd.  
Arcadia, CA 91006  
(626) 500-6881

implants that had migrated from the original insertion location, but none were observed to be in pain or distress.

The IACUC reviewed the IACUC team's report of this case at its October meeting and requested two mitigations

- The PI and his laboratory staff needed to be formally retrained on recognizing signs of illness, pain, or other clinical problems in mice. The attending veterinarian provided a presentation on recognizing health concerns in rodents as well as techniques and assessment methods to determine if an animal is ill or in distress. The veterinarian made it clear that the laboratory is required to contact the veterinarian when animals are exhibiting pain or distress.
- Changes in technique were needed to prevent the minipump from migrating from the subcutaneous implantation pocket. Some suggestions provided by the IACUC were to use a smaller implant, add a suture to secure the pump, or find a different delivery system.

The IACUC will follow up by random inspections to monitor future minipump implantations and do this monthly to ensure that mice in pain or distress are promptly reported for action by the veterinary staff. The attending veterinarian and an IACUC member must observe the next pump implantation procedure.

Should you have further questions regarding this matter, please contact the IACUC Chair at (b)(6) or the IACUC Coordinator at (b)(6).

  
Steven E. Braverman, M.D.  
Medical Center Director

cc: Chief of Staff (691/11)  
Associate Chief of Staff/R&D (691/151)  
Research Compliance Officer (691/00EI)  
Research Compliance Analyst (691/00EI)  
IACUC Chair (691/151)  
Research and Development Committee Chair (691/151)  
Animal Program Compliance Officer (691/151)  
Chief Veterinary Medical Officer (508/151V)  
AAALAC International



**Gopee, Neera (NIH/OD) [E]**

**From:** Gopee, Neera (NIH/OD) [E]  
**Sent:** Monday, October 28, 2019 7:10 AM  
**To:** (b)(6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b)(6)  
**Subject:** RE: Report of a noncompliance on an animal study

Thank you for this final report (b)(6). We will send an official response soon.

Best Regards,  
Neera

Neera V. Gopee, DVM, PhD, DABT, DACLAM  
Director, Division of Policy and Education  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive  
Bethesda, MD 20892-6910  
Phone: (b)(6)  
(b)(6)@od.nih.gov

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**From:** (b)(6) (b)(6)@va.gov  
**Sent:** Friday, October 25, 2019 6:25 PM  
**To:** Gopee, Neera (NIH/OD) [E] (b)(6)@nih.gov  
**Cc:** (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; (b)(6) (b)(6)@va.gov; 'AAALAC International' <accredit@AAALAC.org> (b)(6) (b)(6)@va.gov  
**Subject:** Report of a noncompliance on an animal study

Dear Dr. Gopee,

Attached is a report on a recent noncompliance.

Although not noted in the memo, the laboratory in question is now on a monitoring program of random visits at least once a week for the next six months to ensure they stay fully complaint.

Sincerely

(b)(6)

**Department of Veterans Affairs  
Greater Los Angeles Healthcare System**

(b)(6)

Los Angeles, CA 90073

b)(6) [REDACTED]@va.gov



## Initial Report of Noncompliance

By: *awl*

Date: *8/28/19*

Time: *1:00*

Name of Person reporting: (b)(6)  
 Telephone #: (b)(6)  
 Fax #:  
 Email:

Name of Institution: *Greater Los Angeles VA*  
 Assurance number: *A3002*

Did incident involve PHS funded activity? \_\_\_\_\_  
 Funding component: \_\_\_\_\_  
 Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*Mouse had subcutaneous pump which slipped from back  
 to side, impaired movement*

Species involved: *Mouse*

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

*Euthanize mouse, interview surgeon*

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_