#### DEPARTMENT OF HEALTH & HUMAN SERVICES



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

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

August 13, 2019

Re: Animal Welfare Assurance #A3002-01 [OLAW Case 1Q] Reply: 691/MC

Dr. Robert McKenrick Acting Medical Center Director VA Greater Los Angeles Healthcare System Department of Veterans Affairs 11301 Wilshire Boulevard Los Angeles, CA 90073

Dear Dr. McKenrick,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated July 29, 2019 regarding a reportable incident at the Department of Veterans Affairs, Greater Los Angeles Healthcare System. This letter had been preceded by two preliminary reports to OLAW.

According to the information provided, our office understands that a rat had become entangled in a cable that had disconnected from a recording device. The incident happened at approximately 6:00 A.M. on November 24, 2018, based on the time recording had stopped, and the animal was discovered by Veterinary Medical Unit personnel to be entangled approximately two hours later. The decision was made to euthanize the animal based on veterinary examination. At that time, two water bottles in the laboratory were found to have a greenish tint and were immediately replaced at the time of discovery.

Corrective measures consisted of the Principle Investigator (P.I.) switching to commercially manufactured commutators to reduce likelihood of mechanical and cable related issues and committing to ordering freshwater bottles from the animal facility on a weekly basis. In addition, enhanced monitoring was initiated by the IACUC. As of the end of July, three IACUC visits to the laboratory revealed that the corrective actions appear to be effective.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office.

Sincerel	у,
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(b)(6) Nicolette Petervary, VMD, DACAW

Veterinary Medical Officer Office of Laboratory Animal Welfare

cc: IACUC Contact

(b)(6) (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

July 29, 2019

In Reply Refer To: 691/MC

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

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

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

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

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

Dear Dr. Gopee:

This is the final report on the issue with an animal found tangled in the recording wire initially reported to you on December 21, 2018. The OLAW case number is A3002-1Q.

An investigation by the Institutional Animal Care and Use Committee (IACUC) revealed that an electrical cable became unattached from the recording device resulting in the animal becoming entangled. Room logs were marked daily and had been marked the previous day. The lab indicated that the animal had last been checked at 11:00 p.m. the previous night. The recording stopped at 5:59 a.m. indicating the time the electrical cable had become detached from the recording equipment. VMU staff found the animal around 8:00 a.m. The animal could reach water before it was tangled and did not approach the water bottle after it was untangled. VMU personnel indicated the rat was not dehydrated.

Corrective actions were immediately taken by the PI. The PI solved the mechanical and cable-related issues by switching to commercial commutators and satisfactorily demonstrated this change to IACUC members during a follow-up visit to the lab. The PI also committed to regularly requesting clean water bottles from the animal facility. In subsequent visits to the lab In April, May, and June, the IACUC monitoring team and vivarium staff have confirmed there are no issues with the commercial commutators and that the laboratory staff has obtained fresh water bottles from the VMU weekly.

The IACUC considers this case closed. Should you have further questions regarding this matter, please contact the IACUC Chair at  $[^{(b)(6)}]$ 

or the IACUC Coordinator at (b)(6)

Robert McKenrick

Acting Director

(b)(6)

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

From: Sent: To: Subject:	Wolff, Axel (NIH/OD) [E] Tuesday, August 13, 2019 7:08 AM (b)(6) RE: Final reports on OLAW cases A3002-1Q and A3002-1R
Thank you for these reports, $(b)(6)$ Axel Wolff	We will send responses soon.
From:         (b)(6)         p)(6)           Sent:         Monday, August 12, 2019 1           To:         Wolff, Axel (NIH/OD) (b)(6)           Cc:         Gopee, Neera (NIH/OD) [E](b)(6)           (b)(6)         @va.gov>; (b)(6)           Subject:         Final reports on OLAW c	@od.nih.gov> 6) @nih.gov> <sup>(b)(6)</sup> (b)(6) @va.gov>; <sup>(b)(6)</sup> @va.gov>
Dear Dr. Wolff, The final reports on two	cases (A3002-1Q and A3002-1R) are attached.

The third case was an initial telephone report that the IACUC investigated and decided was not reportable. (I believe I already discussed that case with Dr. Gopee a few weeks ago).

Please fell free to contact me with any questions or concerns.

Sincerely,

(b)(6)

Department of Veterans Affairs Greater Los Angeles Healthcare System

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Los Angeles. C/ (b)(6)	A 90073
(b)(6)	@va.gov

From: Wolff, Axel (NIH/OD) [E] Sent: Friday, July 5, 2019 8:39 AM

Subject: Open OLAW cases

Hello Dr. (b)(6)

OLAW currently has 3 open cases from LA VA as follows: 12/21/18 rat tangled in wiring; 12/12/18 husbandry problems in a satellite facility; 3/20/19 problems with sutures. Please send me final reports on these issues as soon as possible so that we can close out these cases.

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Thank you.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

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From:
Sent:
To:
Subject:

 Wolff, Axel (NIH/OD) [E]

 Friday, July 5, 2019 8:39 AM

 (b)(6)
 @va.gov'

 Open OLAW cases

Hello	(b)(6)
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OLAW currently has 3 open cases from LA VA as follows: 12/21/18 rat tangled in wiring; 12/12/18 husbandry problems in a satellite facility; 3/20/19 problems with sutures. Please send me final reports on these issues as soon as possible so that we can close out these cases. Thank you.

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Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

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

December 21, 2018

In Reply Refer To: 691/MC

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

A3002-10 A3002-10

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

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

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

Dear Dr. Gopee:

In accordance with our PHS Assurance # D16-00002 and consistent with VA agency policies, we are sending a preliminary report of noncompliance with PHS Policy. This research is funded by the Department of Veterans Affairs.

On Saturday, November 24<sup>th</sup>, vivarium personnel were checking labs that maintain animals in satellite housing. One cage contained a rat with a head implant with plugged-in wiring for recording EEG. The cable connector had failed so the wiring was no longer connected to the recording equipment, and the rat was tangled up in the wiring.

The animal was unwrapped and assessed. The PI was contacted by the Veterinary Medical Officer (VMO) and vivarium facilities manager and came immediately to his lab. The animal was debilitated and nonreactive from being tangled up and was euthanized by laboratory staff at the request of the Veterinary Medical Officer to prevent additional suffering.

In addition, two water bottles on other cages in this lab had a greenish tint and were immediately replaced.

The IACUC Chair assigned two members to do an investigation and a preliminary report was provided to the IACUC at their December 12<sup>th</sup> meeting. The IACUC voted that this was a reportable noncompliance, and the investigation is continuing. They are requiring that the PI use lab-made connectors that are demonstrated to be strong enough to prevent this ever happening again, or to use commercial connectors instead. Other remediation's may be required by the IACUC as a result of the continuing investigation.

Should you have further questions regarding this matter, please contact the IACUC Chair at (b)(6) or the Animal Program Compliance Officer at (b)(6)

Ann R. Brown, FACHE Medical Center Director

cc: Chief of Staff (691/11) Associate Chief of Staff/R&D (691/151) Research Compliance Officer (691/00El) Research Compliance Analyst (691/00El) 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]

(b)(6)

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<u>dva.gov</u>

From	Conce Neers (NIH/OD)	rc1		
From: Sent:	Gopee, Neera (NIH/OD) Thursday, January 03, 20			
To:	(b)(6)	19 10.22 Alvi		
Cc:	(b)(6)			
сс.	(b)(6)			
Subject:	RE: Report to OLAW of t	wo noncompliances ir	a laboratory	
Thank you for this final report <sup>(b)</sup>	(6) We will send an o	fficial response soon.		
Best Regards, Neera				
Neera V. Gopee, DVM, PhD, DA Veterinary Medical Officer Office of Laboratory Animal Wel National Institutes of Health				
Please note that this message a confidential, protected or privileg received this message in error,	ged information that should	are intended for the na not be distributed to u	amed recipient(s) only unauthorized individua	and may contain Is. If you have
Sent: Wednesday, January 02, 2 To: Gopee, Neera (NIH/OD) [E]	<sup>o)(6)</sup> @nih.gov>			
<b>Cc</b> (b)(6)	@va.gov>; (b)(6)	b)(6)	Dva.gov>; (b)(6)	
(b)(6) @va.gov>; (b)(6)		@va.gov>; (b)(6)	(b)(6)	@va.gov>;
Fallon, (b)(6) )(6)			ccredit@AAALAC.org>	
Subject: Report to OLAW of two	o noncompliances in a labo	ratory		
Dear Dr. Gopee, This is the written repo visit. I discussed this with you back ir	ort on two noncompliances n early December.	s that were found in o	ne of our laboratories	during a routine
Fredricka				
b)(6)				
Department of Veterans Affai				
Greater Los Angeles Healthca	re System			
Los Angeles. CA 00073 b)(6)				

A (3002-1Q



# Initial Report of Noncompliance

By: Neera Gapee

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Date: 11-29-18	Time: V. Vage
Name of Person reporting: <sup>(b)(6)</sup> Telephone # <sup>(b)(6)</sup> Fax #: Email:	
Name of Institution: <u>NA-LA</u> Assurance number: <u>B3002-01</u>	
Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessa	arv):
What happened? Owing an inspection, algas for with 22G racording with the	beggeren elles ant top elles hore i br bro beingri son bro 6 Emere besnerti
Species involved: Personnel involved: Dates and times: Animal deaths:	
Projected plan and schedule for correction/pre	vention (if known):
	50 m 12 m 13 m
Projected submission to OLAW of final report	from Institutional Official:
OFFICE USE ONLY Case #	



DEPARTMENT OF HEALTH & HUMAN SERVICES

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 PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

> FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

August 13, 2019

Re: Animal Welfare Assurance #A3002-01 [OLAW Case 1R] Reply: 691/MC

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Dr. Robert McKenrick Acting Medical Center Director VA Greater Los Angeles Healthcare System Department of Veterans Affairs 11301 Wilshire Boulevard Los Angeles, CA 90073

Dear Dr. McKenrick,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated July 29, 2019 regarding a reportable noncompliance at the Department of Veterans Affairs, Greater Los Angeles Healthcare System. This letter had been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that on December 7, 2018, vivarium staff performing a routine check found two partially dehydrated rats. The water bottles were empty, bedding was soiled, and the overnight housing log had not been checked for the previous three days. The Principle Investigator (P.I.) was immediately notified and the cages were cleaned, as well as provisioned with fresh food and water. The animals made a complete recovery.

An IACUC investigation revealed the issue stemmed from poor communication within the laboratory. The responsible technician was away and had not arranged alternate care arrangements.

Corrective measures consisted of the Principle Investigator (P.I.) creating a calendar system to track caretaker responsibilities, in conjunction with email confirmations of any changes in assigned responsibilities. In addition, the IACUC initiated enhanced monitoring of the laboratory. As of July 2019, the IACUC visits to the laboratory revealed that the corrective actions appear to be effective.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office.

Sincerely,

Nicolette Petervary, VMD, DACAW Veterinary Medical Officer Office of Laboratory Animal Welfare Page 2 – Dr. McKernick August 13, 2019 OLAW Case A3002-1R

#### cc: IACUC Contact

(b)(6) (b)(6) VHA, VA

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

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July 29, 2019

In Reply Refer To: 691/MC

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:

This is the final report on the issue with inadequate animal husbandry initially reported to you on December 12, 2018. The OLAW case number is A3002-1R.

On Friday, December 7, 2018, during a routine check, vivarium staff discovered two partially dehydrated rats. Vivarium staff found empty water bottles and soiled bedding in a chamber. The Overnight Housing Logs had not been checked for the previous three days.

The PI was notified and immediately changed the cages and provided the animals with food and water. The rats made a complete recovery.

The IACUC conducted an investigation and determined that the cause of the incident was poor communication within the laboratory. The technician responsible for the daily care of the animals went on vacation and alternate arrangements for care of the animals were not made. After reviewing the investigation report, the IACUC determined that this was a reportable incident of noncompliance with PHS Policy.

To prevent recurrence, the PI developed a system of designating responsibility of animal care among the laboratory staff utilizing a calendar posted at the entrance to the laboratory. Each day has the name of the person assigned responsibility for animal care. When the person on duty cannot provide care on a certain date, he or she marks the calendar and notifies the second person on duty. When both first and second persons on duty would be absent, the second person notifies the third person and marks on the calendar, and so on. Emails Bakersfield Community Based Outpatient Clinic 1801 Westwind Drive Bakersfield, CA 93301 (661) 632-1800

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

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

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West Los Angeles Healthcare Center 11301 Wilshire Boulevard Los Angeles, CA 90073 (310) 478-3711 confirming changes in the responsibility of animal care will also be sent.

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In addition to routine weekly checks by vivarium personnel, IACUC members monitored the calendar and the cages about every two weeks from April to June. The IACUC monitoring team and vivarium staff have confirmed that all animals have had clean cages and food and water, and the room logs show that daily care has been provided consistently.

The IACUC considers this case closed. Should you have further auestions regarding this matter, please contact the IACUC Chair at (b)(6)or the IACUC Coordinator at (b)(6)

Robert McKenrick Acting Director

cc: Chief of Staff (691/11) Associate Chief of Staff, Research (691/151) Research Compliance Officer (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) IACUC Coordinator (691/151) AAALAC International

From:Wolff, Axel (NIH/OD) [E]Sent:Tuesday, August 13, 2019 7:08 AMTo:(b)(6)Subject:RE: Final reports on OLAW cases A3002-1Q and A3002-1R
Thank you for these reports, (b)(6) /e will send responses soon. Axel Wolff
From:       (b)(6)       @va.gov>         Sent:       Monday, August 12, 2019 1:49 PM         To:       Wolff, Axel (NIH/OD) [E]       (b)(6)       @od.nih.gov>         Cc:       Gopee, Neera (NIH/OD) [E]       (b)(6)       @nih.gov>; (b)(6)       (b)(6)       @va.gov>; (b)(6)          (b)(6)       @va.gov>       (b)(6)       @va.gov>         Subject:       Final reports on OLAW cases A3002-1Q and A3002-1R       A3002-1R
Dear Dr. Wolff, The final reports on two cases (A3002-1Q and A3002-1R) are attached. The third case was an initial telephone report that the IACUC investigated and decided was not reportable. (I believe I already discussed that case with Dr. Gopee a few weeks ago). Please fell free to contact me with any questions or concerns.
Sincerely, (b)(6) Department of Veterans Affairs Greater Los Angeles Healthcare System (b)(6) Los Angeles. CA 90073
(b)(6) (b)(6) @va.gov From: Wolff, Axel (NIH/OD) [E]

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Sent: Friday, July 5, 2019 8:39 AM

#### Subject: Open OLAW cases

Hello (b)(6)

OLAW currently has 3 open cases from LA VA as follows: 12/21/18 rat tangled in wiring; 12/12/18 husbandry problems in a satellite facility; 3/20/19 problems with sutures. Please send me final reports on these issues as soon as possible so that we can close out these cases. Thank you.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

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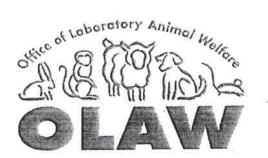
From: Sent: To: Subject: Wolff, Axel (NIH/OD) [E] Friday, July 5, 2019 8:39 AM (b)(6) @va.gov' Open OLAW cases

### Helld<sup>(b)(6)</sup>

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Axel Wolff, M.S., D.V.M. Deputy Director, OLAW



# Initial Report of Noncompliance

By: Meana Gogee

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Date: 12-12-18		Time: 3:201			
Name of Person repor Telephone #: Fax #: Email:	(b)(6) b)(6)			* * *	
Name of Institution: Assurance number:	NA-LA				
	nent contacted (if necessary):		2		
What happened? 2 tot had 2 tot had Species involved: Personnel involved: Dates and times: Animal deaths:		villite bester o, besterby be of petiod	into and eges next teens i buscond sure roun feitren gesterni	the case had 1/2 was not u daup u daup those to	beeld con

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #\_\_\_\_\_