



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 22, 2017



Re: New Iberia Research Center of the University of Louisiana

Dear  (b) (6)

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding the deaths of nonhuman primates at the New Iberia Research Center of the University of Louisiana, Lafayette. Background information was reviewed and interviews conducted. The results of the investigation included a review of the incidents of conspecific aggression. OLAW has determined that although the incidents were reportable to OLAW, they did not result from noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, but were the unfortunate and unintended consequences of socially housing animals that are expected to be compatible. The institution has updated their policy regarding the reporting of such incidents to OLAW.

OLAW shares your concern for the welfare of laboratory animals. We find no cause for further action by this office at this time.

Sincerely,

(b) (6)

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



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Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 22, 2017

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1C]

Dr. Ramesh Kolluru
Vice President for Research
University of Louisiana at Lafayette
P.O. Box 43610
Lafayette, LA 70504-3610

Dear Dr. Kolluru,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated August 17, 2017 responding to Dr. Gopee's June 27, 2017 letter wherein she requested further information regarding your IACUC's policy of reporting major trauma events within social groups of nonhuman primates at the University of Louisiana at Lafayette - New Iberia Research Center. According to the information provided, OLAW understands that the IACUC has developed a new Policy for Reporting Animal Issues. Included in this policy is the expectation that cases of death or serious injury will be reported to the IACUC, OLAW and the funding agency in a monthly report, and that in the event of a traumatic injury resulting from conspecific aggression leading to subsequent death of the animal, the PI (or designate) of the program will communicate the details of the incident by phone to OLAW. When a detailed written report is required by OLAW, the facts of the incident (accident) will be verified, and a final written report will be submitted to OLAW by way of a letter from the IO.

In the event that the veterinarian or IACUC notes a trend in deaths resulting from conspecific aggression, the IACUC will initiate an investigation. Assessment of possible trends may be done by the program assigned veterinarian and subsequently reported to the IACUC or will be done by the IACUC via assessment of mortality and morbidity reports reviewed during the meeting. Once the IACUC completes the investigation, the IACUC will submit a written report to the IO. The IO will submit a report in the form of a letter to OLAW describing in detail the events and plans for remediation of the problem if applicable.

OLAW appreciates the understanding and cooperation of the University of Louisiana at Lafayette - New Iberia Research Center. We agree with your decision to provide OLAW with the above information and recognize your desire for programmatic transparency with this office. We find your program to be in compliance with the PHS Policy and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC



UNIVERSITY
OF
LOUISIANA
L a f a y e t t e

Office of the Vice President for Research,
Innovation & Economic Development

P.O. Box 43610
Lafayette, LA 70504-3610
Office: (337) 482-5811
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Université des Acadiens

August 17, 2017

Dr. Brent, DVM
Office of Laboratory Animal Welfare
National Institutes of Health
Department of Compliance Oversight
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance A3029-01 [OLAW Case 1C]

Dear Dr. Morse,

University of Louisiana at Lafayette acknowledges the receipt of Dr. Gopee's letter dated June 27, 2017. In response to your request for procedures to ensure prompt reporting of reportable issues concerning animal welfare, I created a subcommittee of the IACUC, avoiding conflicts of interest, and sought their assistance in reviewing our institutional practices related to reporting animal related issues and in recommending new policies, if needed. The IACUC has reviewed, and approved the recommendations of this subcommittee, leading to the establishment of the following new Policy for Reporting Animal Issues that I include in its totality in the following:

Policy for Reporting Animal Issues

Introduction

In accordance with the Office of Laboratory Animal Welfare (OLAW) guidance on prompt reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animal (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>), which state that "*conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanisms failures, resulting in actual harm or deaths to animals, is an example of a situation that is reportable to OLAW*", the IACUC has developed this policy to provide guidance on the process of reporting.

Policies/Procedures

1. Animals supported by PHS or NSF funds will be monitored and cared for in accordance with the contract or grant statements of work, UL Lafayette NIRC Standard Operating Procedures, the Animal Welfare Act, PHS Policy and the Guide for the Care and Use of Laboratory Animals.
2. In the event facility or handling failures result in serious injury or death, the incident will be reported to the IACUC for further investigation and subsequent reporting the IO. Reporting to OLAW will be accomplished in the form of a letter from the IO.
3. All other cases of death or serious injury will be reported to the IACUC, OLAW and the funding agency in a monthly report. In the event of a traumatic injury resulting from conspecific aggression leading to subsequent death of the animal, the PI (or designate) of the program will communicate the details of the incident by phone to OLAW. When a detailed written report is required by OLAW, the facts of the

incident (accident) will be verified, and a final written report will be submitted to OLAW by way of a letter from the IO.

4. In the event that the veterinarian or IACUC notes a trend in deaths resulting from conspecific aggression, the IACUC will initiate an investigation. Assessment of possible trends may be done by the program assigned veterinarian and subsequently reported to the IACUC or will be done by the IACUC via assessment of mortality and morbidity reports reviewed during the meeting. Once the IACUC completes the investigation, the IACUC will submit a written report to the IO. The IO will submit a report in the form of a letter to OLAW describing in detail the events and plans for remediation of the problem if applicable.

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This new policy was emailed to all animal investigators and added to the IACUC manual, which can be found on the IACUC website (<http://vpresearch.louisiana.edu/research-compliance/institutional-animal-care-and-use-committee/iacucresources>).

We thank you for the opportunity to improve our understanding of the information needed by the OLAW and the opportunity to develop a policy to ensure more appropriate provision of the same.

Sincerely,

(b) (6)


Ramesh Koliuru
Vice President for Research, Innovation, and Economic Development
Institutional Official

CC: Dr. Robin Broussard, Director, Office of Research Integrity
Ms. Sarah Hebert, IACUC Chair
Dr. Francois Villinger, Director, New Iberia Research Center

Enclosure: University of Louisiana at Lafayette Policy for Reporting Animal Issues.

University of Louisiana at Lafayette
Institutional Animal Care and Use Committee
Policy for Reporting Animal Issues

Introduction

In accordance with the Office of Laboratory Animal Welfare (OLAW) guidance on prompt reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animal (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD05-034.html>), which state that *“conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanisms failures, resulting in actual harm or deaths to animals, is an example of a situation that is reportable to OLAW”*, the IACUC has developed this policy to provide guidance on the process of reporting.

Policies/Procedures

1. Animals supported by PHS or NSF funds will be monitored and cared for in accordance with the contract or grant statements of work, UL Lafayette NIRC Standard Operating Procedures, the Animal Welfare Act, PHS Policy and the Guide for the Care and Use of Laboratory Animals.
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3. All other cases of death or serious injury will be reported to the IACUC, OLAW and the funding agency in a monthly report. In the event of a traumatic injury resulting from conspecific aggression leading to subsequent death of the animal, the PI (or designate) of the program will communicate the details of the incident by phone to OLAW. When a detailed written report is required by OLAW, the facts of the incident (accident) will be verified, and a final written report will be submitted to OLAW by way of a letter from the IO.
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Reviewed and approved August 15, 2017

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, August 16, 2017 10:04 AM
To: 'Dr. Ramesh Kolluru'
Cc: iacuc@louisiana.edu; 'Dr. Robin Broussard'; 'Francois J Villinger'
Subject: RE: OLAW Case A3029-1C

Thank you Dr. Kolluru for sending this information. We appreciate your time, cooperation and programmatic transparency. We will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting 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: Dr. Ramesh Kolluru [mailto:kolluru@louisiana.edu]
Sent: Wednesday, August 16, 2017 9:27 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: iacuc@louisiana.edu; 'Dr. Robin Broussard' <robin.broussard@louisiana.edu>; 'Francois J Villinger' <fjv5939@louisiana.edu>
Subject: OLAW Case A3029-1C
Importance: High

Dear Dr. Morse:

Good morning. Pursuant to our phone call on August 3, 2017, please find attached our response to Dr. Gopee's guidance on procedures to ensure prompt reporting on reportable issues concerning animal welfare. We are truly appreciative that our interactions with you and Dr. Gopee gave us additional clarity on OLAW's guidance, which will have a positive impact on our animal welfare program.

Sincerely,

Ramesh

Ramesh "*Hon. Cajun*" Kolluru, Ph.D.
Vice President for Research, Innovation, and Economic Development
Professor, School of Computing and Informatics
University of Louisiana at Lafayette
Cell: (b) (6)
Office: (b) (6)

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Tuesday, July 25, 2017 2:33 PM
To: 'Ramesh Kolluru'
Cc: (b) (6) Dr. Ramesh Kolluru; Ward, Joan (NIH/OD) [E]; Morse, Brent (NIH/OD) [E]; iacuc@louisiana.edu; Gibbens, Robert - APHIS; Dr. Robin Broussard
Subject: RE: OLAW Case A3029-1C

You're more than welcome Dr. Kolluru.

Neera

From: Ramesh Kolluru [mailto:rxk6962@louisiana.edu]
Sent: Tuesday, July 25, 2017 1:43 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: (b) (6) Dr. Ramesh Kolluru <kolluru@louisiana.edu>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; iacuc@louisiana.edu; Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>; Dr. Robin Broussard <robin.broussard@louisiana.edu>
Subject: Re: OLAW Case A3029-1C

Thank you, Dr. Gopee. We look forward to the conversation.

Ramesh Kolluru, Ph.D.
VP for Research, Innovation and Economic Development
Professor, School of Computing and Informatics
UL Lafayette
(b) (6) (cell)
Sent from my iPhone

On Jul 25, 2017, at 12:33 PM, Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov> wrote:

(b) (6) 9:30 am CST (10:30 ET) on Thursday August 3, 2017 is fine with us. My contact number is (b) (6)
(b) (6)

Neera

From: (b) (6)
Sent: Tuesday, July 25, 2017 1:27 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>; Dr. Ramesh Kolluru <kolluru@louisiana.edu>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: iacuc@louisiana.edu; Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>; Dr. Robin Broussard <robin.broussard@louisiana.edu>
Subject: RE: OLAW Case A3029-1C

Neera,

Can we schedule the conference call for August 3rd – 9:30 am CST?

(b) (6)

(b) (6)

From: Gopee, Neera (NIH/OD) [E] [mailto:neera.gopee@nih.gov]
Sent: Tuesday, July 25, 2017 12:16 PM
To: Dr. Ramesh Kolluru <kolluru@louisiana.edu>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: iacuc@louisiana.edu; Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>; Dr. Robin Broussard <robin.broussard@louisiana.edu>; (b) (6)
Subject: RE: OLAW Case A3029-1C

Dear Dr. Kolluru,

Dr. Morse and I would be happy to schedule a conference call with you and Dr. Broussard anytime between 8:30 am-4:00 pm ET on 8/1/17 or 8/3/17? Please confirm if you are available any of those days as well as a convenient time to schedule the call.

Your request to extend the deadline date to August 17, 2017 for a response to OLAW is acceptable.

Best Regards,
Neera

From: Dr. Ramesh Kolluru [mailto:kolluru@louisiana.edu]
Sent: Tuesday, July 25, 2017 11:11 AM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: iacuc@louisiana.edu; Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>; Dr. Robin Broussard <robin.broussard@louisiana.edu>; (b) (6)
Subject: RE: OLAW Case A3029-1C
Importance: High

Dear Dr. Gopee:

Good morning. I am writing as a follow up to your letter dated June 27, 2017. In this letter you had directed me to instruct the IACUC to describe the procedures that will be established to ensure prompt reporting of reportable issues concerning animal welfare in accordance with OLAW's guidance.

Pursuant to your directive, I convened a sub-committee of the IACUC to review the issues of concern and help develop appropriate procedures. As part of their efforts, the subcommittee has met, reviewed guidance and current procedures, and has raised a few questions that will require your input and clarifications. As such, may I kindly request the following:

- Schedule a phone call with my colleague, Dr. Robin Broussard, director of the Office of Research Integrity and myself.
- Grant an extension on the deadline for the requested information to August 15, 2017, so we can provide a comprehensive report.

I am on travel to (b) (6) effective today, and will be back at the office on July 31. Please let me know what dates might work best for you for a phone call.

Sincerely,

Ramesh "*Hon. Cajun*" Kolluru, Ph.D.
Professor, School of Computing and Informatics
Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette
Cell: (b) (6)
Office: (b) (6)



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June 27, 2017

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1C]

Dr. Ramesh Kolluru
President for Research, Innovation and
Economic Development
University of Louisiana at Lafayette
New Iberia Research Center
104 University Circle, (b) (4)
Lafayette, LA 70504

Dear Dr. Kolluru,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 16, 2017 letter responding to my May 22, 2017 request for information concerning (b) (6) (b) (6) allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Lafayette- New Iberia Research Center. The allegations included six major trauma incidents identified in the "Health Status" section of selected monthly reports between January 2016 and March 2017, including the euthanasia of one of the animals involved in the major trauma case in November 2016. According to the information provided, OLAW understands the following:

- 1) All six nonhuman primates involved in the major trauma incidents referenced in the monthly reports were rhesus macaques.
- 2) Three macaques, two males and one female, were found dead with lesions either indicative or consistent with attacks from other animals in their social groups in January, May and August of 2016. On November 28, 2016, the veterinarian euthanized a comatose female macaque which was found with assault wounds inflicted by the other animals within the group. A fifth macaque delivered a stillborn on February 15, 2017 but had not yet passed the placenta and presented with lethargy, as well as wounds consistent with aggression from other animals within the social group. The animal was unresponsive to treatment and at the veterinarian's discretion, the animal was euthanized due to her deteriorating condition. The last remaining female macaque was observed to be clinically ill and presented with lethargy on March 15, 2017 but died later that day despite the provision of veterinary care. Wounds consistent with aggression were identified while performing a necropsy on this animal.
- 3) The University of Lafayette- New Iberia Research Center ACUC has determined that the implementation of a corrective plan to alleviate future deaths or life threatening injuries to socially housed macaques is not necessary since this is an acceptable risk that is inherent to enhancing the well-being of macaques through social housing. These risks are currently mitigated by procedures which include twice daily observations by animal care personnel; routine observations by behavioral staff; continuous monitoring for the first hour, with subsequent repeated observations by behavioral staff during initial introductions; prompt reporting to the veterinarians or behavioral personnel of animals that are sick, injured or displaying unusual behavior and the availability of an on call veterinarian after hours.

OLAW requests additional information to the following concern:

- 1) The report stated that six major trauma incidents did not meet the reporting requirements as detailed in IV.F.3 of the PHS Policy. OLAW concurs that the six major trauma events were not attributable to negligence or noncompliance, however, these incidents do meet the threshold for reporting to this Office. Based on the information provided, failure to report these recurring incidents is inconsistent with OLAW's "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" (Notice Number NOT-OD-05-034, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>), which states that "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or deaths to animals" is an example of a situation that is reportable to OLAW. Please instruct the Institutional Animal Care and Use Committee, avoiding any conflicts of interest, to describe the procedures that will be established to ensure prompt reporting of reportable issues concerning animal welfare in accordance with OLAW's guidance.

Please provide the requested information to this Office by **July 31, 2017**.

If you require further assistance, please don't hesitate to contact me directly at (b) (6)

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair
Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC

June 16, 2017

Dr. Neera V. Gopee, DVM, PhD, DACLAM, DABT
Office of Laboratory Animal Welfare
National Institutes of Health
Department of Compliance Oversight
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance A3029-01 [OLAW Case 1C]

Dear Dr. Gopee,

University of Louisiana at Lafayette acknowledges the receipt of your letter dated May 22, 2017. In response to your request for information, I respectfully offer the following:

- 1) **Please provide the species involved in the six major trauma incidents referenced in the January 2016, May 2016, August 2016, November 2016, February 2017, and March 2017 monthly Reports.**
All 6 animals were Rhesus monkeys.
- 2) **Please provide a comprehensive description of the nature of each of the six major trauma incidents referenced in the above mentioned monthly reports, be sure to include the provision of veterinary care in response to each described major trauma event.**

January 2016 – A15V018 was a male born August 10, 2015. The animal was in a social group with his mother and had been in this social group since December 22, 2015. On January 28, 2016, the animal was found dead in the cage during observation rounds. During necropsy, injury indicative of a fight wound caused by another animal was found by the veterinarian. Medical intervention was not possible.

May 2016 – A13V001 was a male born Jan 14, 2013. The most recent physical exam was on March 24, 2016; he was found to be in good health. The animal was in a social group of juveniles, and had been in this group since March 26, 2016. On May 24, 2016, the animal was found dead in the cage during observation rounds. During necropsy, he was found to have wounds consistent with attacks from other animal(s) in the group. Medical intervention was not possible.

August 2016 – A5V025 was a female born May 12, 2005. The most recent physical exam was on June 15, 2016; she was found to be in good health. The animal was in a breeding social group, and had been in this group since December 22, 2015. On August 03, 2016, the animal was found dead in the cage during observation rounds. During necropsy, she

was found to have wounds consistent with attacks from other animal(s) in the group. Medical intervention was not possible.

November 2016 – A3P007 was a female born July 06, 2003. The most recent physical exam was on Jun 15, 2016; she was found to be in good health. She was in a breeding social group, and had been in this group since November 3, 2016. On November 28, 2016, the animal was found unresponsive in the cage during observation rounds. Medical examination by the veterinarian determined the animal to be comatose. She had wounds consistent with attacks from other animal(s) in the group, and the veterinarian determined that euthanasia was the best course of action for this animal.

February 2017 – A10V148 was a female born October 09, 2010. The most recent physical exam was on Jun 15, 2016; she was found to be in good health. The animal was in a breeding social group, and had been in this group since January 11, 2017. On February 15, 2017, she had a stillborn infant. She presented with lethargy and had not passed the placenta yet at observation rounds. She was transferred to the clinic for treatment and further observation where she was found to have wounds consistent with attacks from other animal(s) in the group. The veterinarian prescribed treatment with antibiotics, anti-inflammatories and pain medicine. Over the course of the next week the animal's wounds deteriorated despite treatment. The veterinarian determined that the damage to the hands, feet and legs would not heal enough to allow for future use of the appendages and decided that euthanasia was the best course of action for this animal.

March 2017 – 05D224 was a female born on June 18, 2005. The most recent physical exam was on Jun 21, 2016; she was found to be in good health. The animal was in a breeding social group, and had been in this group since December 15, 2015. On March 15, 2017 the animal presented with lethargy and was transferred to the clinic for treatment. The veterinarian prescribed supportive treatment (antibiotics, fluid therapy, nutritional supplementation) but the animal did not recover and died later the same day. During necropsy, it was noted that she had wounds consistent with attacks from other animal(s) in the group.

3) Did any of the major trauma incidents result in euthanasia or death of the animal(s) involved?

Yes, all six major trauma incidents resulted in euthanasia or death.

4) If any of the major trauma incidents were determined to have jeopardized the health or well-being, including accidents, resulting in actual harm or death to of the animals involved or was the result of noncompliance, please provide an explanation for the failure to report to OLAW.

None of the incidents were the result of noncompliance. The injuries were due to animal on animal aggression in stably, socially-housed animals. The PHS policy, IV.F.3., requires reports of:

- a) Any serious or continuing non-compliance with the PHS policy,
- b) Any deviation from the provisions of the *Guide*, or

c) Any suspension of an activity by the IACUC.


Since the injuries and subsequent deaths were not caused by failure of facilities or negligent staff, these deaths did not fall into any of the above categories and therefore were not reported to OLAW.

5) Please describe all corrective measures taken by the IACUC and the Institution to prevent recurrence of major trauma incidents at the University of Louisiana at Lafayette, New Iberia Research Center.

Since the trauma incidents in question were a consequence of animal aggression in social groups, the subcommittee reviewed procedures for placing animals in groups and for routine monitoring of aggression in these settings. This review did not identify a need for corrective measures. While social housing increases the potential for aggressive interactions among the animals, it is generally considered that this is an acceptable risk for the enhanced wellbeing of the animals. Moreover, procedures are in place for minimizing this risk. The New Iberia Research Center implements exceptional standard of care with twice-daily observations by animal care staff and regular observations by behavioral staff. When animals are introduced into a new social group, continuous monitoring by behavioral experts for one hour is followed by repeated observations by these experts for the first 24 hours of the introduction. For all animals, injuries and aggressive behaviors are reported by the animal care staff to veterinarians and to behavioral staff. This is done daily via colony reports or immediately by phone call when situations require immediate attention; these notifications allow expert observations and interventions to be made to ensure stable social groups. Veterinary staff triage the written colony reports and follow-up on each report. All staff at NIRC have the responsibility to report unusual behaviors. There is always a veterinarian on call outside of regular business hours.

The IACUC has determined that no corrective action plan is needed. Please let me know if I can be of further assistance to you.

Sincerely,

(b) (6)


Ramesh Kolluru
Vice President for Research, Innovation, and Economic Development
Institutional Official

CC: Sarah Hebert, IACUC Chair
Dr. Francois Villinger, Director, New Iberia Research Center



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May 22, 2017

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1C]

Dr. Ramesh Kolluru
President for Research, Innovation and
Economic Development
University of Louisiana at Lafayette
New Iberia Research Center
104 University Circle, (b) (4)
Lafayette, LA 70504

Dear Dr. Kolluru,

The Office of Laboratory Animal Welfare (OLAW) received from (b) (6) (b) (6) allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Lafayette- New Iberia Research Center. (b) (6) submitted an inquiry regarding six major trauma incidents identified in the "Health Status" section of selected monthly reports between January 2016 and March 2017. One incident of major trauma was referenced in each of the January 2016, May 2016, August 2016, November 2016, February 2017 and March 2017 monthly reports. The allegations also included euthanasia of one of the animals involved in the major trauma case in November 2016. Please direct the Institutional Animal Care and Use Committee (IACUC), avoiding any conflicts of interest, to address the following:

- 1) Please provide the species involved in the six major trauma incidents referenced in the January 2016, May 2016, August 2016, November 2016, February 2017 and March 2017 monthly reports.
- 2) Please provide comprehensive descriptions of the nature of each of the six major trauma incidents referenced in the above mentioned monthly reports, be sure to include the provision of veterinary care in response to each described major trauma event.
- 3) Did any of the major trauma incidents result in euthanasia or death of the animal(s) involved?
- 4) If any of the major trauma incidents were determined to have jeopardized the health or well-being, including accidents, resulting in actual harm or death to of the animals involved or was the result of noncompliance, please provide an explanation for the failure to report to OLAW.
- 5) Please describe all corrective measures taken by the IACUC and the Institution to prevent recurrence of major trauma incidents at the University of Louisiana at Lafayette, New Iberia Research Center.

Please provide the requested information and if substantiated, a plan and schedule for correction, by **June 19, 2017**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair
Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC

Group asks investigation of Louisiana university primate lab

By - Associated Press - Thursday, May 18, 2017

NEW IBERIA, La. (AP) - An animal rights group wants a federal investigation of a Louisiana university's primate lab, saying six reports of major trauma to monkeys indicate problems at the New Iberia Research Center.

The University of Louisiana at Lafayette did not immediately respond Thursday to a request for comment about the statement from Michael Budkie of Stop Animal Exploitation Now.

He asked the U.S. Department of Agriculture to investigate six monthly health reports from 2016 and 2017 for a colony of about 540 monkeys. The reports are signed by a research center veterinarian and were obtained from the National Institutes of Health.

Each notes one case of "major trauma." The November report states that a monkey was euthanized because of that. Budkie says trauma is "often connected to violations of the Animal Welfare Act."

Wolff, Axel (NIH/OD) [E]

A3029-1C

From: Wolff, Axel (NIH/OD) [E]
Sent: Thursday, May 18, 2017 8:58 AM
To: (b) (6)
Subject: RE: OLAW Complaint -- University of Louisiana, Lafayette

Thank you for this report. We will investigate the allegations and you will be apprised of OLAW's findings upon completion.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: (b) (6)
Sent: Thursday, May 18, 2017 8:51 AM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Subject: OLAW Complaint -- University of Louisiana, Lafayette

(b) (6)

Dr. Axel
Wolff
5/18/17
Director, Western Region
USDA/APHIS/AC
2150 Center Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dr. Wolff,

I am contacting you today regarding the New Iberia Research Center of the University of Louisiana, Lafayette (72-R-0007) (ULL).

According to the information provided by you the NIH Guide states that examples of reportable situations are "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."

As you know, (b) (6) files regular requests for OLAW reports filed by research facilities across the U.S. One of the facilities for which we have regularly requested documents is the University of Louisiana, Lafayette. However, despite filing multiple requests relevant to ULL we have not received any ULL reports during 2016 or 2017.

However, recent information about ULL has come to light through a set of government reports obtained by (b) (6). The reports are relevant to an individual colony of SPF monkeys at ULL. These documents contain data on injuries and/or causes of death for primates within this colony.

The different causes of death/injury listed include euthanasia, natural, enteritis, and "major trauma." While "major trauma" is not defined anywhere in this document, it is clear that these are significant issues, otherwise they would not have been mentioned. Additionally, one primate discussed in the report for November of 2016 was euthanized as a result of trauma. So, clearly these cases of "major trauma" are very serious.

Collectively, these reports discuss incidents of Major trauma in January 2016, May 2016, August 2016, November 2016, February 2017, and March of 2017. As I mentioned above, a primate was euthanized due to trauma in November of 2016.

Traumatic injuries are very often connected to violations of the Animal Welfare Act including, but not limited to, Sec. 2.38 Misc (f)(1) Animal Handling and/or Sec. 2.33 Attending Veterinarian and Adequate Veterinary Care. There are multiple other possibilities as well.

However, there is an additional serious concern here. There is no reason to assume that this specific primate colony at the University of Louisiana, Lafayette, is significantly different from any other colony within this facility. The group for which we have records consists of roughly 540 primates at the beginning of 2016. A September 2016 USDA inspection report lists an animal inventory at this facility of roughly 6600 non-human primates. If we assume that all primate colonies at University of Louisiana, Lafayette, are functioning similarly, then it is possible that during this same time period of roughly sixteen months, there may have been as many as seventy-four traumatic injuries to primates at the University of Louisiana, Lafayette, including as many as six which were severe enough to require euthanasia. This is an appalling number of injuries and deaths. Therefore, the entire primate colony at the University of Louisiana, Lafayette must be investigated in terms of traumatic injuries.

(b)(6)

I hereby request that your office immediately institute an investigation of "major trauma" at the University of Louisiana, Lafayette. At the conclusion of your investigation, I must insist that you revoke the Animal Welfare Assurance of the University of Louisiana, Lafayette. As you know, ULL is also currently the target of a USDA complaint which has been assigned docket number 15-0086.

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations kill or seriously injure animals. Therefore you must consider the negligence by the University of Louisiana, Lafayette, extremely serious and justifying a major penalty.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

(b)(6)

(b)(6)

(b)(6)

Attachments: Multiple NIH Reports

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Haselchwert

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 January-31 January 2016

Quantitative Description of Overall Progress: Requested physicals have been performed.

Census:

Socially housed: 535

Pair housed: 2 (1 pairs)

Individually housed: 8

Quarantine: None

Number of females in breeding groups (age 2+): 139 adults

Number of females of reproductive age in breeding groups (Age 4+): 139 (of 150 adult breeding females)

Census:

	Current Month	YTD
Live births (#)	0	0
Abortions/stillbirths	0	0
Infants (<1 yr) deaths(#)	2	2
Juvenile (1-4 yrs) deaths(#)	2	2
Adult deaths (#)	1	1
Animals received (#)	0	0
Animals shipped (#)	0	0

Number of animals given physical exams: There were 146 ext physicals performed during this reporting.

Number of known pregnant females: 11 additional pregnancies have been identified during the previous reporting period.

Number of SPF animals: 542

Number of non-SPF animals: 1 SRV-isolated pending euthanasia

Number of animals currently being derived: N/A

Number of serological test performed: No serological samples were obtained during this reporting period

Current production rate (1+years): 65% 139 female breeders, 91 infants w/wastages

Current conception rate: 70% 139 females, 91 infants and 6 fetal wastages

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Description of animals recommended to be used for research: *No active research on site at this time*

Health Status:

Major trauma: 1

Chronic enteritis: 2 (euthanized)

Surgeries: 0

Euthanasia: 2 (colitis)

Number of non-routine clinical cases: none

Infectious diseases: *Shigella and Campylobacter are known endemic in the colony, no specific outbreaks during this reporting period.*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals.

"Qnat" pff indicators are being obtained and a method for use to validate disinfectant will be implemented.

Current problems and corrective action: *none*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

02 Feb 2016

Date

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 May-31 May 2016

Quantitative Description of Overall Progress: Semi-annual physicals will carry on 25 May-June 2016

Census:

Socially housed: 302

Pair housed: 10 (5 pairs)

Individually housed: 24 (includes 8 clinical)

Quarantine: None

Number of females in breeding groups (age 2+): 135 adults

Number of females of reproductive age in breeding groups (Age 4+): 135 (of 150 adult breeding females)

Census:

	Current Month	YTD
Live births (#)	17	45
Abortions/stillbirths	1	3
Infants (<1 yr) deaths(#)	2	8
Juvenile (1-4 yrs) deaths(#)	2	9
Adult deaths (#)	1	3
Animals received (#)	0	0
Animals shipped (#)	20	225

Number of animals given physical exams: 24 animals underwent physical examinations for shipment and 48 underwent semi-annual physical exams during this reporting period.

Number of known pregnant females: Seven females were determined to be pregnant during this reporting period.

Number of SPF animals: 347

Number of non-SPF animals: None

Number of animals currently being derived: N/A

Number of serological test performed: 48 serological samples were obtained during this reporting period.

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Current production rate (1+ years): *Calculated annually.*

Current conception rate: *Calculated annually*

Description of animals recommended to be used for research: *No active research on site at this time*

Health Status:

Major trauma: *1*

Chronic enteritis: *2 (1 euthanized for colitis)*

Surgeries: *0*

Euthanasia: *2 (1 colitis; 1 pending histopathology)*

Number of non-routine clinical cases: *none*

Infectious diseases: *Shigella and Campylobacter are known endemic in the colony, no specific outbreaks during this reporting period.*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals.

Current problems and corrective action: *none.*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

02 May 16

Date

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 Aug-31 Aug 2016

Quantitative Description of Overall Progress: Semi-annual physicals have been completed as of last report.

Census:

Socially housed: 353

Pair housed: 6 (3 pairs)

Individually housed: 1 (clinical)

Quarantine: None

Number of females in breeding groups (age 2+): 129 adults

Number of females of reproductive age in breeding groups (Age 4+): 129 (of 150 adult breeding females. Note the additional 34 females are currently being integrating into social breeding groups.

Census:

	Current Month	YTD
Live births (#)	8	98
Abortions/stillbirths	0	6
Infants (<1 yr) deaths(#)	0	11
Juvenile (1-4 yrs) deaths(#)	1	12
Adult deaths (#)	3	8
Animals received (#)	0	0
Animals shipped (#)	0	223

Number of animals given physical exams: No animals had physicals during this reporting period.

Number of known pregnant females: Unknown at this reporting period

Number of SPF animals: 382

Number of non-SPF animals: None.

Number of animals currently being derived: N/A

Number of serological test performed: No serological samples were obtained during the last reporting period; none during this reporting period.

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Current production rate (4+ years): *Calculated annually.*

Current conception rate: *Calculated annually.*

Description of animals recommended to be used for research: *No active research on site at this time*

Health Status:

Major trauma: 1 (ASP025)

Chronic enteritis: 3 (euthanized)

Surgeries: 0

Euthanasia: 3

Number of non-routine clinical cases: 0

Infectious diseases: *Shigella and Campylobacter are known endemic in the colony, no specific outbreaks during this reporting period.*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals

Current problems and corrective action: *None*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

08 Sep 16

Date

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 Nov-30 Nov 2016

Quantitative Description of Overall Progress: *Animals have been set up in appropriate breeding groups. Physical examinations have started as of this writing.*

Census:

Socially housed: 374

Pair housed: 22 (11 pairs)

Individually housed: 8-6 will go into social groups; 2 clinical

Quarantine: None

Number of females in breeding groups (age 2+): 164 adults

Number of females of reproductive age in breeding groups (Age 4+): 159

Census:

	Current Month:	YTD
Live births (#)	3	104
Abortions/stillbirths	0	7
Infants (<1 yr) deaths(#)	0	13
Juvenile (1-4 yrs) deaths(#)	1	15
Adult deaths(#)	2	13
Animals received (#)	0	0
Animals shipped (#)	0	225

Number of animals given physical exams: 84 animals had physicals during this reporting period.

Number of known pregnant females: Unknown at this reporting period

Number of SPF animals: 382

Number of non-SPF animals: None.

Number of animals currently being derived: N/A

Number of serological test performed: No serological samples were obtained during the last reporting period; none during this reporting period

Current production rate (4+ years): Calculated annually.

Current conception rate: Calculated annually

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Description of animals recommended to be used for research: *No active research on site at this time*

Health Status:

Major trauma: 1

Chronic enteritis: 2 (euthanized)

Surgeries: 0

Euthanasia: 3 (2 enteritis; 1 trauma)

Number of non-routine clinical cases: 0

Infectious diseases: *Shigella and Campylobacter are known endemic in the colony, no specific outbreaks during this reporting period*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals.

Current problems and corrective action: *None*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

02 Dec 16
Date

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 Feb-28 Feb 2017

Quantitative Description of Overall Progress: *Animals have been set up in appropriate breeding groups. Physical examinations will begin in March.*

Census:

Socially housed: 349

Pair housed: 32 (16 pairs)

Individually housed: 26 will go into social groups

Quarantine: None

Number of females in breeding groups (age 2+): 136

Number of females of reproductive age in breeding groups (Age 4+): 131

Census:

	Current Month	YTD
Live births (#)	1	1
Abortions/stillbirths	1	1
Infants (<1 yr) deaths(#)	1	2
Juvenile (1-4 yrs) deaths(#)	1	1
Adult deaths (#)	1	2
Animals received (#)	0	0
Animals shipped (#)	0	0

Number of animals given physical exams: *No animals had physicals during this reporting period.*

Number of known pregnant females: *Unknown at this reporting period*

Number of SPF animals: 375

Number of non-SPF animals: *None.*

Number of animals currently being derived: *N/A*

Number of serological test performed: *None during this reporting period.*

Current production rate (4+ years): *best calculated annually*

Current conception rate: *best calculated annually*

Description of animals recommended to be used for research: *No active research on site at this time*

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Health Status:

Major trauma: 1

Chronic enteritis: 1

Surgeries: 0

Euthanasia: 2

Number of non-routine clinical cases : 0

Infectious diseases: *None*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals

Current problems and corrective action: *None*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

02 Mar '17

Date

Monthly Report
University of Louisiana at Lafayette
New Iberia Research Center

Dates: 01 March - 31 March 2017

Quantitative Description of Overall Progress: Animals have been set up in appropriate breeding groups. Physical examinations have started as of this writing. Females that have been in for various reasons and are already pregnant will go into a peer group without a male until they are ready to breed again.

Census:

Socially housed: 372

Pair housed: 16 (8 pairs)

Individually housed: 10 will go into social groups

Quarantine: None

Number of females in breeding groups (age 2+): 139

Number of females of reproductive age in breeding groups (Age 4+): 133

Census:

	Current Month	YTD
Live births (#)	9	10
Abortions/stillbirths	1	2
Infants (<1 yr) deaths (#)	1	3
Juvenile (1-4 yrs) deaths (#)	0	1
Adult deaths (#)	1	3
Animals received (#)	0	0
Animals shipped (#)	0	0

Number of animals given physical exams: There were 104 animals that had physicals during this reporting period.

Number of known pregnant females: There were 25 of the 104 females examined that were determined to be pregnant.

Number of SPF animals: 382

Number of non-SPF animals: None.

Number of animals currently being derived: N/A

Number of serological test performed: None during this reporting period.

Current production rate (4+ years): best calculated annually

Contract No.: NIAID-VRC-07-57

Co-PI: D.L. Hasselschwert

Current conception rate: *has calculated annually*

Description of animals recommended to be used for research: *No active research on site at this time*

Health Status:

Major trauma: *1*

Chronic enteritis: *1*

Surgeries: *0*

Euthanasia: *1*

Number of non-routine clinical cases: *0*

Infectious diseases: *None*

Issues related to Animal Welfare: *None*

Project Progress:

Goals/tasks to be completed next reporting period:

Positive reinforcement training has been implemented to assist with transfer of animals.

Current problems and corrective action: *None*

Signatures:

(b) (6)

Dr. D. L. Hasselschwert, MS, MS, DVM, DACLAM
Co-Principal Investigator

07/04/17
Date