4/19/18

Dr. Patricia A. Brown VMD, Director,
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Via Email: brownp@od.nih.gov

Dr. Francis Collins, Director,
Office of the Director,
National Institutes of Health,
9000 Rockville Pike
Bethesda, Maryland 20892
Via Email: francis.collins@nih.gov

CC: Dr. Axel Wolff, Deputy Director,
Office of Laboratory Animal Welfare (OLAW)
Via Email: wolffa@od.nih.gov

Dr. Collins, Dr. Brown, Dr. Wolff,

I am writing to you today relevant to the University of California, Davis (UCD). There are several issues which are relevant to the humane care and use of animals, relevant to PHS policy, reporting of non-compliances, etc. which must be addressed.

As you know, PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
a) any serious or continuing noncompliance with this Policy;
b) any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals] ; or
c) any suspension of an activity by the IACUC."

These reporting requirements are further elucidated in this text from the Office of Laboratory Animal Welfare website:

Examples of reportable situations:

- ***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;***
- ***conduct of animal-related activities without appropriate IACUC review and approval;***
- ***failure to adhere to IACUC-approved protocols;***
- ***implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;***

- ***conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);***

- ***chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;***

- ***participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;***

- ***failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);***

- ***failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);***

- ***failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO 2);***

- ***failure of animal care and use personnel to carry out veterinary orders (e.g., treatments);***

The OLAW website also provides guidance regarding the timeframe for reporting:

Time Frame for Reporting

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

It is clear that the University of California, Davis, should potentially be reporting on a wide range of non-compliance issues. This is particularly relevant to UCD because UCD currently has over $110 Million in NIH funding relevant to animal experiments. Therefore UCD should definitely be reporting non-compliances to the NIH's Office of Laboratory Animal Welfare.

As you may know, SAEN consistently files FOIA requests with OLAW to obtain **ALL** correspondence in which U.S. labs report failures to comply with PHS policy on animal care & use, the requirements for this reporting are listed above. SAEN has consistently been filing FOIA requests for documents relevant to University of California, Davis, since 2015. Therefore we should have a large file of non-compliance reports filed by UCD with OLAW.

As you will note from the attached documents obtained from University of California, Davis, issues concerning failures to comply with PHS policy have occurred from August of 2017 to March of 2018. These are internal reports of non-compliances filed with the UCD Institutional Animal Care & Use Committee (IACUC). One would think that all non-compliances reported to the UCD IACUC would also have been reported to OLAW.

Now, as a result of filing multiple FOIA requests to OLAW, we should have all non-compliance reports made by UCD for the period of 9/21/16 - 12/15/17, this includes three files - r_3433-2H, r_3433-2I, and r_3433-2J. The first of these chronologically precedes any of the incidents listed in the

UCD IACUC documents. The two remaining files coincide with two reports made internally to the UCD IACUC.

However, the UCD IACUC documents also list a total of five incidents of non-compliance which were NOT reported to OLAW, and two which were reported to OLAW. These incidents are serious. The first of these incidents dated 8/22/17 discusses the deaths of 3 mice due to lack of food (not reported to OLAW). The second incident in the UCD IACUC documents is dated 8/11/17 and is relevant to a dog fight which resulted in injuries (not reported to OLAW). The third of these incidents dated 9/22/17 is relevant to a rabbit's broken leg which resulted in euthanasia (not reported to OLAW). The fourth incident, dated 7/27/17 is relevant to a rabbit's death during an experiment from an embolism(not reported to OLAW). The fifth incident, dated 9/21/17 was reported to OLAW, and is relevant to insufficient analgesia. The sixth incident was dated 11/5/17 and is relevant to the death of a cat(not reported to OLAW). The seventh incident was dated 12/15/17, was relevant to rodent analgesia, and was reported to OLAW.

This chronology lists five internal reports which were not provided to OLAW. These five incidents are surrounded by UCD events which were reported to OLAW, however they do not appear in any NIH documents.

Additionally, the documents which were obtained from UCD also include a letter from OLAW to UCD. This correspondence (dated 3/8/17) discusses an incident in which a primate was negligently released into the wrong enclosure. The case number assigned to this incident by OLAW ends in 2K, demonstrating that it was the last one reported following the other three reports which we had already received, and further demonstrating that the earlier incidents, despite their seriousness, were not reported to OLAW. There are no gaps in the report numbers to accommodate these incidents.

Now, since UCD has roughly $110 million in active NIH funding for animal projects, the incidents listed above should definitely been reported to OLAW. However, the NIH FOIA system has provided us with no reports relevant to these incidents.

Therefore, there can only be two possibilities. Either the NIH has violated the requirements of Freedom of Information Act by withholding documents, or the University of California, Davis, has failed to make reports of these documented non-compliances. My experience with the National Institutes of Health's FOIA system has always been a positive one. The NIH FOIA staff is highly professional and very proficient at their work. Also, the reports which have been provided appear, considering the sequential naming of the files, appear to have been provided in sequential date order.

The only conclusion that I can draw is that the University of California, Davis, has not filed a single report with OLAW in this time period to cover these incidents. If there had been only one incident of non-compliance, it might be possible to assume that it was simply overlooked. However, there are five separate incidents, all of which are serious. The only conclusion that can be drawn is that the University of California, Davis, has engaged in a consistent and deliberate pattern of non-reporting. This is nothing short of an intentional cover-up by the University of California, Davis.

In light of the clear and irrefutable information which we have provided, I am hereby officially calling on your offices to initiate an investigation into the failure of the University of California, Davis, to report these incidents to the Office of Laboratory Animal Welfare. And, since it is clear that this institution has failed utterly to fulfill the responsibilities which are required to maintain an Animal Welfare Assurance, I hereby also call upon your offices to immediately terminate the Animal Welfare Assurance of the University of California, Davis, thereby also terminating all NIH funding for animal based research projects at this institution.

I have attached the relevant Internal reports from the University of California, Davis,, and I will look forward to the resolution of these matters by OLAW in the near future.

Sincerely,

Michael A. Budkie, A.H.T.

Michael A. Budkie, A.H.T.,

Executive Director, SAEN

Attachments: Multiple internal non-compliance reports for the University of California, Davis.

Incident Report

Date of Occurrence: August 22, 2017

Location: [redacted]

PI: [redacted]

Details: On August 22, 2017, it was reported to CVS and the IACUC office that a cage of sentinel mice (3) was found dead in room [redacted] The room is PI maintained under [redacted] The research animals in this room are feed a study diet daily in a cup on the cage floor. The sentinel animals are feed standard rodent chow in the food hopper. The animals are checked every day by the PI's staff. During the previous weekend, the [redacted] in charge observed the sentinel mice to be low on food but chose to wait until Monday to provide more food with their scheduled cage change. On Monday, 8/21/17, the entire room was serviced, including cage changes, however the [redacted] forgot to feed the sentinel mice. All other animals in the room were fed. On Tuesday, 8/22/17, all three sentinel animals were found dead. The water bottle on the cage had plenty of water and the lixit worked.

The student has been working in [redacted] lab for a long time and the PI stated that [redacted] is one of his best technicians with the mice.

The facility manger reports that the vivarium has had PI maintained rooms for over 25 years and this is the first time sentinel animals were accidently not fed by the PI's staff.

The animals were submitted to CPL for necropsy.

Proposed solution/Preventative Action: PI talked with [redacted] and it was clear this was an accident. The [redacted] took full responsibility. They discussed ideas to ensure this never happens again and they came up with the following plan:

1. Move the sentinel cage so they are more visible to anyone who does checks in the room

2. Ensure that the room log sheet is completed just before the person exists the room and not before to ensure credit was not given before a task has actually been completed

3. During re-training of the [redacted] and training new [redacted] the PI will make certain to instruct them to immediately top off the feeder if the amount of food is perceived to be low.

8/24/17- Discussed at a convened IACUC meeting. All members thought the PI's retraining and plan regarding the logs and movement of the cage for better visibility were good preventive measures and should prevent a reoccurrence. Pending necropsy report, no further action required.

9/12/17 – Pathology findings were consistent with inanition.

9/21/17-Discussed a convened IACUC meeting pathology results and PI's plan for training/re-training of staff to include topping off feed as soon as it is perceived as being low.

UCDAVIS

TEACHING AND RESEARCH ANIMAL CARE SERVICES

WORK FLOW REVIEW

INSTRUCTIONS

1) **Fill out for any incident that impacts animal health or welfare.**
2) **Use blue or black pen.**
3) **Any incidents that resulted in Animal Room temperatures going above and beyond 5 degrees the high range needs to be reported or 5 degrees below the low range.**
4) **The person who witnessed or committed the incident should fill out the form, though a supervisor may do so.**
5) ***Submit original within 24hrs of occurrence* to the Associate Director – Husbandry and the Director of TRACS. Depending on type of incident, copies may need to be submitted to other departments.**

Date: August 11th, 2017

Area Supervisor:

[redacted]

Location of Occurrence:

[redacted]

Animal Involved: Canine

Details: While trying to get one dog [redacted] outside to the exercise area, a dog fight broke out between [redacted] and [redacted] and I were able to separate dogs, but unfortunately this resulted into a few contusions to [redacted], and [redacted].

Proposed Solution/Preventative Action: [redacted] was not leashed on the assumption that the initial contact with the other dogs would not result in aggression. All dogs will be leashed prior to removing them from their home cage.

Signature: [redacted]

FM-048v2

6/24/16 PV

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TEACHING AND RESEARCH ANIMAL CARE SERVICES

WORK FLOW REVIEW

INSTRUCTIONS

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4) **The person who witnessed or committed the incident should fill out the form, though a supervisor may do so.**
5) ***Submit original within 24hrs of occurrence* to the Associate Director – Husbandry and the Director of TRACS. Depending on type of incident, copies may need to be submitted to other departments.**

Date: 9/25/17

Area Supervisor: [redacted]

[redacted]

Location of Occurrence:

[redacted]

Animal Involved: Rabbit 2476

Details: On 9/22/17, during routine nail trimming in [redacted], a rabbit abruptly jumped while attempting to be placed inside the cat/restraining bag used for minor procedures such as nail trims. The rabbit managed to leap off of the procedure cart being used as a work surface. The rabbit landed hard on the concrete floor approximately 3.5 feet away. Upon picking up and re-restraining the rabbit, it was noted that the rabbit's left hind leg dangled lower than right. After placing rabbit into the nearest cage, the Animal Care Technician called her area supervisor, who contacted CVS immediately to assess rabbit. A femur fracture was identified and rabbit was humanely euthanized.

Proposed Solution/Preventative Action:

- The area veterinarian will re-train all technicians and supervisors working in this facility, on rabbit restraint for nail trimming procedures.
- A larger, mobile cart will be placed within this building for these types of procedures.

Signature [redacted]

Amendment to Protocol #
Summary/Purpose: *Unanticipated Outcome*
PI:
Date Received: 09-01-2017
Funding Source(s): UC Davis Health System
Protocol Approval Date: 04-26-2017
Review Status: ***Approved* - 09-21-2017**

1. Proposed Changes:

This amendment is serving to report an unanticipated event which led to the death of a rabbit, and proposes to prevent similar complications from occurring in the future.

The events surrounding the unexpected death of rabbit #4093 on 7/27/17 immediately following an injection of contrast dye for a fluoroscopic procedure. Approximately 6ml of dye was injected with a 10cc syringe, a stopcock and an extension tubing. The syringe was filled, the extension tubing was flushed and the stopcock closed prior to connecting to the rabbit's IV line. Due to purchasing surgical supplies from a new vendor recently, the brand of stopcock has changed and the action of the stopcock has changed. It is now completely opposite of those we have used for over 30 years. What was once a locking mechanism on the stopcock is now the "open" pathway. Purely from muscle memory based on working with stopcocks for over 30 years, the locking mechanism on this particular stopcock was accidentally not activated when it was placed into the IV catheter and the dye had drained out when the dye was injected. The rabbit immediately succumbed to an air embolism which was confirmed by necropsy at CPL. CVS was notified.

We have now eliminated the use of the stopcocks and two people will witness that the extension line is flushed before attaching it to the IV catheter. Now we are using just the 10ml syringe and the extension tubing.

2. Justification for Proposed Changes:

Eliminating the use of the stopcock creates less confusion and is really not necessary.

3. Potential Adverse Effects:

N/A

4. Additional Animals:

N/A

5. Justification for Additional Animals:

N/A

Uploaded Documents:

upload/delete Amendment File Uploaded File(s): No Files Found.

Amendment Request Status: Approved - 09/21/2017

UNIVERSITY OF CALIFORNIA, DAVIS

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OFFICE OF RESEARCH

CAMERON S. CARTER
INTERIM VICE CHANCELLOR FOR RESEARCH

TELEPHONE: (530) 754-7764
FAX: (530) 752-7269

September 21, 2017

Neera Gopee, Ph.D., D.V.M.
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: Institutional Prompt Report

Dear Dr. Gopee:

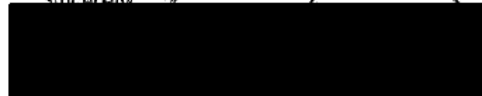
In accordance with Assurance A3433-01 and Policy IV.F.3., UC Davis is bringing the following incident and corrective action to your attention.

During a post-approval monitoring visit, it was noted that analgesics had been given less frequently than what was described in the approved animal care and use protocol and a different anesthetic had been used (isoflurane instead of ketamine/xylazine). The mice had been observed by research staff and had recovered well from the procedure so they made the decision to stop analgesics after two days instead of the five days approved in the protocol.

The PI responded promptly and submitted amendments to update both the anesthetic and analgesic regimen which was reviewed by veterinary staff followed by review and approval by the IACUC. The PI and staff have been retrained and reminded of their responsibilities to ensure the protocol is followed and changes are reviewed and approved by the IACUC prior to implementation. The laboratory will also be inspected at an increased frequency to ensure corrective actions have been effective. The work was being supported by the National Institute of Health grant #

The IACUC believes the above actions have corrected the issue and will prevent any reoccurrence. If you have any questions please do not hesitate to contact our IACUC Office at (530) 752-2364.

Sincerely,



Institutional Official
University of California, Davis

c: IACUC
AAALAC

UC Davis Institutional Animal Care and Use
Animal Incident Reporting Form

(FOR IACUC INTERNAL USE ONLY)

1. **Summary of Incident:** Adult cat found dead

   On 11/15/17 an adult cat was found dead in a large gang-style cat housing room within the [redacted] Vivarium. The front and back of the room's interior caging is made up of standard, heavy gauge, chain link mesh fencing; the cat had become caught in the fencing. Similar gang style chain link fencing has been used without incident for over 25 years in at least three campus facilities.

   The caging was examined by IACUC staff on 11/17/17 and found to be in good repair with no loose, slack, broken, or otherwise damaged mesh.

   This incident was self-reported to CVS by the vivarium staff on 11/15/17. The incident was reported to the IACUC on 11/16/17 and will be reviewed at the next Leadership Team meeting.

Name of person documenting incident: [redacted]

IACUC notification:

Discussion: 11/16 and 11/30/17 IACUC meetings

Date Final Report to IACUC: 11/30/17

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December 15, 2017

NEERA GOPEE, PH.D., D.V.M.
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: Institutional Prompt Report

Dear Dr. Gopee:

In accordance with Assurance A3433-01 and Policy IV.F.3., UC Davis is bringing the following incident and corrective action to your attention.

During a post-approval monitoring visit, it was noted that analgesics had not been given to 13 rats as described in the approved animal care and use protocol after a spinal contusion surgical procedure was performed. The work was being conducted under the National Institute of Health grant #

The PI responded promptly to this finding by retraining the surgeons on the protocol-related procedures to ensure the proper post-operative analgesia is used according to the IACUC protocol. The laboratory has the appropriate analgesic and the surgeons have taken the IACUC course on rodent survival surgery.

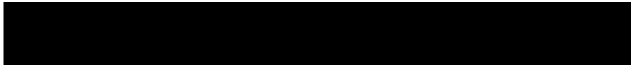
The IACUC believes the above actions have corrected the issue and will prevent any reoccurrence.

If you have any questions please do not hesitate to contact our IACUC Office at (530) 752-2364.

Best wishes,

Institutional Official
University of California, Davis

c: IACUC
AAALAC



Amendment to Protoco

Summary/Purpose: *Adverse event report - 2 mortalities*

PI:

Date Received: 12-12-2017

Funding Source(s): National Eye Institute

Protocol Approval Date: 07-26-2017

Review Status: ***Approved*** **- 12-14-2017**

1. Proposed Changes:

On Nov. 2, 2017, two adult female frogs were imaged and then placed in a clean 10L tank in the Facility. Animals were never hooked into the flow-through system due to a miscommunication between research staff and the animal caretakers. Animals were being fed, but never underwent a water change, and despite a lack of clinical signs, were both found dead on Dec. 3, 2017. No water was saved nor tested, and carcasses were frozen so post-mortem examination was not performed. We can only assume poor water quality was the most likely cause of death in this case, CVS veterinarians were notified. Presence of static caging within the Facility was addressed by the IACUC following a recent facility inspection. Corrective actions including amending husbandry SOPs, additional training, and removal of static caging from the facility have since been performed by the PI.

2. Justification for Proposed Changes:

Please see section 1

3. Potential Adverse Effects:

Please see section 1

4. Additional Animals:

N/A

5. Justification for Additional Animals:

N/A

Uploaded Documents:

upload/delete Amendment File Uploaded File(s): No Files Found.

Amendment Request Status: Approved - 12/14/2017

Incident Report

Date of Occurrence: February 7, 2018
Protocol
PI:
Species: Fish
Number of animals involved: 184
Location:
Director:

Details: the IACUC Office received an incident report via e-mail with copy to the Campus Veterinary staff from the director on the morning of February 7, 2018 concerning the loss of 184 white sturgeon housed in one of the tanks at The reports that yesterday (2/6/18) shut off the water valve to a row of tanks to work on some plumbing without realizing there were fish in one of the tanks, and this morning (2/7/18) fish were found dead most likely due to lack of fresh water circulation. The valve delivers fresh water to three thanks of about 250 gallons each, and the middle one was holding these fish (~11 inches) for future experiments on s protocol

further states that personnel usually drip the tanks for winter to prevent the pipes from freezing and she thought that was the only thing occurring in those tanks at the time. The individual took full responsibility for the incident and is working on immediate corrective actions.

Concerning the animals, these are white sturgeon (~11 inches) that were on hold for future experiments.

Follow up with Investigators. 2/7/2018 IACUC staff met at to check the fish tanks, review the incident, discuss case details and future corrective actions.

A draft "Incident Report–IACUC Summary" was presented at the 2/8/18 IACUC convened meeting.

Proposed solution/Preventative Action discussed at the 2/22/18 convened meeting:

As a corrective action, director have modified their Physical Plant SOP to include a section on plumbing repairs. The section includes the need for communication in advance, the determination of potentially affected tanks and the identification of tanks actively containing fish. The SOP will be in review with other members of the Facility and will try to finalize the SOP by the end of February and submitted to the IACUC Office.

Follow up of preventive actions 2/28/18:

Director submitted via e-mail final physical plant SOP revised 2/25/18 and checklist for plumbing upgrades to be used on a clipboard before a person starts the project.

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

March 8, 2018

Re: Animal Welfare Assurance
A3433-01 [OLAW Case 2K]

Dr. Cameron Carter
Interim Vice Chancellor for Research
University of California, Davis

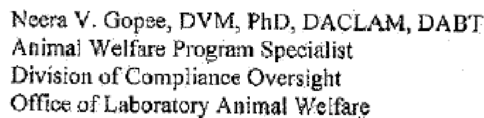
Dear Dr. Carter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 27, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Davis, following up on an initial telephone notification on February 7, 2018. According to the information provided, OLAW understands that an animal technician inadvertently discharged the incorrect rhesus macaque from the hospital to an outdoor field cage. Apparently the technician failed to follow established standard operating procedures (SOP) which resulted in the discharge of the wrong nonhuman primate. The animal sustained some injury and upon discovery of the error was immediately removed from the field cage and treated until fully recovered.

The corrective actions consisted of temporarily relieving the responsible technician of hospital discharge duty until appropriately retrained on the relevant SOP and Human Resources issuing a letter of expectation regarding the technician's assigned responsibilities and tasks.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Davis are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,



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

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