



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 29, 2023

Re: Animal Welfare Assurance
A3156-01 [OLAW Case G]

Mei Wei, Ph.D.
Vice President for Research
Rowan University
South Jersey Technical Pkwy
107 Gilbreth Parkway, (b) (4)
Mullica Hill, NJ 08062

Dear Dr. Wei,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2023 letter providing further requested information concerning the Minority Views that were attached to the January 2022 semi-annual inspection regarding the mis-sexing of mouse pups, cage overcrowding, and possible protocol noncompliance. From the additional information provided, it is understood that a mis-sexed female successfully mated during postpartum estrus and produced a second litter. No further instances of animal welfare concerns (overcrowding, fighting, use of wrong sex in studies, etc.) were found during post-approval monitoring, reported to the IACUC, or observed by veterinarian and animal care staff. A monogamous pair breeding program was outlined in the referenced, active, and approved protocol. Breeding monitoring is performed by the PI/research staff with periodic veterinarian clinical checks, daily monitoring by vivarium animal staff, and semi- annual program and facility reviews.

The vivarium animal staff quickly identified the newborn litter and subsequent overcrowding, immediately separated the dam and pups from the adult males, and timely response of the PI remediated the situation.

Other corrective and preventive actions included Veterinarian-led training on animal sexing, which was attended by the Principal Investigator and research staff, amendments to the protocol to include more detailed description of the PI's breeding program, pup weaning, and record-keeping.

NSF Grant Number: 1941296

OLAW appreciates the prompt consideration of this matter by Rowan University, which was consistent with the philosophy of institutional self-regulation. We especially want to recognize your part in providing transparency between your Office and OLAW. We appreciate your cooperation as Institutional Official regarding this matter in particular and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2023.08.30 17:02:16 -04'00'

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

cc: IACUC contact
NSF Animal Welfare Officer

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, July 21, 2023 2:30 PM
To: (b) (6)
Subject: RE: [EXTERNAL] OLAW Case A3156-G

Thank you for contacting OLAW. I think your plan is fine. Since the new I.O. has accepted responsibility for the program, Dr. Wei should sign your response letter.

Sincerely, Brent Morsr

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

From: (b) (6)
Sent: Friday, July 21, 2023 1:07 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: FW: [EXTERNAL] OLAW Case A3156-G

Hi Dr. Morse,

I am working with the IACUC Chair, Dr. David Devilbiss, on the letter requested in the attachment. We recently have changed our IO, so I just have a quick question about who should sign and send the letter to OLAW/you. Yesterday, we received acknowledgement from OLAW of our submission changing the IO to Dr. Mei Wei, but the letter was sent to Dr. Tabbetha Dobbins, former IO for Rowan's animal welfare program. Before identifying the IO signatory from Rowan, wanted to get your perspective and recommendation, just in case it is better for OLAW purposes to have the letter coming from Dr. Tabbetha Dobbins. We plan on including either Dr. Dobbins or Dr. Wei as a cc recipient on the letter to ensure all current and former IO's are aware of the communication with OLAW regarding the request.

Sorry about the long email and any guidance/recommendation is appreciated.

(b) (6)



From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Sent: Thursday, July 20, 2023 11:24 AM
To: Dobbins, Tabbetha Amanda <Dobbins@rowan.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Devilbiss, David M.

<devilbiss@rowan.edu>; (b) (6)

Subject: [EXTERNAL] OLAW Case A3156-G

Good morning Dr. Dobbins,

Attached please find Dr. Morse's report for OLAW Case A3156-G. Please note that a response is being requested by August 25, 2023. If you have any questions, feel free to contact us by phone or by email.

Thanks,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

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A3156-G

August 14, 2023

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Dear Dr. Morse:

In reference to your letter, dated July 20, 2023, and the request for further information on the Minority View included in the Rowan University, assurance D16-00096 (A3156-01) 2022 Annual Report, we are providing further information and explanation related to the circumstances surrounding the minority view. We apologize for not providing a thorough explanation and further action taken by the IACUC regarding the minority view in the 2022 Annual Report.

Rowan IACUC Report Related to Mis-sexing and Cage Overcrowding Minority View

During the incident regarding mis-sexing of mice and cage overcrowding from a new litter, a mis-sexed female successfully mated during postpartum estrus and produced a second litter. No further instances of animal welfare concerns (overcrowding, fighting, use of wrong sex in studies, etc.) were found during post-approval monitoring, reported to the IACUC, or observed by veterinarian and animal care staff. A monogamous pair breeding program was outlined in the referenced, active and approved protocol. Breeding monitoring is performed by the PI/research staff with periodic veterinarian clinical checks, daily monitoring by vivarium animal staff, and semi-annual program and facility reviews.

A non-compliance subcommittee was formed and investigated the incident. The subcommittee's report to the IACUC did not indicate that animals were harmed or injured, including death, from the incident. The IACUC reviewed the incident and non-compliance subcommittee report during the September 2021 meeting and determined this incident was not a case of non-compliance nor a serious deviation from the provisions of the *Guide*. The IACUC did not identify this incidence as a programmatic failure, as breeding details and procedures are included in IACUC protocols involving such procedures, daily monitoring by vivarium animal staff quickly

Division of University Research
SJTP Sam Jones Innovation Center
107 Gilbreth Parkway, Suite 103
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Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/11/2023



RowanUniversity

identified the newborn litter and subsequent overcrowding, immediate separation of the dam and pups from the adult males, and timely response of the PI to remediate the situation.

The IACUC recommended a series of corrective and preventive actions that included Veterinarian-led training on animal sexing, which was attended by the Principal Investigator and research staff on November 8, 2021, amendments to the protocol to include more detailed description of the PI's breeding program, pup weaning, and record-keeping which was reviewed and approved by the IACUC on November 15, 2021. During these incidents, the Rowan IACUC Chair was Dr. Eduard Dedkov succeeded by Dr. David Devilbiss on 11/1/2021.

Federal Sponsor: National Science Foundation

Project Title: CAREER: Metabolic Control of Purkinje Cell Dendritic Development and Mouse Behavior.

NSF Grant Number: 1941296

Sincerely,

(b) (6)

Mei Wei

VP for Research

Institutional Official

Cc: Former Rowan IACUC Institutional Official – Tabbetha Dobbins; IACUC Chairperson - David Devilbiss;

(b) (6)

(b) (6)

Division of University Research

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Uploaded to Animal Research Laboratory Overview (ARLO) on 12/11/2023

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 14, 2023 3:37 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Assurance A3156-01 (OLAW Case G)

Good afternoon (b) (6)

Thank you for sending us this report regarding case A3156-G and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Monday, August 14, 2023 11:27 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Wei, Mei <weim@rowan.edu>; Dobbins, Tabbetha Amanda <Dobbins@rowan.edu>; (b) (6) Devilbiss, David M. <devilbiss@rowan.edu>
Subject: [EXTERNAL] Animal Welfare Assurance A3156-01 (OLAW Case G)

Dear Office of Laboratory Animal Welfare,

Attached is the report signed by the Institutional Official regarding Minority Views in the 2022 Annual Report to OLAW.

Please let me know if any additional information is needed.

(b) (6)



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July 20, 2023

Re: Animal Welfare Assurance
A3156-01 [OLAW Case G]

Tabbatha Dobbins, Ph.D.
Vice President for Research
Rowan University
107 Gilbreth Parkway, (b) (4)
Glassboro, NJ 08028

Dear Dr. Dobbins,

Upon review of your 2022 Annual Report to OLAW, our Division of Assurances referred the Minority Views that were attached to the Division of Compliance Oversight. OLAW is requesting further information regarding the Minority View referencing the January 2022 semi-annual inspection. In that report, there was a concern regarding the mis-sexing of mouse pups and a reference to cage overcrowding. In addition, it appears there was protocol noncompliance since a mouse breeding scheme was not described in the protocol. The IACUC determined this not to be noncompliance. OLAW is requesting answers to the following questions:

1. Did the mis-sexing of the mouse pups result in any further animal welfare concerns, such as overcrowding, fighting, multiple litters, use of wrong sex in studies, etc.?
2. Was breeding allowed on the referenced protocol? How was your program monitoring the breeding?

Since corrective and preventive actions were not included in the Minority View description, and as authorized under section V. A. 4. of the PHS Policy, and as referenced in your Animal Welfare Assurance for Humane Care and Use of Laboratory Animals, OLAW is requesting that your institution provide an explanation of the circumstances surrounding the above concerns. Please instruct the IACUC, avoiding any conflict of interest, to send a report, signed by you as the Institutional Official, to the following OLAW email inbox: OLAWdco@od.nih.gov and provide a description of the occurrences and any/all corrective/preventive actions. Please have them consider if the occurrence represented a programmatic failure and why they determined it was not reportable to this Office. Please also include information regarding any PHS/NSF/DHHS funding of activities related to the occurrence, including grant or contract numbers.

We appreciate your cooperation and ask that you please provide the requested information **by August 25, 2023, and reference Case A3156-G**. Please contact me if I can be of assistance at morseb@mail.nih.gov

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2023.07.20 09:15:24 -04'00'

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

cc: IACUC contact

McCoy, Devora (NIH/OD) [E]

From: Na, Jane (NIH/OD) [E]
Sent: Friday, July 7, 2023 8:02 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Knapp, Paula (NIH/OD) [E]
Subject: FW: minority view on AR + use of ketamine without DEA license
Attachments: Nov 2022 Annual Report to OLAW signed.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear DCO,

Upon review of the Rowan University D16-00096 (A3156-01) 2022 Annual Report (attached but DOA does not intend to retain the semiannual report to the IO with the final AR uploaded to AARMS), there are a few items concerning noncompliance.

Minority view (pg 2 and excerpt copied below):

January 2022 Semi-annual Inspection (See Attachment)

Following a discussion related to the non-compliance sub-committee report of Post Approval Monitoring report on 8/31/2021 the committee found that the incident involving mis-sexing of animals was not non-compliance given mis-sexing mice happens even with seasoned, experienced animal researchers/staff. **Minority Opinion/View:** Chair said it was non-compliance because of overcrowding and mentioned there was no description in the protocol on how breeding should be done.

The Chair submitted a minority view that said it was noncompliance due to overcrowding and a lack of breeding description in the protocol. The above makes it seem like the committee did not agree that there was overcrowding or potential protocol noncompliance, or at the very least, it isn't clear if there was any discussion regarding these points.

Use of ketamine without a DEA license (page 13 and excerpt copied below):

S	Spark surgery areas	<p>Deficiency: Use of a controlled substance (ketamine) without a DEA license. This represents a Departure from the Guide (p. 122), "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely."</p> <p>Plan for Correction: Pause/halt all research activity that involves the use of Ketamine or other Controlled Substances until it can be demonstrated that use of the Ketamine/Xylazine is allowable under Federal, State, and University regulations and policies or valid DEA license exists.</p>	PI (Dr. Mazurek)
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They incorrectly state this is a departure from the Guide. This is not anything an IACUC would or should approve so it's not a departure. It's a noncompliance. They may need education regarding what a departure is, and depending on the funding source, they may need to have reported the noncompliance to OLAW.

FYI: Paula is the assigned AR Reviewer and she hasn't sent the AR Acknowledgment letter yet.

Jane
(301) 402-1922