

**From:** [Gibbens, Robert - APHIS](#)  
**To:** [Tonya - APHIS Hadjis \(tonya.hadjis@usda.gov\)](#); [Tanya A - APHIS Tims \(tanya.a.tims@usda.gov\)](#)  
**Subject:** FW: OLAW Case A3685-H  
**Date:** Friday, May 22, 2020 11:42:00 AM  
**Attachments:** [0291\\_001.pdf](#)

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FYI

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**From:** Walker, Keri (NIH/OD) [C] [mailto:keri.walker@nih.gov]  
**Sent:** Friday, May 22, 2020 7:07 AM  
**To:** kressler@mclean.harvard.edu  
**Cc:** (b) (6) Gibbens, Robert - APHIS <robert.m.gibbens@usda.gov>; Fleming, Pam (NIH/NIDA) [E] <pfleming@nida.nih.gov>  
**Subject:** OLAW Case A3685-H

Dear Dr. Ressler,

Attached please find Dr. Tubbs' final response to OLAW Case A3685-H.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,  
Keri

*Keri Walker  
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 11, 2020

Re: Animal Welfare Assurance  
#A3685-01 (OLAW Case H)

Dr. Kerry Ressler  
Chief Scientific Officer  
McLean Hospital  
115 Mill Street  
Belmont, MA 02478-9106

Dear Dr. Ressler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 8, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the McLean Hospital following up on an initial June 5, 2019 notification by telephone. According to the information provided, this Office understands that the McLean Hospital Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: conduct of an animal-related activity without prior IACUC approval. The final report states that on May 14, 2019 it came to the attention of the IACUC Chair that an online pre-print appeared in the journal J Med Primatology entitled "An assay of drug-induced emesis in the squirrel monkey." After review of the pre-print, the IACUC Chair realized that the exact studies described in the paper had not been reviewed or approved by the IACUC. The IACUC Chair had concern that these studies were not adequately described in the PI's IACUC protocol. The PI was contacted and stated that they believed they had "coverage" for studying emesis, as it is a side effect of many of the drugs they administer and perform "observational studies" of which this would be a part. However, the report states that emesis as a readout was not specifically described in the protocol.

The IACUC Chair informed the Institutional Official of the concern and convened an internal meeting including the Attending Veterinarian and Assistant IACUC Chair to review the protocol and the paper and discuss the concern. As a result, a consensus was made to involve the USDA Inspector to obtain their input. The report states on May 29, 2019 the USDA Inspector visited the facility to review the materials with an exit interview the following day. Ultimately, the USDA issued a critical citation indicating that investigators conducting regulated research activity failed to submit a proposal for new activity to the IACUC for review. It is stated the new activity was conducted without IACUC approval from September 2017 through September 2018 as part of the generation of the data that went into the report. It was determined that the investigators did not recognize the activity as a deviation and did not realize the necessity of submitting the activity to the IACUC for review. In the citation, it was noted that this noncompliant item was voluntarily self-reported by the facility at the time of discovery and that the facility had instituted corrective measures to prevent recurrence. The corrective actions included the following:

- The PI submitted an amendment to their IACUC protocol for these procedures. The amendment was reviewed and approved by the IACUC on June 6, 2019 prior to official publication of the paper (August 2019).

- On the recommendation by the USDA Inspector, the IACUC established a Routine Compliance Monitoring agenda which involves regular meetings between IACUC officers and the PIs of all IACUC protocols describing NHP work. The purpose is to identify any potential issues between ongoing work and those procedures described in the protocols.

The report states the first meeting of this group was in October 2019. Also, the USDA revisited the facility on October 16, 2019 as follow-up to the critical citation. At that visit, no non-compliant items were identified and documented on the Institution's latest USDA Inspection Report.

It is noted that this research was supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the McLean Hospital- Belmont has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. This Office advises the institution to contact the NIDA Program Officer regarding the publication. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations

Pamela Fleming, Chief Grants Management Officer (NIDA)