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Wolff, Axel (NH/OD) [E]

From: OLAW Division of Compliance Oversight (NH/OD)  
Sent: Wednesday, February 28, 2018 7:19 AM  
To: (b) (6)  
Cc: OLAW Division of Compliance Oversight (NH/OD)  
Subject: RE: [A3085-01] TJU Final Report - 171201

Thank you for this report, (b) (6). We will respond soon.

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

From: (b) (6) [jefferson.edu]  
Sent: Tuesday, February 27, 2018 3:01 PM  
To: OLAW Division of Compliance Oversight (NH/OD) <olawdco@od.nih.gov>  
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>  
Subject: [A3085-01] TJU Final Report - 171201

Dear Dr. Morse and the Office of Laboratory Animal Welfare,

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide the final report for an incident of noncompliance at Thomas Jefferson University. (See attached.) Please don't hesitate to contact us if you have any questions or concerns.

Sincerely,

(b) (6)



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## Gopee, Neera (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 01, 2017 4:54 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: [A3085-01] Preliminary Report

Thank you for this preliminary report, (b) (6). We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Best Regards,  
 Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
 Veterinary Medical Officer  
 Office of Laboratory Animal Welfare  
 National Institutes of Health

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**From:** (b) (6)@jefferson.edu]  
**Sent:** Friday, December 01, 2017 4:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)@jefferson.edu>; (b) (6)@jefferson.edu>  
**Subject:** [A3085-01] Preliminary Report

Dear OLAW,

Please accept this e-mail as a preliminary notification of a reportable offense that has recently occurred at our institution.

### Name and Contact Information of Person Reporting:

(b) (6)

**Name of Institution:** Thomas Jefferson University

**Assurance Number:** A3085-01

**Funding Component and If Contacted:** To Be Determined

### Brief Description of Incident:

On November 14, 2017, the IACUC became aware of an issue involving a laboratory's failure to maintain appropriate animal-related records (i.e., post-procedural). The laboratory uses mice for a mechanical loading forearm injury. The protocol states that a single dose of buprenorphine will be given before the procedure, and that a second dose will be

given on the following day "if needed." The laboratory could not provide evidence of any next-day monitoring of the condition of these animals that would allow them to determine the need for a second dose of buprenorphine, and in conversations with veterinary staff and IACUC personnel, it became clear that this follow-up assessment was often not being done.

**Plan and Schedule for Correction and Prevention (if known):**

Upon identification of this incident, the PI was immediately asked to stop work involving this procedure, and did comply with this request. The Post Approval Monitor, Clinical Veterinarian, and IACUC Chair have all been in contact with the PI and laboratory personnel to discuss this issue since then. The PI is being fully cooperative and has demonstrated that he understands the need to properly perform and document post-procedural monitoring. The IACUC is currently working with the PI to establish proper monitoring procedures including changes to the protocol(s).

**Timeframe for Final Report from the Institutional Official:** A final report should be submitted within 90 days.

Sincerely,

(b) (6)



(b) (6)

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