

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

October 22, 2018

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

Re: Animal Welfare Assurance A4628-01 [OLAW Case A]

Dr. Michelle Creamer-Hente Attending Veterinarian Synchrony Labs, LLC 3908 Patriot Drive, (b) (4) Durham, NC 27703

Dear Dr. Creamer-Hente,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 17, 2018 letter reporting an adverse event involving a pig at Synchrony Labs. According to the information provided, OLAW understands that a pig had its rear leg trapped in a gap between the wall panel and floor.

The immediate action taken upon discovery consisted of sedating the animal and freeing the leg. The animal was euthanized while sedated, in accordance with the protocol. All wall panels will be replaced with chain link fencing which meets the floor without gaps. The repairs are expected to be finalized by December 2018 and any gaps identified in the interim will be filled.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Please remember to have all final reports signed by the Institutional Official. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair Mark Urtz, Institutional Official

(b) (6)



October 17, 2018

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

Dr. Brent Morse,

We would like to inform you of an unexpected adverse event that took place at Synchrony Labs, Assurance **#**: A4628-01

On Tuesday evening, October 16, 2018 a farm pig was found with its right hind foot caught between the cage's stainless steel wall panel and the grated flooring. The Attending Veterinarian was notified Immediately and the animal was heavily sedated prior to freeing the limb. The Study Director and Institutional Official were promptly notified on 10/16/18 via phone and follow-up email regarding the incident. The animal was scheduled for euthanasia per the protocol on 10/16/18 and euthanasia was performed following sedation.

Upon inspection of the cage, a very small gap was present between the flooring and the stainless steel paneling however no other obvious defects in the paneling or flooring were noted. Veterinary recommendations to assess all caging and replace any stainless steel paneling with an alternative product were approved by the Institutional Official. The Institutional Official immediately allocated resources to address the cage paneling. Cage modifications to replace stainless steel paneling with chain link fencing that extends to the cage floor without any gaps has begun on 10/17/18. The expected time to complete the modification of all remaining cages with stainless steel paneling is December 15, 2018. In the interim, any gaps in the stainless steel to flooring will be temporarily modified with material that will prohibit the potential for an incident of this nature from happening again while the permanent modifications are being done.

Synchrony Labs is committed to providing high quality animal care and will continue to assess the facility for any additional structural improvements that are needed. Please let us know if you have any further questions, concerns, or recommendations.

Sincerely,

(b) (6) Michelle Creamer-Hente, DVM, MS, DACLAM Attending Veterinarian	(b) (6)

3908 Patriot Drive, Suite 170, Durham, NC 27703 919 541 9977 A4628-A

Morse, Brent (NIH/OD) [E]

From: Sent: To: Cc: Subject: Morse, Brent (NIH/OD) [E] Thursday, October 18, 2018 11:30 AM (b) (6) Michelle Creamer-Hente RE: Adverse Event Report

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM 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:

(b) (6)

Sent: Thursday, October 18, 2018 11:13 AM To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> Cc: Michelle Creamer-Hente <MCreamer-Hente@synchronylabs.com> Subject: Adverse Event Report

Dear Dr. Morse,

Attached is a report of an adverse event that occurred at our facility earlier in the week. Please don't hesitate to contact our Attending Veterinarian (copied), Dr. Michelle Creamer-Hente or myself if you have any questions or would like to discuss further.

Best,

