



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) 402-2803

May 8, 2017

Re: Animal Welfare Assurance
A3363-01 [OLAW Case C]

Mr. Thomas L. Spalding
President
Pacific BioLabs
551 Linus Pauling Drive
Hercules, CA 94547

Dear Mr. Spalding,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 4, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Pacific BioLabs, following up on an initial report on April 13, 2017. According to the information provided, OLAW understands that five mice were inadvertently assigned to an expired protocol and used on a study. An employee had assigned the mice using the electronic database but failed to confirm that the protocol was still active.

The corrective actions consisted of counseling the individual to use only active protocols, retraining all staff on protocol use, and implementing use of an online list of protocol expiration dates. The protocol was revised and reviewed and approved by the Institutional Animal Care and Use Committee.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Note that if the study in question was supported by PHS/NIH, the funding component also needs to be notified and the activity cannot be charged to the grant. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

May 4, 2017

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

Follow-up Report

Animal Welfare Assurance number: A3363-01

Pacific BioLabs, in accordance with Assurance A3363-01 and PHS Policy IV.F.3., provides this follow-up report regarding a noncompliance that was reported on April 13, 2017. Specifically, the noncompliance involved five mice that were inadvertently assigned to an expired Animal Care and Use Protocol (ACUP), 17C-05, General Safety Test (Biologics) - Mice. The ACUP expired on 03/26/17 and animals were assigned 3/27/17. The study was completed on 03/29/17. No other animals were assigned to this ACUP after this time.

An investigation was immediately instituted by the IACUC Chair and Attending Veterinarian to determine the root cause of the oversight. The investigation revealed that a staff member had assigned the animals to ACUP17C-05 in the Pacific BioLabs Animal Management System database without confirming with the Study Director that the ACUP was still active.

Toxicology Management immediately counseled the involved employee and reiterated the importance of assuring animals are only assigned to active, IACUC approved ACUPs.

A department-wide training was also conducted by the IACUC Chair regarding ACUPs to ensure all Toxicology staff is clear as to the requirements and regulations involving ACUP assignment and use. Resources included OLAW, the Guide for the Care and Use of Laboratory Animals and the USDA Animal Welfare Act and Animal Welfare Regulations.

Additionally, the IACUC Administrator has developed a centralized, on-line resource easily accessible for all staff to review ACUP expiration dates so that this can be assessed at the time of animal assignment.

Thank you for your consideration of this matter. Please do not hesitate to contact me further for clarifications or information.

Sincerely,



Thomas L. Spalding
President
Institutional Official
Pacific BioLabs

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 08, 2017 9:18 AM
To: [REDACTED]@PacificBioLabs.com'
Subject: RE: Final Report

Thank you for this report, [REDACTED]. We will respond soon.

Axel Wolff

From: [REDACTED]@PacificBioLabs.com [mailto:[REDACTED]@PacificBioLabs.com]
Sent: Friday, May 05, 2017 12:48 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Angela@PacificBioLabs.com; [REDACTED]@PacificBioLabs.com; TomSpalding@PacificBioLabs.com
Subject: Final Report

Director, Division of Compliance Oversight-

Find attached the final report following an IACUC investigation for an animal incident originally reported to OLAW on April 14, 2017.

If you have any further questions, please do not hesitate to contact me.

[REDACTED]
Secondary Individual

Executive Vice President

Responsible Official, Select Toxin Program

[REDACTED]@PacificBioLabs.com

[REDACTED] (main)

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Friday, April 14, 2017 7:34 AM
To: [REDACTED]
Subject: RE: Prompt Reporting

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

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: [REDACTED]@PacificBioLabs.com [mailto:[REDACTED]@PacificBioLabs.com]
Sent: Friday, April 14, 2017 9:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: TomSpalding@PacificBioLabs.com; [REDACTED]@PacificBioLabs.com; Angela@PacificBioLabs.com
Subject: Prompt Reporting

Director, Division of Compliance Oversight:

Please find attached notification of an animal incident that requires prompt reporting per PHS Policy, IV.F.3. If you have any further questions, please do not hesitate to contact me.

Thank you for your time and attention.

Regards,

Angela Colagross-Schouten
IACUC Chair

Pacific BioLabs
551 Linus Pauling Drive
Hercules, Ca 94547
Phone Number

Executive Vice President, Toxicology Services
Responsible Official, Select Toxin Program

Secondary Individual **@PacificBioLabs.com**
Phone Number (main)

PBL Pacific BioLabs

The Service Leader in Bioscience Testing

April 13, 2017

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

Preliminary Report

Animal Welfare Assurance number: A3363-01

Pacific BioLabs, in accordance with Assurance A3363-01 and PHS Policy IV.F.3., provides this preliminary report of noncompliance regarding five mice assigned to an expired animal care and use protocol.

Animal Care and Use Protocol (ACUP) 17C-05 General Safety Test (Biologics) – Mice expired on 03/26/17. Five (5) animals were assigned to this procedure on 03/27/17 and the study was completed on 03/29/17. No other animals were assigned to this ACUP after this time. The non-compliance was noted the week of 04/10/17. The ACUP was reviewed, revised and approved by the IACUC on 04/13/17.

A preliminary assessment of the oversight was conducted and it appears that the assignment of the animals was inadvertently performed by a team member that failed to confirm the expiry date of the ACUP. The IACUC Chair and Committee Members will continue to work to explore areas of improvement in the PBL animal tracking system to prevent a reoccurrence.

We expect to have a complete report within 30 days. A copy of the report will be sent as soon as it is available.

Thank you for your consideration of this matter.

Sincerely,

Thomas L. Spalding
President
Institutional Official
Pacific BioLabs

Secondary Individual

Executive Vice President, signing on behalf of Tom Spalding

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 14, 2017 10:34 AM
To: 'Secondary Individual@PacificBioLabs.com'
Subject: RE: Prompt Reporting

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

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: Secondary Individual@PacificBioLabs.com [mailto:Secondary Individual@PacificBioLabs.com]
Sent: Friday, April 14, 2017 9:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: TomSpalding@PacificBioLabs.com; Secondary Individual@PacificBioLabs.com; Angela@PacificBioLabs.com
Subject: Prompt Reporting

Director, Division of Compliance Oversight:

Please find attached notification of an animal incident that requires prompt reporting per PHS Policy, IV.F.3. If you have any further questions, please do not hesitate to contact me.

Thank you for your time and attention.

Regards,

Angela Colagross-Schouten
IACUC Chair

Pacific BioLabs
551 Linus Pauling Drive
Hercules, Ca 94547

Phone Number

Secondary Individual
Executive Vice President, Toxicology Services
Responsible Official, Select Toxin Program

Secondary Individual@PacificBioLabs.com
Phone Number (main)