



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) 402-7065

October 10, 2018

Re: Animal Welfare Assurance
A3330-01 (OLAW Case M)

Dr. Raimund Hirschberg
IACUC Chair
Los Angeles Biomedical Research Institute
1124 West Carson Street
Torrance, CA 90502

Dear Dr. Hirschberg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 20, 2018 letter reporting an instance of noncompliance with institutional policy at the Los Angeles Biomedical Research Institute (LA BioMed), following up on an initial July 20, 2018 email notification. According to the information provided, OLAW understands that a Principal Investigator at LA BioMed failed to submit an annual report for a protocol involving the performance of pulmonary function tests (PFT) in rats in accordance with the annual renewal policy at the University of Southern California (USC), the collaborating institute responsible for conducting the PFT.

The corrective action consisted of the USC IACUC approving, by unanimous vote, to discontinue the requirement for annual renewals of protocols involving non-USDA regulated species.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Please be advised that all future final reports of noncompliance must be submitted to OLAW by the Institutional Official, in accordance with section IV.F.3 of the PHS Policy. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. David Meyer, Institutional Official, Los Angeles Biomedical Research Institute

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The LA BioMed IACUC acknowledged that the protocol underwent a de novo review and was renewed on June 26, 2014, with an expiration date of June 23, 2017, as required by PHS Policy; however, annual reviews were still required at USC for non-USDA covered species. As such, although there was a mechanism in place between the institutions to verify protocol approval status prior to transferring animals, the LA BioMed IACUC office requested that the USC IACUC office provide the annual approval notifications going forward. In response to this request, the USC IACUC voted on August 22, 2018, to stop requiring annual approvals on protocols using only non-USDA covered species. A detailed explanation of their corrective plan, dated September 18, 2018, is provided in an email from the IACUC Chair at the University of Southern California, Dr. Lund, which is attached to this letter.

LA BioMed receives Public Health Service support for this animal work under agreement number 23RT-0018 and grant numbers 1R01HL127237-01A1; 1R21HD071731-01A1; 5R01HD051857-03; 5R21HL107118-02. LA BioMed's Assurance number is D16-00213.

Thank you in advance for your review of the above. If you have any questions, please contact the Compliance Office at complianceac@labiomed.org or call (b) (6)

Sincerely,

(b) (6)

Raimund Hirschberg, M.D.

Chair

On behalf of the Institutional Animal Care and Use Committee

Attachment

Cc:

(b) (6)

(b) (6) Brett T. Lund, Ph.D.

Harmon, Rosa

Subject: RE: USC IACUC Protocol #11658-CR004

From: Brett Thomas Lund <blund@usc.edu>
Sent: Tuesday, September 18, 2018 1:36 PM
To: Complianceac <complianceac@labiomed.org>
Subject: RE: USC IACUC Protocol #11658-CR004

Dear Dr Hirschberg,

My sincere apologies for the tardiness of my response. I had assumed that the IACUC office was submitting the response to you and just found out otherwise.

The USC IACUC met on July 25th and briefly discussed this matter in an otherwise very busy agenda. The matter was further discussed and final action taken at our August 22nd meeting.

From our investigation we agreed that the requirement of an annual renewal on a protocol that in the previous year (or two years prior) received a 3 year approval clearly creates confusion. In this case both with the PI who omitted to renew his protocol also the veterinarian in charge of approving incoming shipments, who used the 3 year expiration date in his/her assessment. There is no absolute necessity to have this annual renewal on non-USDA covered species. As such the USC IACUC committee voted unanimously at our August 22nd meeting to stop requiring annual approvals on the protocols using only non-USDA covered species. Though this mandate should be effective immediately we are currently waiting for the updating of our electronic protocol and records system [REDACTED] to be updated to include this change, and have been told that this will happen by the end of the year.

Given these changes to our procedures we are confident that an issue such as this will not occur again.

We thank you for your diligence and professionalism.

Should you have any further questions please do not hesitate to reach out to myself or the IACUC office.

Brett T. Lund, Ph.D.
Chair, USC Institutional Animal Care and Use Committee

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Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, July 20, 2018 1:23 PM
To: (b) (6)
Subject: RE: preliminary report of unapproved animal activities

Thank you for this preliminary report (b) (6) We will open a case file and await further information as noted in your email below.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Friday, July 20, 2018 12:45 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: preliminary report of unapproved animal activities

Hi Dr. Morse,

On July 6, 2018, our IACUC confirmed that 80 rats were used at USC, a collaborator, in March 2017 during a lapse of protocol approval. This was discovered during a triennial review of our PI's IACUC protocol which reflected that pulmonary function tests are performed on rats at USC. Upon requesting the approved protocol from USC, the LA BioMed compliance office found that the USC protocol indicated all of the work was performed at LA BioMed. At that time, 5/3/2018, the PI at USC submitted an Amendment to add the PFT back in to the protocol (it had been previously described).

The details of the unapproved activity were discussed during a convened IACUC meeting yesterday, 7/19/2018, and the LA BioMed IACUC is working with USC on a corrective action plan. The corrective action plan will be sent to you within six weeks. LA BioMed's assurance number is D16-00213.

Thank you,
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Research Into Tomorrow's
Cures

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