



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

July 9, 2019

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

Dr. David Meyer
President and CEO/Institutional Official
Los Angeles Biomedical Research Institute
1124 West Carson Street
Torrance, CA 90502

Dear Dr. Meyer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 26, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Los Angeles Biomedical Research Institute (LA BioMed). Your letter supplements the information contained in the initial prompt email report to our office on May 17, 2019. According to the information provided, OLAW understands that on May 15, 2019 your Compliance Office was informed that a dual antigen vaccine approved by the IACUC to be administered to mice via the intramuscular route had instead been administered via the subcutaneous route. The animals were not harmed and an amendment was subsequently submitted to add the subcutaneous route to the protocol. This activity was funded by the PHS.

Corrective and preventive actions included requiring the laboratory staff to review his approved protocols prior to working with animals. The investigator was encouraged to reference BRC SOPs in his protocols or create his own that must be approved by the IACUC. He is encouraged to include all possible administration routes in his protocols. A post-approval monitoring visit will be conducted to verify compliance with his protocols.

The prompt consideration of this matter by the Los Angeles Biomedical Research Institute was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



LABioMed

June 26, 2019

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
olaw@od.nih.gov

Los Angeles Biomedical
Research Institute
at Harbor-UCLA Medical Center

1124 West Carson St.
Torrance, CA 90502
www.LABioMed.org

Compliance Office
IACUC
[p] 310-222-3624
[email] complianceac@labiomed.org

RE: Final Report of a Protocol Noncompliance

Dear Dr. Morse,

On May 15, 2019, the Los Angeles Biomedical Research Institute (LA BioMed) Compliance Office was informed that a dual antigen vaccine approved under an animal protocol entitled, "Cross-Kingdom Vaccine Targeting Healthcare-Associated Priority Pathogens" to be administered to mice via the intramuscular route was administered via the subcutaneous route without appropriate approval; this route is approved under another protocol. The investigator informed the attending veterinarian after implementing the change; animals were reportedly not harmed and an amendment was subsequently submitted to add the subcutaneous administration route to the protocol.

During a convened meeting on May 16, 2019, the LA BioMed IACUC reviewed the amendment and the incident and voted to remind the investigator that all significant changes must be approved prior to implementation as required by the approved IACUC Policy on Amendments and to consult with the veterinarian prior to making any changes - in case the Veterinary Verification and Consultation review process can be used according to IACUC Policy. A preliminary report was submitted to you via email by (b) (6) on May 17, 2019. During a convened meeting on June 20, 2019, the Committee reviewed the investigator's response and voted to convey the following to him:

- His staff must review his approved IACUC protocol(s) prior to working with the animals so that they are aware of the approved activities.
- An umbrella protocol for all of the frequently used techniques in his laboratory is not necessary since he may reference BRC SOPs or create his own SOPs that must be approved by the IACUC.
- He is encouraged to include all possible administration routes in his protocols in the event he needs to change an administration route.
- A post-approval monitoring visit will be conducted to verify compliance with his protocols.

LA BioMed receives Public Health Service support for this animal work under agreement number R01AI141202. LA BioMed's Assurance number is D16-00213.

If you have any questions, please contact the Compliance Office at complianceac@labiomed.org or call (310) 222-3624.

Brent Morse, DVM, DACLAM
Page 2

Sincerely,

(b) (6)

David Meyer, D.D.
President and CEO/Institutional Official
On behalf of the Institutional Animal Care and Use Committee

Cc: (b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, July 03, 2019 8:10 AM
To: (b) (6)
Cc:
Subject: RE: Final Report to OLAW

Thank you for providing this final 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: Tuesday, July 02, 2019 7:04 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: Final Report to OLAW

Hi Dr. Morse,

Please see the attached IACUC correspondence signed by our IO.

Thank you,
(b) (6)

(b) (6)



LABioMed
Los Angeles
Biomedical
Research Institute
at Harbor-UCLA Medical Center

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, May 21, 2019 3:09 PM
To: (b) (6)
Subject: RE: query

Importance: High

Hello (b) (6)

I just left you a voicemail. This is a reportable incident of protocol noncompliance. Please have the IACUC provide a final report to OLAW signed by the Institutional Official. That should be submitted within 60 days, but let me know if you need more time. Here is the link to our webpage that might be helpful: <https://olaw.nih.gov/guidance/reporting-noncompliance.htm> and please do not hesitate to call: 301-594-2921.

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: Friday, May 17, 2019 6:45 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: query

Hi Dr. Morse,

I'd like to ask you if the scenario below is a reportable incident:

An investigator submitted an amendment to change the route of vaccine administration from IM to SQ in mice. Prior to submitting the amendment, he had implemented the change then notified the AV (because this route was is approved under another protocol). The research is PHS supported. Animals were not harmed, but the IACUC voted to remind the PI, via formal IACUC correspondence, that all changes must be approved prior to implementation as required by the approved IACUC Policy on Amendments and to consult with the veterinarian prior to making any changes - in case VVC can be used according to IACUC Policy.

Thank you,
(b) (6)

LA BioMed Warning: This email (and any attachments) is intended for the use of the person to which it is addressed. It may contain information that is privileged and confidential. As the recipient, you are obligated to maintain it in a safe, secure and confidential manner. Unauthorized disclosure or failure to maintain confidentiality may subject you to governmental penalties. Should you not be the intended recipient, please notify us by return email, and delete this message from your computer at once.
