



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

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Rockledge One, Suite 360
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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November 14, 2018

Re: Animal Welfare Assurance
#A3471-01 [OLAW Case 3F]

Dr. Wesley Byerly
Associate Vice President
for Research Compliance
UConn Health
263 Farmington Avenue
Farmington, CT 06030

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 1, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at UCONN Health, following up on an initial report on October 9, 2018. According to the information provided, OLAW understands that mice were used in a tumor cell production procedure which was not listed on the approved protocol.

The corrective action consisted of counseling the Principal Investigator on the requirement for Institutional Animal Care and Use Committee (IACUC) approval for all procedures. The PI and staff were retrained and the protocol was amended to include the procedure.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incident was serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at UCONN Health are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

(b) (6)

UConn HEALTH

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7962
Bethesda, MD 20891-7982

November 1, 2018

RE: PHS Assurance D16-00295 (A3471-01), UConn Health

Dear Dr. Morse-

I am writing to you to provide a final report of an incident of non-compliance at UConn Health. You were originally notified of this incident by email from our IACUC Administrator on October 9, 2018.

The original notification informed you that ascites production was being performed that did not have IACUC approval. This turned out to be somewhat incorrect. The research group was injecting MethA tumor cells into mice in order to grow them, not to produce ascites. This activity was not approved by the IACUC.

This incident was brought to the attention of the IACUC on October 25, 2018. The PI had informed the IACUC that the animals (3 cages of mice) did not appear to be in any pain or distress because of this procedure. He also informed the IACUC that it wasn't in the protocol because this method of growing the cancer cells is "standard practice" and he assumed that the IACUC knew about it.

The IACUC sent a letter to the PI informing him that all procedures performed in animals, whether or not they are considered to be "standard practice" need to be described in an animal care and use protocol and approved by the IACUC. The PI submitted a modification to the IACUC to include this procedure which is currently in review. The PI and all research personnel were required to re-attend our initial animal user training 3-hour class. The IACUC informed the PI that should any further incident of non-compliance occur, the protocol will be suspended as this was the third incident of non-compliance with this protocol since 2017.

This non-compliance was not supported by any federal funds.

While all efforts were made to deal with this issue in a timely and meaningful manner, I realize there may be questions that arise following your review of this material. Please feel free to contact me at byerly@uchc.edu or at (b) (6)

Sincerely,

(b) (6)

Wesley G. Byerly, Pharm.D.
Associate Vice President, Research Integrity and Regulatory Affairs / Institutional Official

Institutional Animal Care and Use Committee
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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 13, 2018 12:42 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Final report of non-compliance

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

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From: (b) (6)
Sent: Tuesday, November 13, 2018 8:13 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; (b) (6)
Subject: Final report of non-compliance

Hi, Dr. Morse-

Attached is a final report of non-compliance first reported to OLAW on October 9th via email. Please let me know if you have any additional questions or concerns.

Thank you. Hope you have a wonderful Thanksgiving!

(b) (6)

A large rectangular area of the document is completely redacted with a solid grey fill.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 09, 2018 12:24 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Byerly, Wesley
Subject: RE: Initial report of non-compliance A3471-01 (D16-00295)

Thank you for sending this preliminary report. We will open a case file and await further information. You are welcome to use either or both of the numbers. At this point our compliance case files still use the "A" designator, so if it's all the same to you, that number is better for compliance reports. Thanks for asking.

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: Tuesday, October 09, 2018 11:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Byerly, Wesley <byerly@uchc.edu>
Subject: Initial report of non-compliance A3471-01 (D16-00295)

Good morning.

On behalf of my Institutional Official, I am writing to inform you of an instance of protocol non-compliance at UConn Health, PHS Assurance A3471-01 (D16-00295). It was discovered on Friday, October 5, 2018 that a research group was performing ascites production on 2 cages of mice and this procedure is not approved by the IACUC – this procedure is not listed as being performed in the approved protocol.

We are in the process of getting information regarding this issue. The research group was informed that they cannot continue with this procedure. This incident, along with the information received from the research group, will be discussed during our October IACUC meeting and a final report will be sent when the IACUC has completed its investigation of this issue.

Please let me know if there is any additional information you require at this point.

Also, I have a question- do you prefer that we identify via the "A" Assurance Number, the "D" Assurance Number, or both? Or does it matter which one we use? I'm not positive about this and I want to be sure I am using the correct PHS Assurance Number.

Thank you. Have a great day.

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