



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
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April 18, 2018

Re: Animal Welfare Assurance
A3027-01 [OLAW Case F]

Dr. Mark A. Barteau
Vice President for Research
Texas A&M University College of Dentistry
(b) (4) J.K. Williams Building 1112 TAMU
College State, TX 77843-1112

Dear Dr. Barteau,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Texas A&M University. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) was not properly constituted because the nonaffiliated member was also serving on another institutional committee. This dual appointment was unknown to the institution's Animal Welfare Office (AWO). Official business had been conducted during the period between when the problem was discovered and its resolution.

The corrective action consisted of having the nonaffiliated member serve only on the IACUC. The single protocol and two amendments that had been reviewed and approved following discovery of the issue, were submitted for full committee review and approval. Subsequently the nonaffiliated member unexpectedly died. The IACUC did not conduct any additional official business, a new nonaffiliated member was appointed and trained, and the IACUC resumed business. The AWO will ensure that nonaffiliated members are informed about the requirements for this IACUC position.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

DIVISION OF RESEARCH

Office of the Vice President for Research



April 16, 2018

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

RE: Texas A&M University College of Dentistry Assurance D16-00014
Report of IACUC Composition Noncompliance

Dear Dr. Wolff:

On February 20, 2018, (b) (6) called you to request clarification about a potential IACUC composition issue involving a nonaffiliated IACUC member who was also serving on another institutional committee. During the telephone conversation with (b) (6) you indicated that this was considered noncompliance. (b) (6) immediately responded by providing an initial report of the incident. I was informed that the phone call qualified for a timely response for reporting the issue identified.

Texas A&M University College of Dentistry has an approved Animal Welfare Assurance document number D16-00014. As the Institutional Official for the Texas A&M University College of Dentistry Animal Care and Use Program, I am submitting a formal report including the actions taken to address the situation.

On February 1, 2018, the Animal Welfare Office (AWO), which maintains IACUC compliance oversight for the College of Dentistry, was made aware that a nonaffiliated IACUC member was also serving on another institutional committee. A staff member for the other compliance program requested documentation from the AWO on the IACUC's unaffiliated member, whereupon, the AWO discovered the dual appointment. Prior to that time, the dual appointment was unknown to the AWO. When the issue was identified and confirmed as noncompliance, my office took steps to address the situation by changing the appointment of the nonaffiliated member to only serve on the IACUC as of February 20, 2018.

A records review was conducted for the period of time coinciding with the date of discovery of the committee composition issue, February 1, 2018, through the date that the issue was corrected on February 20, 2018. During this period of time, it was determined that one Animal Use Protocol was approved by the IACUC and two amendments were approved under designated member review. The protocol and amendments were resubmitted to the fully constituted IACUC for review and approval on February 27, 2018.

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Dr. Axel Wolff, Director, Division of Compliance Oversight
April 16, 2018
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The IACUC convened a meeting with a quorum of members on March 6, 2018. Following the meeting, the AWO was informed that the nonaffiliated member died suddenly on March 1, 2018. IACUC business was immediately halted until a new nonaffiliated member was appointed on April 5, 2018. Official IACUC business resumed on April 10, 2018 after the new nonaffiliated member completed the new member trainings and orientation.

Moving forward, the AWO will provide additional training to unaffiliated IACUC members to remind them of the importance of maintaining their unaffiliated status and asking them to notify the AWO if they expect their unaffiliated status to change.

The Texas A&M University College of Dentistry is committed to humane care in the use of any animals and conducts only the highest quality animal research as part of its mission to advance human health care. The institution devotes significant resources to ensure strict oversight of its animal research program.

Should you have any questions, please contact (b) (6) at (b) (6) or me.

Sincerely,

(b) (6)

Dr. Mark A. Barteau
Vice President for Research
Institutional Official

cc:

(b) (6)