



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

DATE: December 3, 2008

TO: Suzanne Servis  
Director, Office of Management Assessment, OM, OD

FROM: Director, Division of Compliance Oversight, OLAW

SUBJECT: Concerns Regarding Tracking of Grant Funds at the University of Wisconsin-Madison

The Office of Laboratory Animal Welfare (OLAW) had received a self report concerning noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin-Madison. The problems involving the animals were successfully resolved, however the University appeared to imply that there were no specific mechanisms in place to accurately track grant funds regarding protocols involving animals. OLAW had specifically asked what measures had been taken to ensure that a PHS-supported grant was not charged for procedures which had not been approved by the Institutional Animal Care and Use Committee (IACUC) and thus did not meet the terms and conditions of the NIH Grants Policy Statement. The Institutional Official indicated that in these situations a new policy had been developed which would cover the costs of animal activities conducted in the absence of valid IACUC approval of the activity.

OLAW expressed concern with this new institutional policy in that it may encourage individuals to conduct animal activities without approval because there is no financial disincentive, this action gives the impression that noncompliance is condoned by the University and will be financially supported, and that many journals require certification that the animal activities were conducted in compliance with relevant regulations including approval by an IACUC and animal data gathered under noncompliant conditions may preclude publication even if the costs were covered. This new policy also did not address the original question as to which measures have been implemented to prevent charging of an unapproved animal activity to the relevant PHS grant.

Although OLAW has closed the case based on the University's appropriate response to the animal concern, the financial aspects involving accurate tracking of grant funds may need to be further explored by your Office. The Director of the Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration has also been copied regarding this issue.

Thank you for your attention to this matter.

Axel Wolff, M.S., D.V.M.



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December 2, 2008

Re: Animal Welfare Assurance  
A3368-01 [OLAW Case 1N]

Dr. William S. Mellon  
Associate Dean for Research Policy  
University of Wisconsin-Madison  
327 Bascom Hall - 500 Lincoln Drive  
Madison, WI 53706-1380

Dear Dr. Mellon,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 24, 2008 letter responding to my October 24, 2008 request for additional information concerning a report of a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* and an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin- Madison. According to the information provided, OLAW understands the following:

- 1) The laboratory procedures instituted by the investigator to prevent the implementation of a significant change to a protocol without prior approval from the Institutional Animal Care and Use Committee (IACUC) consisted of retraining all laboratory staff, instituting use of an animal request form, and amending the protocol.
- 2) An institutional policy has been developed by which costs will be covered by the University in the event that an animal activity is conducted without IACUC approval.
- 3) The grant number was provided for the study which involved animal deaths due to equipment failure. The noncompliant incident was not PHS-funded.
- 4) Temperature and humidity sensors are present in the animal rooms and alarms are sent to staff over a pager.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in both cases to correct and prevent recurrence of the problems. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy however this Office is concerned about the potential for misinterpretation of the intent of item #2 regarding the newly established institutional policy. This Office notes that the University is at liberty to develop such a policy however this action may encourage individuals to conduct animal activities without approval because there is no financial disincentive. This could also give the impression that noncompliance is condoned by the University of Wisconsin and will be financially supported. Many journals require certification that the animal activities were conducted in

compliance with relevant regulations including approval by an IACUC and animal data gathered under noncompliant conditions may preclude publication even if the costs were covered. NIH expects grantees to manage the day-to-day operations of grant supported activities using established controls and policies, as long as they are consistent with NIH requirements. Grantees must ensure that they exercise proper stewardship over Federal funds, ensure that costs charged to the awards are allowable, and that internal accounting and other control systems provide reasonable assurance that financial operations are properly conducted. The establishment of this new policy does not address which measures have been implemented to prevent charging of an unapproved animal activity to the PHS/NIH grant. Although OLAW will hereby close out this case, any additional information concerning the financial actions taken in response to noncompliance on a PHS grant using animals should be forwarded for inclusion in the file.

This letter is also being copied to the Office of Policy for Extramural Research Administration Division of Grants Compliance and Oversight, NIH which may pose additional questions regarding the tracking of grant funds.

Thank you for keeping OLAW apprised on this matter.

Sincerely,



Axel Wolff, M.S., D.V.M.

Director

Division of Compliance Oversight

cc: Norlin Benevanga, Ph.D., IACUC Chair  
Diane Dean, Director, Division of Grants Compliance and Oversight  
John Burke, Assistant Grants Compliance Officer, OER



A3368

November 24, 2008

Dr. Axel Wolff, MS, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360  
6705 Rockledge Drive, MSC 7982  
Bethesda, MD 20892-7892

Dear Dr. Wolff:

This is a response to a request for further information you requested about a communication from us on October 3, 2008.

- “1) Indicate what specific measures were implemented by the investigator to prevent a recurrence of the noncompliance.”
- The principle investigator immediately retrained his entire laboratory about the necessity to follow existing animal use protocols, including review of the protocols. This retraining included additional procedures laboratory personnel must follow before ordering animals for any experiment, including completion of a laboratory-internal request form that must be approved in advance by the principle investigator. In addition, the protocol was promptly amended to include challenge studies with specific microorganisms under BSL-2 conditions.
- “2) Indicate what actions were taken to ensure that the PHS/NIH grant was not charged for procedures which were not approved by the IACUC.”
- The Research Policy Advisory Committee of UW-Madison has developed a policy that states the University will be responsible for covering the costs of animal activities conducted in the absence of valid IACUC approval of the activity.
- “3) Provide the grant number(s) of all protocols involved in the reportable events.
- Grant number(s) for protocol noncompliance—The investigator in this incident does have NIH funding; however, NIH funding was not used for this particular protocol or the noncompliant experiment.
  - Grant number(s) for facility overheating incident—5DTIOD000579, IT20MHO77967.
- “4) Have any measures been taken to promptly alert staff when a mechanical failure occurs which impacts the ventilation system and adversely affects animal well-being?”
- Rooms at this facility have sensors for temperature and humidity. If temperature or humidity ventures outside of preset ranges, an alert is sent automatically via pager to a senior care staff member who is on-call 24/7.

DEC 1 '08 PM 12:08

Graduate School

Bascom Hall University of Wisconsin-Madison 500 Lincoln Drive Madison, Wisconsin 53706-1380

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October 24, 2008

Re: Animal Welfare Assurance  
A3368-01 [OLAW Case 1N]

Dr. William S. Mellon  
Associate Dean for Research Policy  
University of Wisconsin-Madison  
327 Bascom Hall - 500 Lincoln Drive  
Madison, WI 53706-1380

Dear Dr. Mellon,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 3, 2008 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Wisconsin-Madison, following up on an initial telephone report on July 24, 2008. According to the information provided, OLAW understands that three rats died as a result of a sensor failure which caused a ventilation unit to malfunction.

The corrective action consisted of repairing the faulty equipment.

OLAW also acknowledges a report of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals which consisted of the implementation of a significant change without prior approval by the Institutional Animal Care and Use Committee (IACUC). Specifically, mice were infected with a bacterium as a challenge in a vaccine study but this activity was not included in the approved protocol.

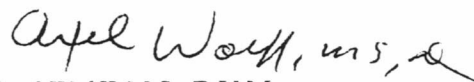
The corrective action consisted of the investigator amending the protocol and instituting laboratory procedures to prevent a recurrence.

In order for OLAW to have a complete understanding of the corrective actions taken in response to these incidents, please provide the following additional information:

- 1) Indicate what specific measures were implemented by the investigator to prevent a recurrence of the noncompliance.
- 2) Indicate what actions were taken to ensure that the PHS/NIH grant was not charged for procedures which were not approved by the IACUC (see enclosed guidance).
- 3) Provide the grant number(s) of all protocols involved in the reportable events.
- 4) Have any measures been taken to promptly alert staff when a mechanical failure occurs which impacts the ventilation system and adversely affects animal well being?

Please provide the requested information by **November 25, 2008**.

Sincerely,

A handwritten signature in cursive script that reads "Axel Wolff, M.S., D.V.M." with a flourish at the end.

Axel Wolff, M.S., D.V.M.

Director

Division of Compliance Oversight

cc: Norlin Benevenga, Ph.D., IACUC Chair

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