



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

June 7, 2007

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

Dr. William S. Mellon  
Interim 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 May 30, 2007 letter reporting five instances 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 about the incidents and the corresponding corrective actions:

- 1) Calorie restriction was used in a mouse study without prior Institutional Animal Care and Use Committee (IACUC) approval.  
Corrective action: The investigator was counseled on the requirement for prior IACUC approval of all animal activities and the protocol was amended to include the procedure.
- 2) The IACUC investigated an allegation about the performance of surgeries by inadequately trained personnel. The allegation was not confirmed however the IACUC found that peri-operative procedures were not being performed as described in the approved protocol.  
Corrective action: The investigative staff was retrained, the protocol was amended, and the IACUC will conduct additional monitoring of the laboratory.
- 3) Mice were being monitored for use of an exercise wheel although the procedure was not described in the approved protocol.  
Corrective action: The investigative staff was retrained and the protocol was amended.
- 4) A mouse irradiation study was conducted differently from what was described in the protocol.  
Corrective action: The unauthorized activity was stopped, the protocol was amended, and the investigative group was retrained.
- 5) A surgical teaching activity was started before final approval was given by the IACUC.  
Corrective action: The investigator was retrained.

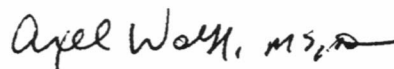
The institutional response to the recurring problem of the conduct of animal activities, including the implementation of significant changes, without prior IACUC approval consisted of assigning two individuals to assist the IACUC in post-approval monitoring. Also, investigators will receive additional ongoing training regarding adherence to the content of approved protocols. The IACUC has noticed enhanced self-reporting of noncompliance to be taking place.

Based on its assessment of these explanations, OLAW understands that University of Wisconsin- Madison has implemented measures to correct and prevent recurrence of the problems at the local and institutional level. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy and supports the program wide approach for addressing the occurrence of similar incidents of noncompliance. Please note the following:

- 1) All reports of noncompliance to OLAW involving PHS/NIH-supported projects must include the relevant grant number.
- 2) All reports of noncompliance to OLAW must include the species involved.
- 3) Please carefully review the enclosed guidance with investigative staff. Note that the conduct of unauthorized animal activities constitutes not only a violation of the PHS Policy but also NIH Grants Policy Statement (NIHGPS) which prohibits charges to grant awards for the conduct of animal activities when the terms and conditions of the NIHGPS are not upheld. Under these circumstances, the funding component needs to be contacted regarding the financial aspects of the grant during the noncompliant period.
- 4) The use of data obtained from unauthorized activities may also be subject to restriction.

We appreciate having been informed about these matters and find no cause for further action by this Office.

Sincerely,



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

Director

Division of Compliance Oversight

Enclosure

cc: Eric Sandgren, Ph.D., IACUC Chair

Janet Welter, D.V.M., M.P.H., Ph.D., Institutional Veterinarian

## NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld

**Notice Number:** NOT-OD-07-044

### Key Dates

Release Date: January 26, 2007

### Issued by

National Institutes of Health (NIH), (<http://www.nih.gov>)

The purpose of this Notice is to clarify that no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval. This notice is applicable to grants and cooperative agreements involving activities with live vertebrate animals.

### Background

Terms and conditions applicable to all grant awards that involve live, vertebrate animals - including research, research training, experimentation, biological testing, custom antibody preparation, or related purposes - require a valid Animal Welfare Assurance (Domestic, Foreign, or Inter-institutional Assurance, as applicable) approved by the NIH Office of Laboratory Animal Welfare (OLAW), and valid IACUC approval. IACUC approval must be dated within the last three years in order to be valid. IACUCs are not authorized to administratively extend approval beyond three years. Foreign grantees receiving direct support are not required to provide IACUC approval, but must have a valid Foreign Assurance on file with OLAW (see <http://grants.nih.gov/grants/olaw/assurance/500index.htm> for list of foreign institutions with approved Assurances).

### Policy

The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
2. The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Additionally, these situations constitute serious noncompliance with section IV.F.3. of the PHS Policy and as such must be promptly reported to OLAW in accord with the PHS Policy. See NOT OD-05-034, Guidance on Prompt Reporting to OLAW (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>)

Grantees are reminded that under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grants funds by all parties, and all other obligations of the grantee as specified in the NIHGPS. The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The prime grantee is responsible for including these requirements in its agreements with collaborating

organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an appropriate Animal Welfare Assurance and that the activity has a valid IACUC approval. (see <http://grants.nih.gov/grants/olaw/assurance/300index.htm> for a list of domestic institutions with Assurances). If the prime grantee does not have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. When the grantee is a domestic institution and there is a foreign performance site using animals, the grantee must ensure that the performance site has an appropriate Foreign Assurance and must provide verification of IACUC approval by the domestic grantee's IACUC, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee. (See NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements, [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600251](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251)).

## Inquiries

Questions concerning this Notice should be directed to:

Office of Policy for Extramural Research Administration  
National Institutes of Health  
Telephone: 301-435-0938  
Email: [grantspolicy@od.nih.gov](mailto:grantspolicy@od.nih.gov)

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Questions about Assurances or IACUC approval of animal activities should be directed to:

Office of Laboratory Animal Welfare  
Division of Assurances  
National Institutes of Health  
Telephone: 301-496-7163  
Email: [olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov)

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National Institutes of Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892