



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

JAN - 4 2010

## FOR US POSTAL SERVICE DELIVERY:

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 Bethesda, Maryland 20892-7982  
 Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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 Office of Laboratory Animal Welfare  
 Rockledge One, Suite 360  
 6705 Rockledge Drive  
 Bethesda, Maryland 20817  
 Telephone: (301) 496-7163  
 Facsimile: (301) 402-2803

December 18, 2009

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

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,

On behalf of the Office of Laboratory Animal Welfare (OLAW) we wish to thank you and your staff for the hospitality shown to us during the site visit of the University of Wisconsin-Madison conducted by our Office and the US Department of Agriculture on December 1-2, 2009. We appreciate the time spent and information provided by you, Rick Lane, Dr. Eric Sandgren, Dr. Janet Welter, [REDACTED], Dr. Buddy Capuano, [REDACTED] Holly McEntee, [REDACTED] the Find-it/Fix-it (FIFI) staff, [REDACTED] the Institutional Animal Care and Use Committee (IACUC) members, and all other animal program staff. As discussed in our exit briefing we found all the animals examined to be in good condition and comprehensive environmental enrichment strategies for the [REDACTED] and the [REDACTED] including extensive social housing for the nonhuman primates. The animal study proposal forms appeared to be sufficiently detailed to solicit adequate information for the IACUC reviews which, based on minutes review, are very thorough.

As we also indicated, several issues were identified which need to be addressed and modified or corrected. In order for OLAW to monitor the plans and schedules for correction the University of Wisconsin-Madison is hereby placed on an enhanced reporting schedule. The specific items needing attention are as follows:

- 1) Each of the five IACUCs is to independently promptly report, through the Institutional Official, to OLAW any serious or continuing noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* (*Guide*), or any suspension of an activity by the IACUC as required by the PHS Policy at IV.F.3. The IACUCs are to carefully review NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals (enclosed) and are encouraged to contact the OLAW Division of Compliance Oversight regarding questions on prompt reporting.
- 2) The institution must operate in accordance with NOT-OD-07-044 NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld (enclosed) and not allow charges to be made to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIH Grants Policy Statement are not upheld. This includes the implementation of significant changes to protocols without prior IACUC approval.

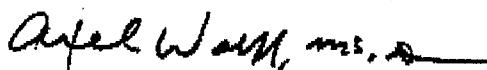
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- 3) Significant changes must receive prior IACUC approval either by full committee review or designated member review. Significant changes cannot be approved by the veterinarian and/or IACUC chair unless all IACUC members have been given the opportunity to call for full committee review and no one requested such a review. OLAW has published examples of significant changes which include changes in anesthesia, analgesia, or euthanasia method. The IACUCs are to conduct continuing review of each previously approved, ongoing activity covered by the Policy at appropriate intervals as determined by the IACUC.
- 4) The role of the All Campus IACUC needs to be reevaluated. This committee is not to overrule the decisions made by any other IACUC or modify the semiannual review findings of any other IACUC. The All Campus IACUC must not usurp the authority of any other IACUC or the Institutional Official. Having a central committee such as the All Campus IACUC serve in an advisory role for development of institutional policies and harmonization of animal care and use practices is acceptable.
- 5) Measures must be taken to address animal rooms which do not have a centralized monitoring capacity for temperature ranges to ensure that procedures are in place to address fluctuations which could negatively impact the animals. See OLAW Frequently Asked Question at <http://grants.nih.gov/grants/olaw/faqs.htm#f6>. If there are animal rooms that cannot achieve air changes as recommended in the *Guide*, such as in the [REDACTED], there should be a consideration given for discontinuing their use as animal holding rooms.
- 6) Vehicles used to transport animals must have appropriate climate control.
- 7) OLAW strongly encourages the continuation of pair or group housing of primates wherever possible. OLAW supports the plan of placing animals not eligible for inclusion on active studies due to age or other condition as partners for single housed primates on Simian Immunodeficiency Virus-studies.
- 8) The concept of the FiFi staff providing assistance to investigators to achieve protocol compliance is a good approach. Instances of noncompliance identified by FiFi staff must be reported to the appropriate IACUC which is to assess whether the item also needs to be reported to OLAW and whether corrective actions proposed are appropriate.
- 9) Oversight of the numbers of animals used on protocols must be enhanced especially in locations where investigators using rodents are under minimal restrictions regarding the numbers of animals ordered or bred.
- 10) The concept of reviewing the same protocols by more than one IACUC should be assessed to ensure that this practice does not lead to conflicting authorities.
- 11) The chickens housed in the [REDACTED] are to be maintained in accordance with the provisions outlined in the *Guide*, page 42-44, and this must be overseen by the IACUC and veterinarian. Having the bedding changed annually and the watering equipment sanitized once per year is not consistent with the provisions of the *Guide*.
- 12) OLAW recommends that overarching policies for the animal care and use program be developed for transportation, environmental enrichment, post-approval monitoring of ongoing animal activities, an inventory control system for pharmaceuticals, animal tracking, animal ordering, including common forms and cage cards, rather than having these policies emanate from the individual college or building.

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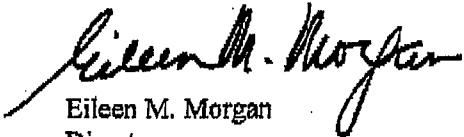
As noted above, OLAW is placing the University of Wisconsin- Madison on an enhanced reporting schedule to monitor progress regarding the implementation of corrective actions or modifications as described. Please provide an assessment of all items outlined by April 1, 2010 to the OLAW Division of Compliance Oversight (DCO), attention Dr. Axel Wolff. Provide a copy of the next complete semiannual program review and facility inspection report to DCO, ensuring that it is prepared in accordance with IV.B.1-3 of the PHS Policy. Upon review of these documents by this Office, additional guidance on further reporting will be provided. The Annual Report is to be submitted independent of these documents to the Division of Assurances. Feel free to contact us should you have any questions.

Sincerely,



Axel Wolff, M.S., D.V.M.  
Director  
Division of Compliance Oversight

Sincerely,



Eileen M. Morgan  
Director  
Division of Assurances

cc: Elizabeth Goldentyer, D.V.M., Eastern Regional Director, USDA-APHIS-AC  
Daniel Uhlrich, IACUC Chair School of Medicine and Public Health  
Nancy Schultz-Darken, Ph.D., IACUC Chair Graduate School  
Norlin Benevenga, Ph.D., IACUC Chair CALS  
Hannah Carey, Ph.D., IACUC Chair School of Veterinary Medicine  
Robert Streiffer, Ph.D., IACUC Chair College of Letters & Science

Enclosures

NOT-OD-07-044: NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms are not Upheld Page 1 of 2

## 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

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If the grantee has 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)

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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Health (NIH)  
9000 Rockville Pike  
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and Human Services  
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NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and... Page 1 of 4

# Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

**Notice Number:** NOT-OD-05-034

## Key Dates

Release Date: February, 24, 2005

## Issued by

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<http://grants.nih.gov/grants/olaw/olaw.htm>)

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

## Background

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide [for the Care and Use of Laboratory Animals]*; or
- c) any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-15 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

## Guidance on Prompt Reporting

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for

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Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

**Examples of reportable situations:**

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO 2);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide*. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

**Examples of situations *not* normally required to be reported:**

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;

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- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).

**Time Frame for Reporting**

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

**Information to Be Reported**

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

**Information to be included:**

- Animal Welfare Assurance number (<http://grants.nih.gov/grants/olaw/assurance/300index.htm>);
- relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
- a full description of any potential or actual effect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by the institution to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

**Preliminary and final reports should be made to:**

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 300, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Phone: 301-594-2061  
FAX: 301-402-2803  
E-mail: [olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

**Inquiries**

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For questions or further information, contact:

Director, Office of Laboratory Animal Welfare

Office of Extramural Research,

Office of the Director, National Institutes of Health

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[olaw@od.nih.gov](mailto:olaw@od.nih.gov)

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and Human Services  
(HHS)



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