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NIH to Report to Congress Noncompliance with Federal Policy on Animal Research

In a recently enacted appropriations bill for the Department Health and Human Services, Congress has asked the National Institutes of Health (NIH) to investigate noncompliance with federal policy on animal research.

The bill, which encourages NIH to investigate allegations of noncompliance with the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals* and report its findings to Congress, states, "The Committee is concerned about allegations that several institutions receiving NIH funding may

not be in full compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Committee encourages NIH to determine the extent and scope of any such allegations and notify the Committee of its findings¹." The bill thus strengthens oversight of animal research institutions by both Congress and NIH. The bill does not identify specific noncompliant research institutions.

PHS regulations require research institutions to comply with PHS policies and provide appropriate Assurance documents

to NIH before receiving PHS funds. This differs from USDA animal welfare regulations, which apply regardless of funding, and from FDA regulations, which, as secondary regulations under the Federal Food and Drug and Cosmetics Act, must be followed as a requirement for the release of new products.

Two key sections of NIH Grants Policy Statement relevant to compliance with PHS *Policy on Humane Care and Use of Laboratory Animals*, and misconduct in research are excerpted in the following boxes:

**NIH Grants Policy Statement (03/01)
Part II: Terms and Conditions of NIH Grant Awards
Subpart A: General—Part 1 of 7**

Research Misconduct

http://grants2.nih.gov/grants/policy/nihgps_2001/part_ii_a_1.htm

The grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. Regulations at 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," specify grantee responsibilities in dealing with and reporting possible research misconduct. The signature of the authorized organizational official on the application certifies that the organization has established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available from the Office of Research Integrity (ORI) on its home page (<http://www.ori.dhhs.gov>) and, in hard copy, at the address shown in Part III.

As stated throughout this NIH GPS, the primary responsibility for ensuring that an NIH-funded project is being conducted in accordance with the approved application and budget and the terms and conditions of the award rests with the grantee. These responsibilities must be carried out with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR 50.103 and 50.104. The grantee shall report promptly to ORI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise ORI of any decision to initiate an investigation. The regulations also require that the grantee submit an annual report (see "Administrative Requirements Monitoring Reporting").

If a misconduct investigation has been initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project(s), protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the conduct of the investigation, if appropriate. ORI staff are available to assist grantees with respect to research misconduct investigations and reporting, and IC staff are available to provide technical assistance and to work jointly with grantees to protect funded projects from the adverse effects of research misconduct.

The grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. When a finding of research misconduct has been made regarding conduct by an individual(s) working on an NIH grant-supported project, whether at the grantee organization or at a third-party organization, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and must promptly obtain NIH approval of any intended change of PI or other key personnel. A finding of research misconduct may result in a range of possible sanctions by NIH, including, but not limited to, withdrawal of approval of the PI or other key personnel, debarment, disallowance of costs associated with the invalid or unreliable research, withholding of all or part of a continuation award, and/or suspension or termination, in whole or in part, of the current award. These actions are described in "Administrative Requirements Enforcement Actions."

Where the validity or reliability of data has been affected by research misconduct, the grantee and its employee/collaborator authors are responsible for submitting a correction or retraction of the data to a journal, as appropriate, and/or publishing the corrected data, if required. ORI or NIH may require corrections or retractions. If the grantee does not comply with this requirement, NIH may invoke its rights, under 45 CFR Part 74 or 92, to access the data, including copyrightable material developed under the award, have the data reviewed, and submit the correction.

Issues involving potential criminal violations, such as misappropriation of Federal funds, must be promptly reported to the HHS Office of the Inspector General (see Part III).

NIH Grants Policy Statement (03/01)**Part II: Terms and Conditions of NIH Grant Awards
Subpart A: General—Part 2 of 7****Animal Welfare**

http://grants2.nih.gov/grants/policy/nihgps_2001/part_ii_a_2.htm#_Toc504811828

No NIH award for research involving live vertebrate animals will be made unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy. Applications from organizations with approved Assurances will be considered incomplete if they do not include verification of IACUC review or do not contain the information concerning the use of vertebrate animals required as part of the application's research plan (see instructions for completion of the PHS-398 for the five specific points that need to be addressed). In the case of apparent or potential violations of the Policy, NIH may refer applications back to the applicant for further IACUC review.

Foreign organizations proposing activities involving vertebrate animals are required to comply with the Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. NIH will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW.

The Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. In addition, all organizations are required to comply, as applicable, with the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

Information concerning the preparation and submission of Animal Welfare Assurances as well as copies of the Policy and other relevant materials are available from OLAW (see Part III for contact information). Information concerning ways in which to reduce the administrative burden associated with these requirements also is available at OLAW web site <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-007.html>.

Regulation Update

Occupational Health and Safety in the Care and Use of Nonhuman Primates—A New Book

The Institute for Laboratory Animal Resources (ILAR) has recently added *Occupational Health and Safety in the Care and Use of Nonhuman Primates*² to their list of important publications on safety. The book, which is intended as a reference for research, professional, and technical personnel working with nonhuman primates, includes information on the identification of hazards, risk assessment and management, applicable safety regulations, and personnel training.

As is the case with related publications, this book may be helpful in the developing and managing policies on the safe handling of nonhuman primates, and in improving compliance with USDA rules, NIH guidelines, and AAALAC requirements. This book may be viewed, purchased in paperback, or downloaded from the National Academy Press website (<http://stills.nap.edu/books/030908914X/html>).

References

1. Making further continuing appropriations for fiscal year 2003. Congressional Record S645 (15 January 2003). http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=s645&dbname=2003_record.
2. Institute for Laboratory Animal Research, National Research Council. *Occupational Health and Safety in the Care and Use of Nonhuman Primates* (National Academy Press, Washington, DC, 2003).