

National Institutes of Health
Bethesda, Maryland 20892

May 27, 2005

TO: Addressees

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Communicating Animal Care and Use Concerns within the NIH Intramural Research Program

This memorandum reaffirms my commitment to maintain full and open communications regarding animal care and use in the NIH Intramural Research Program (IRP). I feel strongly that all IRP staff must clearly and thoroughly understand NIH management and administrative practices to best enhance our research environment. The care and use of animals in NIH research requires compliance with Federal laws, regulations and policies.

Anyone in the NIH IRP, including NIH employees and contractors, who has concerns regarding the care and use of animals in research at NIH should voice that concern. In the animal facilities, the facility veterinarians are responsible for ensuring compliance with standards and will receive initial concerns related to the facilities. The Chairs of the Institute/Centers (IC) Animal Care and Use Committees (ACUC) will field concerns about animal research procedures, especially those performed in laboratory settings. Concerns not directly related to a particular facility or IC, should be addressed to the Director, Office of Animal Care and Use (OACU) or directly to me. Concerns relayed through any of these routes will be reviewed and corrective measures instituted.

The OACU Director assists me, as Institutional Official, in assessing all concerns. I determine the level at which the concern is pursued, including involving the Animal Research Advisory Committee (ARAC) Ombudsman, who mobilizes further resources as outlined in the ARAC Guideline (<http://oacu.od.nih.gov/ARAC/Ombdsmn.pdf>). As needed, I will ask the ACUC Chair to assemble an investigative team made up of scientists, veterinarians and other appropriate individuals to assure a balanced and thorough assessment of the concern. Alternatively, the investigation will be conducted out of my immediate office.

The Office of Laboratory Animal Welfare (OLAW) recently issued updated prompt reporting guidance (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>). Any of the following incidents, extracted from OLAW's recent guidance, must be reported to the responsible IC ACUC and then to the OACU as quickly as possible. That initial report should include a summary of the incident, the initial corrective steps to be taken by the ACUC and/or the IC, and the plan of action. It is imperative that this initial reporting be accomplished within 24 hours.

Reportable incidents include:

- 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 ACUC review and approval;
- failure to adhere to ACUC-approved protocols;
- implementation of any significant change to ACUC-approved protocols without prior ACUC approval;
- conduct of animal-related activities beyond the expiration date established by the ACUC;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide*;
- participation in animal-related activities by individuals who have not been appropriately trained;
- failure to monitor animals post-procedurally as necessary to ensure well-being;
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures;
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments).

If you are uncertain about whether an incident or activity should be reported, please report it.

Upon notification of an incident and following my review of the results of the related investigation, I will report noncompliant activities and the resultant corrective actions to OLAW. In addition to the incidents that must be reported, I expect continuing communications between ACUC Chairs and the Director, OACU about matters arising within their ICs to augment regular semiannual reports. The Director, OACU will summarize these discussions for me.

In summary, any individual who has concerns related to the use of animals in research at NIH must voice those concerns. I stress that NIH will not tolerate any reprisal against an individual who has come forward with concerns involving the care and use of animals. Such reprisal is prohibited by law and perpetrators are subject to sanctions. Individuals who feel that a personnel action has been taken against them because they reported an apparent violation of animal care and use requirements, should present their case to their supervisor, their IC Director, the NIH Director, the Office of the Inspector General, or the Office of Special Counsel. If individuals allege any form of discrimination, they should file their complaint with the Office of Equal Opportunity.

Please direct questions or comments regarding the intent or contents of this memorandum to me or to the Director, Office of Animal Care and Use.

Michael M. Gottesman, M.D.

Addressees:

IC Directors and Scientific Directors
IC ACUC Chairs and Animal Program Directors
IC Facility Veterinarians and Animal Facility Managers
NIH IRP Principal Investigators and Animal Users