

Procedures for Response to Animal Care and Use Complaints from Outside the NIH

In April 1992, the following process was implemented by the NIH Intramural Research Program Institutional Official, the Deputy Director for Intramural Research (DDIR). The process was developed by the predecessor to the trans-NIH Animal Research Advisory Committee.

The NIH has a responsibility to respond vigorously and expeditiously to all complaints concerning the care and use of animals in the intramural program. While cognizant that allegations must be fully and promptly investigated, and that appropriate measures must be taken to correct any deficiencies as soon as possible, the NIH also recognizes that this process should respect the rights of the individuals involved and should not disrupt legitimate research without due cause.

DDIR has appointed a senior NIH scientist with experience in animal research to function as an ARAC ombudsman to receive, review, and assure an appropriate initial response within hours to complaints concerning the care and use of animals in the intramural program, especially when the complaint may involve more than one IC. Since most complaints originating within the NIH should be properly resolved within the ICs, complaints to the ombudsman would be expected to come mostly from outside the NIH. However, the ombudsman also will be available at the request of the ICs to review unresolved complaints that originate within the ICs. The ombudsman will serve as a member of the ARAC. The DDIR will designate an individual to serve in the ombudsman's absence.

- A. The ombudsman will inform the DDIR and the chairperson of the NIH-ARAC about any complaint and decide whether the allegations have sufficient substance to merit an inquiry. If the ombudsman finds that an inquiry is warranted, then he/she will immediately inform the DDIR and assemble a task force, the members to be drawn from outside the IC(s) involved and to include - but not necessarily be limited to - a tenured NIH scientist who is currently active in animal research and a veterinarian from the Office of Animal Care and Use. To meet this requirement, the ombudsman will maintain a list of suitably qualified personnel upon whom he/she can draw at short notice. The ombudsman shall be assigned as an ex officio member of each IC-ACUC and will be representing that/those ACUCs as one of their agents during the immediate on-site assessment by the task force.
- B. The ombudsman and his/her task force will make an immediate on-site assessment of the situation solely to determine whether there are any problems of compliance in regard to existing policies and regulations governing the care and use of animals. The task force will be granted ready access to all relevant facilities, individuals and documents. Key personnel who are also expected to be involved during this assessment include the Principal Investigator(s), the Laboratory/Branch Chief(s), the Attending Veterinarian(s), the IC Scientific Director(s), and the Chairperson(s) of the IC-ACUC(s). The ombudsman will discuss his/her preliminary findings with the IC-ACUC(s) and the Scientific

Director(s) who are responsible for taking whatever measures are required to assure immediate and continued compliance so that approved research can proceed. These measures may include temporary monitoring or supervision of the research in question. The ombudsman does not usurp the role of the ACUC(s) in the evaluation of concerns or in the actions taken or in the communication of findings and recommendations to the Institutional Official, including the suspension of research in accordance with the authorities vested in the ACUC(s) under PHS Policy. The IC-ACUC(s) involved in the assessment shall proceed, in accordance with PHS Policy and in a timely fashion, with appropriate actions based upon the findings of the assessment. Those actions would include either an IC-ACUC finding that the complaint was unfounded, or the initiation of an investigation to identify further the facts related to the complaint and implementation of corrective actions.

- C. The OACU will notify the Public Information Office and the Office of Scientific Affairs of any public relations concerns, and alert the Division of Public Safety to possible security concerns.
- D. The ombudsman will, in a timely fashion, submit a written report of all findings and actions to the DDIR, the IC Scientific Director(s), and the NIH-ARAC. The DDIR may choose to conduct further investigation(s) based on the original complaint and the ombudsman's report, either by tasking the IC-ACUC(s) to conduct such investigations (or acknowledging the IC-ACUC investigation(s) already underway) or by assembling an independent investigative team directed by the DDIR's office.
- E. In addition to the actions described above for handling complaints or allegations received from outside the NIH, NIH staff members shall be guided by the DDIR's May 27, 2005 memorandum which delineates the procedures to be followed for handling animal welfare concerns within the NIH intramural program.

Attachment - DDIR memorandum, dated May 27, 2005.

Approved by the DDIR 4/23/92

Readopted by ARAC 5/8/96

Revised by ARAC 4/9/97, Approved by the DDIR 4/9/97

Revised by ARAC 5/28/97, Approved by the DDIR 5/30/97

Revised 11/10/98, 11/14/01, 2/11/04, 6/1/05, Approved by the DDIR 6/1/05

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