Guidelines for Responding to Animal Care and Use Complaints from Outside the NIH

In 1992, the NIH Intramural Research Program Institutional Official, the Deputy Director for Intramural Research (DDIR), appointed a senior NIH scientist with experience in animal research to function as an Animal Research Advisory Committee (ARAC) ombudsman.

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.

It is the responsibility of the 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 Institute or Center (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, if needed, in the ombudsman's absence.

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 (OACU). 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 (non-voting) member of each IC-Animal Care and Use Committee (ACUC), and will be representing that/those ACUCs as one of their agents during the immediate on-site assessment by the task force.

When the ombudsman is asked to participate in a complaint process:

- 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) both of who are responsible for taking appropriate measures to assure immediate and continued compliance so that approved research can proceed. The ombudsman does not usurp the role of the ACUC(s) in their evaluation of concerns or in their recommendation of actions to be taken or in their communication of findings and recommendations to the Institutional Official. The IC-ACUC(s) involved in the assessment would proceed, in accordance with PHS Policy, with appropriate actions based upon the findings of the ombudsman’s

assessment. Those IC ACUC actions would include either finding that the complaint was unfounded, or the initiation of an investigation to further identify facts related to the complaint and then implementation of corrective actions.

- The OACU will notify the Office of Communications and Public Liaison of any public relations concerns and alert the Security and Emergency Response office to possible security concerns.
- 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.

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 March 26, 2010 memorandum which delineates the procedures to be followed for handling animal welfare concerns within the NIH intramural program.

Attachment - DDIR memorandum, Reporting Animal Welfare Concerns, 3/26/10

Approved by the DDIR 4/23/92
Readopted by ARAC 5/8/96; 01/09/2013
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
Revised 4/10/2010; Approved by the DDIR 4/10/2010

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

March 26, 2010

TO: Addressees

FROM: Deputy Director for Intramural Research, National Institutes of Health

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

As the NIH Institutional Official (IO) for Intramural animal research 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.

I strongly encourage anyone in the NIH IRP, including NIH employees and contractors, who have concerns regarding the care and use of animals in research at NIH to voice those concerns. The concerns may be reported *anonymously* to me, and/or the Director, Office of Animal Care and Use. Additionally, any animal welfare concern can be reported to the members of the Institutes/Centers (IC) Animal Care and Use Committees (ACUC) or to the IC Facility Veterinarians. Concerns relayed through any of these routes will be reviewed by the respective IC ACUC and corrective measures instituted, if appropriate.

The OACU Director assists me in assessing all concerns. My office determines the level at which the concern is pursued, including involving the Animal Research Advisory Committee (ARAC) Ombudsman, who can mobilize further resources as outlined in the ARAC Guideline: Responding to Animal Care and Use Complaints from Outside the NIH, [http://oacu.od.nih.gov/ARAC/documents/Complaint_Response.pdf].

The Office of Laboratory Animal Welfare (OLAW) issued reporting guidance in 2005. Any of the following incidents (extracted from OLAW's guidance) must be reported promptly to one of the responsible individuals described above. [OLAW guidance: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html]

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 any related investigation, I will report noncompliant activities and the resultant corrective actions to OLAW.

In summary, I strongly encourage any individual who has concerns related to the use of animals in research at NIH to 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. 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.

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, telephone: 301-496-5424.

Michael M. Gottesman, M.D.

Michael M. Gottesman, M.D.

Addressees:
IC Directors and Scientific Directors
IC Lab/Branch Chiefs
IC ACUC Members and Animal Program Directors
IC Facility Veterinarians and Animal Facility Managers
Animal Care Staff Members
NIH IRP Principal Investigators and Animal Users