

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

In 1992, the NIH Intramural Research Program (IRP) Institutional Official (IO), 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 IRP. 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.

Upon request, the ARAC Ombudsman is available to review and assure an appropriate initial response to complaints concerning the care and use of animals in the IRP, especially when the complaint may involve more than one Institute or Center (IC). Since most complaints originating within the NIH are 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 and will assist in a general leadership role for addressing concerns and building consensus. The DDIR will designate an individual to serve, if needed, in the Ombudsman's absence.

The Ombudsman will inform the DDIR, the Director, Office of Animal Care & Use (OACU), and the Chairperson of the NIH-ARAC of any complaints he/she is asked to investigate and will then decide whether the allegations have sufficient substance to merit an inquiry. If the Ombudsman finds that an inquiry is warranted, he/she will immediately inform the DDIR and assemble a task force. The task force membership will consist of individuals from outside the IC(s) involved and will include, but not necessarily be limited to, a tenured NIH scientist who is currently active in animal research and the Director, OACU or their designee. To facilitate prompt action, 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 investigating allegations.

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 whom 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, in their recommendation of actions to be taken or in their communication of findings and recommendations to the IO. The IC-ACUC(s) involved in the assessment would proceed, in accordance with Public Health Service (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. Based on the findings task force findings:

- The Director, OACU will notify the Office of Laboratory Animal Welfare if the events are deemed reportable and/or to keep them informed; the Office of Communications and Public Liaison of any public relations concerns; the Security and Emergency Response office for possible security concerns.
- The Ombudsman will, in a timely fashion, submit a written report of all findings and actions to the DDIR; Director, OACU; the impacted IC Scientific Director(s); and the 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.
- OACU will respond back to the complainant, summarizing the actions taken to address the complaint.

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 Policy Memo: [Communicating Animal Care and Use Concerns within the NIH Intramural Research Program](#) which describes the procedures to be followed regarding animal welfare concerns identified within the NIH intramural program.

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