

Guideline for Responding to Animal Care and Use Complaints from Outside NIH

In 1992, the NIH Intramural Research Program (IRP) Institutional Official (IO), the Deputy Director for Intramural Research (DDIR), appointed a NIH scientist with experience in animal research to function as an Animal Research Advisory Committee (ARAC) Ombuds (NIH Policy Manual Chapter [3040-2](#)).

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.

The ARAC Ombuds 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 ARAC Ombuds would be expected to come mostly from outside the NIH. However, the ARAC Ombuds also will be available, at the request of the ICs, to review unresolved complaints that originate within the ICs. The ARAC Ombuds 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 ARAC Ombuds's absence.

The ARAC Ombuds will inform the DDIR, the Director, Office of Animal Care and Use (OACU), and the Chairperson of the ARAC of any investigation requests and determine if the allegations have sufficient substance to merit an inquiry. If the ARAC Ombuds finds that an inquiry is warranted, they will immediately inform the DDIR and assemble a task force. The task force membership will consist of the ARAC Ombuds acting as Chair, individuals from a nonaffiliated IC(s), a tenured NIH scientist who is currently active in animal research, the Director, OACU or their designee, and other subject matter experts as needed. To facilitate prompt action, the ARAC Ombuds 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 ARAC Ombuds is asked to participate in a complaint process, task force will make an immediate on-site assessment of the situation solely to determine whether there are any problems of compliance with 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) (PI), the Laboratory/Branch Chief(s), the Attending Veterinarian(s), the IC Scientific Director(s) (SD), and the Chairperson(s) of the IC ACUC(s). The ARAC Ombuds will discuss the task force preliminary findings with the IC ACUC(s), the SD(s) (or equivalent), and IO. The ARAC Ombuds does not supersede the roles of the ACUCs, SDs, and IO in their evaluation of concerns. The IC ACUC(s) involved in the assessment would proceed, in accordance with all relevant regulations and policies, with appropriate actions based upon the findings of the ARAC Ombuds's assessment. Those IC ACUC actions would include their conclusion related to the complaint and any additional corrective actions. Based on the findings task force findings:

- The Director, OACU will notify relevant external authorities (i.e., OLAW, USDA, AAALAC International) if the events are deemed reportable and/or to keep them informed; the Office of Communications and Public Liaison of any public relations concerns; and the Security and Emergency Response office for possible security concerns.
- The ARAC Ombuds will, in a timely fashion, submit a written report of all findings and actions to the DDIR; Director, OACU; the impacted IC SD(s); and the ARAC. The DDIR may choose to conduct further investigation(s) based on the original complaint and the ARAC Ombuds'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 any actions taken.

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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