

## **Guidelines for ACUC Oversight of Animal Activities in Shared and Central Facilities**

Oversight and monitoring of ongoing animal activities to ensure compliance with all regulations, policies and procedures is a priority for all NIH Animal Care and Use Committees (ACUC). Of utmost importance in this monitoring process is appropriate and timely action to address issues that potentially or actually impact the health or well-being of animals.

Because management practices supporting animals in shared or central facilities are under the purview of a lead Institute/Center (IC) and its ACUC, systems to address program monitoring must be established between the lead and user ICs and their ACUCs. [Per Policy Manual 3040-2: "Lead Institute - The user IC, which other user ICs authorize through an intra-agency agreement, to manage a Shared Animal Facility(ies)."]

This guideline outlines the processes for the monitoring of animal activities in shared and central facilities. The final responsibility for the research use of each animal is with the Principal Investigator and that IC ACUC.

Although the principal responsibility for monitoring animal activities in shared or central facilities lies with the lead IC, user ACUCs are required to monitor the activities of their IC's investigators within shared or central facilities. That function is typically delegated to the Animal Program Director (APD) of each IC. The APD, as an agent of their ACUC, takes an active role in monitoring to ensure that the animals' well-being is being provided for, and that actions taken by the Principal Investigators and associated IC investigative and technical staff are in compliance with procedures described in Animal Study Proposals (ASP)s associated with their studies. User IC APDs may further delegate that monitoring function to members of their staff. Monitoring will be performed through:

- physical visits,
- professional interactions, and/or
- review of reports and records.

In addition, two members of the user ACUC shall perform semiannual on-site assessments of their animals and associated animal activities in shared or central facilities, as noted in Policy Manual 3040-2, paragraph F.13.b.(1). These visits are NOT intended to be equivalent to the in-depth semiannual facility inspections to be performed by the IC managing the facility. The user IC visits should be limited to:

- assessment of IC animals,
- facility operations that directly affect those animals and
- procedure spaces used by IC investigators

Such assessment visits will be coordinated with the facility management of the shared or central facility.

Minor operational issues that arise may be handled informally by the user IC's veterinary or management staff. Observations affecting the ICs animals should be shared with facility

management and the lead IC ACUC. In the event corrective action(s) taken by the Shared or Central facility management are deemed incomplete or inadequate, the User IC ACUC and the Lead IC ACUC shall then meet and attempt resolution of the remaining disagreement(s). Only observations for which agreement could not be reached should be included in the IC's semiannual report.

Issues that potentially or actually impact the health or well-being of animals require ACUC investigation and reporting as outlined by the March 26, 2010 memorandum from the Deputy Director for Intramural Research, Communicating Animal Care and Use Concerns within the NIH Intramural Research Program. In those cases the following steps will be taken:

- The ACUC Chairs of the lead and user ICs will determine which ACUC will be the investigating ACUC. ACUCs are encouraged to use the [“Checklist for ACUC Incident Investigation”](#) as a resource in conducting and reporting the investigation.
  - When an investigation results from actions/inactions by the facility staff or as a result of a facility related event, the lead IC ACUC, ORS ACUC, or ORF will assume primary responsibility for the investigation and resolution of the issue.
  - When an investigation results from actions/inactions by an investigator or their staff, the PI's IC ACUC will assume primary responsibility for the investigation and resolution of the issue.
- The Office of Animal Care and Use will be informed as soon as possible of any pending investigation and will participate as necessary.
- The investigating ACUC, with the participation of member(s) from the directly involved ACUC(s), as appropriate, will conduct the investigation and prepare a report, describing:
  - the conclusions of the investigation,
  - recommendations made and adopted, and
  - corrective actions implemented.
- The investigating ACUC will share the draft report and discuss it with other involved ACUCs, prior to submitting a final version of the report to the involved ACUC(s) as well as to the Deputy Director for Intramural Research.

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