Guidelines for Communication Between User and Lead ACUCs, Oversight of Animal Study Proposal Activities, and Management in Animal Facilities

Definitions:

The following definitions are included in NIH Policy Manual Chapter 3040-2, Animal Care and Use in the Intramural Research Program(1). They are summarized here to ensure an understanding of this guideline:

1. **Animal Facility** - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.
    a. **Central Animal Facility (CAF)**: An animal facility managed by the Office of Research Services (ORS), Division of Veterinary Resources (DVR) and utilized by more than one Institute/Center (IC).
    b. **Shared Animal Facility (SAF)**: An animal facility shared by more than one IC and managed by a Lead IC. The Lead IC takes primary responsibility for at least animal care and husbandry
    c. **Satellite Facility (SF)**: Any building, room, area, enclosure, or other containment outside of a core animal facility or centrally designated or managed area in which animals are housed for more than 24 hours.
    d. **Study Area (SA)**: Any building, room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.
2. **Lead Institute, Center, or Office**: An IC authorized to manage a Central or Shared Animal Facility.

For the purpose of this guideline, the following definitions are also important. These are not included in NIH Policy Manual Chapter 3040-2:

1. **Core Facility:** A centralized, shared resource that provides access to instruments, technologies, services, as well as expert consultation and other services to researchers.
2. **Lead IC Animal Care and Use Committee (Lead-IC-ACUC)**: The ACUC of the lead institute, center or office.
3. **User IC Animal Care and Use Committee (User-IC-ACUC)**: The ACUC of the institute, center or office of animal users within an animal facility.

Background: Oversight and monitoring of ongoing Animal Study Proposal (ASP) activities to ensure compliance with all regulations, policies, and procedures is a priority for all NIH ACUCs. As part of this responsibility, it is critically important for each IC ACUC to monitor every facility for:

1. Management of facility and housing conditions.
2. Ensuring appropriate animal use and ASP compliance.
3. Enabling effective communication between the Lead-IC-ACUC and User-IC-ACUCs

Management of Facility and Housing Conditions:

Primary responsibility for standard operating procedures (SOPs) related to animal care and husbandry, training husbandry staff, and monitoring animal husbandry and care in animal facilities lies with the Lead-IC-ACUC. The Lead-IC-ACUC shall perform on-site assessments of the facility, its operation, facility practices, the care of animals housed within it, and their associated animal research activities in each facility. Monitoring shall be performed through physical visits at least semiannually. These physical visits

may include professional interactions, review of reports and records, assessment of animals, assessment of the animal facilities, and assessment of procedure and support spaces.

Ensuring Appropriate Animal Use and ASP Compliance:

Primary responsibility for monitoring research activities of investigators lies with that investigator's ACUC. As a result, both the Lead-IC-ACUC and User-IC-ACUC have some responsibility to ensure appropriate animal use and ASP compliance depending on the specific investigator and their animals.

For Lead-IC-ACUCs, this should be included in their semiannual physical visit described above. User-IC-ACUCs should perform their own semiannual physical visit. While focused on research activity, ASP compliance, and the health and care of their IC's animals, these visits may also include an assessment of the animal facilities and assessment of procedure and support spaces utilized by their investigators. Note that Lead-IC-ACUC and User-IC-ACUC visits can be consolidated into fewer visits if the User-IC-ACUC elects to designate the Lead-IC-ACUC members as qualified ad hoc inspectors.

Enabling Effective Communication Between the Lead-IC-ACUC and User-IC-ACUCs:

The Lead-IC-ACUC and User-IC-ACUCs must communicate effectively to ensure proper oversight of both the facility itself, and the health of animals housed there. The following points should be considered:

1. Semiannual physical visits should be coordinated in advance between the Lead-IC-ACUC or User-IC-ACUC and the facility management and veterinarian of the animal facility.
2. Minor deficiencies may be handled informally:
    a. Minor issues would include those that do not directly impact the health and well-being of the animals in any significant manner.
    b. Communications on minor issues affecting the IC's animals or housing conditions should be shared with animal facility management during the physical visit and/or the Lead-IC-ACUC as described in the IAA(2)/MOU/Work Order. Either the facility management or the Lead-IC-ACUC may quickly propose corrective action to remedy the situation.
    c. In the event a User-IC-ACUC deems the corrective action(s) taken by the lead IC animal facility's management incomplete or inadequate, the User-IC-ACUC and the Lead-IC-ACUC shall then meet and attempt resolution of the disagreement(s).
3. Significant deficiencies should be handled more formally:
    a. Issues considered to be "significant deficiencies" or reportable. These are issues that potentially or actually impact the health or well-being of animals. These must be promptly reported to the Director, Office of Animal Care and Use (OACU), or their delegate, to determine if reporting to OLAW, AAALAC International, or others is required as outlined in NIH Policy Manual Chapter 3040-2, "ACUC Responsibilities."
    b. The Lead-IC and User-IC should coordinate the reporting of any significant deficiencies or identified reportable issues in a CAF/SAF to determine which ACUC will report to OACU and to minimize duplication of reports or confusion about who is responsible for any corrective actions. It is recommended that significant deficiencies related to husbandry, the animal facility itself, or actions/inactions of the animal facility be reported by the Lead-IC-ACUC while any significant deficiencies resulting from the actions/inactions of an investigator or their staff or related to the specific research ASP should be reported by the User-IC-ACUC.
4. Investigations:
    a. When an animal welfare investigation results from actions/inactions by the facility staff or as a result of a facility related event, the Lead-IC-ACUC will assume primary responsibility for the investigation and resolution of the issue.

b. When an investigation results from actions/inactions by an investigator or their staff, the User-IC-ACUC will assume primary responsibility for the investigation and resolution of the issue.
c. In both situations, the responsible ACUC should include the issue on their semiannual report and track the investigation until resolution is completed.
d. As noted above, communication between the various ACUCs is important and should be maintained through any investigation.

In addition to Policy Manual 3040-2, ACUCs are encouraged to use the *ARAC Guidelines on Assessment and Reporting of Adverse Events, Unexpected Outcomes, and Animal Welfare Concerns*(3) as a resource in conducting and reporting the investigation.

References:

1. NIH Office of Animal Care and Use. 3040-2 - Animal Care and Use in the Intramural Research Program. In: Office of Management Assessment, editor. NIH Policy Manual2023.
2. NIH Office of Financial Management. 1165 - Agency Agreements. In: Office of Management Assessment, editor. NIH Policy Manual2021.
3. NIH Animal Research Advisory Committee. Guidelines for Assessment and Reporting of Adverse Events, Unexpected Outcomes, and Animal Welfare Concerns. NIH OACU2023.

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