

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

Purpose

This guideline outlines the processes for the communication between user and lead IC Animal Care and Use Committees (ACUCs), monitoring of ACUC Animal Study Proposal (ASP) driven activities in Shared Animal Facilities (SAF), Central Animal Facilities (CAF), Satellite Facilities, Study Areas, and Core Facilities, referred henceforth as “animal facilities” and the ACUC monitoring of these animal facilities. The final responsibility for the research use of each animal is with the Principal Investigator (PI) and their IC ACUC.

Background

Oversight and monitoring of ongoing ASP activities to ensure compliance with all regulations, policies and procedures is a priority for all NIH ACUCs. Monitoring of 1) animal use and study proposal compliance and 2) management of facility and housing conditions when animals are housed in animal facilities operated by another Institute/Center (IC) are both critically important to maintain compliance of the animal program.

Because management practices supporting animals in animal facilities are under the purview of a lead IC and its ACUC, systems to address program monitoring must be established between the lead and user ICs and their ACUCs via an Intra-Agency Agreement (IAA), Memorandum of Understanding (MOU), or other Lead IC arrangements.

Monitoring

Monitoring animal care in animal facilities lies with the lead IC, while monitoring activities of IC's investigators lies with the user's IC ACUCs. The user's IC ACUC shall perform on-site assessments of their animals and associated animal activities in animal facilities. Monitoring shall be performed through:

- physical visits (at least semiannually), and may include,
 - professional interactions, and/or
 - review of reports and records
 - assessment of IC animals
 - assessment of IC animal facilities
 - procedure spaces used by IC Investigators

Such assessment visits will be coordinated in advance with the facility management and veterinarian of the animal facility.

Lead ICs create, maintain, and approve animal facility Standard Operating Procedures (SOPs). In addition, lead ICs have mechanisms in place to train and monitor husbandry staff for technical proficiency. Unless otherwise specifying in an approved ASP, routine procedures (not surgical procedures) conducted by animal facility staff will follow the SOPs of the lead IC.

Reporting

Minor issues related to facility operations, veterinary care or technical support may be handled informally by the user IC's veterinary, management staff, or ACUC. Communications on observations

affecting the IC's animals or housing conditions should be shared with animal facility management and/or the lead IC ACUC as described in the IAA/MOU. In the event, a user IC ACUC deems the corrective action(s) taken by the animal facility's lead IC management are incomplete or inadequate, the user IC ACUC and the lead IC ACUC shall then meet and attempt resolution of the disagreement(s).

Issues considered to be "significant deficiencies" or reportable, i.e., that potentially or actually impact the health or well-being of animals, must be promptly reported to the Director, Office of Animal Care & Use (OACU) as described below. OLAW reportable events will be processed as outlined in PM 3040-2, "ACUC Responsibilities."

When an investigation results from actions/inactions by the facility staff or as a result of a facility related event, the lead IC ACUC and/or ORF will assume primary responsibility for the investigation and resolution of the issue. Facility related events in SAF/CAFs will be tracked by the lead IC ACUC, submitted on semi-annual report, and tracked until resolution is completed. In addition, lead IC management will communicate to the user IC ACUC with periodic status updates.

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 investigating ACUC will keep the other impacted ACUCs informed of the outcome of the investigation via direct communications and/or sharing copies of the draft and final summary memos.

In addition to PM 3040-2, ACUCs are encouraged to use the "[Checklist for ACUC Incident Investigation](#)" as a resource in conducting and reporting the investigation.

Definitions

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.
 - 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 USDA-regulated animal species are housed for more than 12 hours.
 - e. **Core Facility:** centralized shared resources that provide access to instruments, technologies, services, as well as expert consultation and other services to researchers.
2. **Lead Institute** - an IC authorized through an Intra-Agency Agreement (IAA) or Memorandum of Understanding (MOU) to manage a SAF/CAF. In addition to the requirements in [MC 1165 Agency Agreements](#), IAA/MOUs for SAF/CAFs will include the management plan/standard operating procedures of the facility, and the composition, structure, and function of the User's Committee.
3. **User's Committee**- a User's Committee will consist of representatives from each Institute chosen by each IC Scientific Director and a representative appointed by the Deputy Director for

Intramural Research. Each Institute should appoint, at a minimum, a veterinarian, a Senior Scientist, and a Senior Administrative Officer to the committee. In all cases, the personnel appointed must be authorized to represent the Institute on matters of finances, personnel, space, and other issues as they may arise. A quorum of the User's Committee shall be defined as a majority of the Committee and a majority of the User Institutes represented.

References

1. NIH Policy Manual 3040-2: [Animal Care and Use in the Intramural Program](#)
2. [PHS Policy on Humane Care and Use of Laboratory Animals](#)

Approved ARAC – 11/12/1997

Reapproved – 3/10/2004

Revised – 11/10/1998, 9/12/2001, 11/21/2002, 6/14/06, 02/13/08, 12/08/10, 12/11/2013, 1/25/2017, 10/23/2019, 12/14/2022