



**Duke University
Animal Care & Use Program
Policy**



**USE OF IACUC SUBCOMMITTEES FOR
ANIMAL PROGRAM INVESTIGATIONS**

PERFORMANCE STANDARD: Reviews conducted by IACUC Subcommittees shall be complete, orderly, and accurate.

BACKGROUND: When deemed necessary, the process of investigation and IACUC decision making must be above reproach

ROLES:

- The Compliance Liaison Associate (CA) will assemble information concerning the incident or issue for review by the IACUC. Issues may be brought forth to the IACUC from investigators and their staff, IACUC members, members of the Duke animal care and use community, or the general public.
- The Director, Office of Animal Welfare Assurance (OAWA) shall provide operational oversight and management of the CA and the compliance program, assure the IACUC receives reports or updates on items of concern, and provide training support as required to assure compliance.
- The IACUC Chair and Attending Veterinarian (AV) will be consulted for guidance on issues or concerns.
- The IACUC will determine when a formal investigation or review is required

PROTECTION POSTURES REQUIRED: N/A

POLICY EXPECTATIONS:

1. The Committee will determine which measures require Subcommittee investigation or review.
2. Members may volunteer for the Subcommittee, or will be appointed by the Chairman of the IACUC (or designee). The Chairman of the Subcommittee will be selected by the IACUC Chairman (or designee).
3. The IACUC Chairman (or designee) will notify the Institutional Official of the initiation of the investigation.

4. For investigations, the Subcommittee's Chair (or designee) will notify the Principal Investigator, animal facility administrator, or other responsible individual of the IACUC's intention to carry out the investigation through the Subcommittee process. This notification should include:
 - a. Citation of the section of the federal regulations which allow for investigations of concerns related to animal care and use.
 - b. Description of the complaint.
 - c. Request for information concerning the incident.
 - d. An invitation to meet with the Subcommittee to review the information.

5. The IACUC Subcommittee may use any legal method it deems necessary to obtain information to assist in the investigation. These may include, but is not limited to the following:
 - a. Unannounced visits to the laboratory or animal facility in question (review procedures, lab/facility documents, or talk with personnel);
 - b. Request documentation from the complainant, co-workers or employees, or from the animal facility staff where animals were housed. Such documentation could include: research records relating to animal experimentation, surgical records, animal health records, purchase orders, standard operating procedures, diagnostic laboratory reports, quality assurance reports, or others which will provide information which will assist in the investigation;
 - c. Request documentation for the individual who is allegedly at fault in the matter;
 - d. Review of Animal Care and Use Protocols, IACUC inspection reports, Reports of Programmatic Reviews, USDA or AAALAC inspection reports, or any other pertinent animal care & Use program record;
 - e. Solicit letters or documentation from individuals who are not directly affected by the allegation but who could provide insight into the issues under review (e.g., correspondence from veterinarians or facility personnel, other committees), or other individuals;
 - f. Review evaluation reports related to the complaint and performed by external reviewers chosen by the committee; or
 - g. Interview any other person who the Subcommittee believes can provide information concerning the investigation.

6. The Subcommittee will report its findings to the IACUC in either a regularly scheduled or a called meeting.

7. The IACUC will review and deliberate the Subcommittee's report and recommendation

- 8.** The IACUC may invite individuals involved in the complaint to directly address the Committee. Individuals may request audience with the Committee, but it is the decision of the IACUC whether the individual is invited to present argument verbally to the IACUC.
- 9.** At the conclusion of the IACUC's deliberation, the IACUC will vote upon the recommendation of the Subcommittee.
- 10.** Following IACUC determination of an outcome:
 - a.** The IACUC will notify the Institutional Official of its decision;
 - b.** The IACUC will notify in writing, the affected individual; and
 - c.** The IACUC will communicate its findings to the complainant. In most circumstances, the details of the investigation or details of the findings will not be conveyed to the complainant.
- 11.** The Subcommittee will file a final report with the IACUC for archival storage.
- 12.** Individuals having conflicts of interest with the concern or issue being discussed may remain in the room to answer questions during IACUC deliberation, but will depart the room prior to the final IACUC deliberation and vote. The same rules of conflict of interest will apply to this policy as all other IACUC policies and procedures.