



THE UNIVERSITY OF TOLEDO
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

SUBJECT: Non-Compliance Investigation Procedures

DATE: 03/13/2013 rev.

Non-Compliance Investigation Procedures

STATEMENT ON INVESTIGATING ALLEGATIONS OF NONCOMPLIANCE OF THE ANIMAL WELFARE ASSURANCE, PHS POLICY, CFR 9, OR THE UT ANIMAL CARE PROGRAM

The Institutional Animal Care and Use Committee (IACUC) of The University of Toledo (UT) has adopted the following guidelines for the investigation of allegations of noncompliance in the animal care program. Noncompliance includes animal use activities that go beyond the scope of an approved protocol or which have not received IACUC approval, as well as other activities that unnecessarily increase risks to animal subjects.

The use of live vertebrate animals is an important component of the Institution's research and teaching missions and the UT community is committed to conducting this use in a humane manner. The use of live vertebrate animals in research is a privilege, and carries with it the responsibility to follow applicable law, policies, and procedures developed by the federal government and the Institution. Noncompliance with the law, policies and procedures of a single individual can place this privilege at risk for the entire UT community. Consequently, the IACUC takes the position that the welfare of animal subjects has priority when there is a conflict between the welfare of animal subjects and the rights and interests of an individual.

Under the AWAR (9 CFR § 2.32 (c) (4), which states that "no facility employee, Committee member or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of regulations or standards under the act", the IACUC is obligated to protect the rights of any employee who has made allegations of impropriety.

General Principles

As the specific guidelines below indicate, to the maximum extent possible,

- Confidentiality will be maintained throughout the investigation. This will be achieved by:

(a) Restricting the dissemination of information about the allegation, the course of the investigation and its outcome, to the following individuals involved in the process: members of the IACUC, other appropriate UT officials, and individuals who may have information regarding the allegation. Should the allegation be found to have merit, it is possible that sponsoring agencies may also have to be notified.

(b) Good faith efforts to maintain the confidentiality of the identity of the Complainant, if requested. Although, due to the nature of the investigation, confidentiality cannot always be assured, whenever possible, the Complainant will be notified prior to the revelation of his or her identity.

- Initial investigations will be a collegial process. The responsible party, e.g., investigator, DLAR director, or supervisor, will be notified of any allegation that has been made. Both the individual reporting the concern and the responsible party will be requested to provide information relevant to the report. It is the obligation of the respondent(s) to cooperate with the committee during this process.
- If possible, the responsible party will be informed if and when their superiors are being made aware of the existence and nature of the allegations of impropriety and the course of any inquiry concerning them.
- Following completion of the investigation, the IACUC may take a variety of actions. Some of these are listed in the following section. It should be noted that under UT's Assurance to the U.S. Department of Health and Human Services, the IACUC has the authority to suspend or terminate on its own accord, any research activity involving animal subjects conducted by an investigator under UT auspices.

Specific Guidelines for Investigating Allegations of Noncompliance

The IACUC Chairperson will appoint a subcommittee consisting of the at least 2 IACUC members without conflict of interest. Typically, the subcommittee includes the IACUC Chairperson, the DLAR Veterinarian and at least one other IACUC member. The subcommittee will communicate with the principal investigator and/or other responsible parties and the individual(s) making the allegation and gather information relevant to the issue.

The subcommittee is authorized to require and institute immediate changes necessary to prevent further unnecessary animal suffering, to protect animal welfare and to preserve UT's regulatory compliance. These actions may include ordering a temporary cessation of activities involving the animals at risk, while maintaining normal appropriate husbandry. The subcommittee is not authorized to suspend the protocol.

If the investigator does not respond in a timely manner or refuses to address the subcommittee's concerns, after informing the responsible party, the subcommittee may inform the responsible party's superiors of the problem and may request their assistance in resolving the matter.

The subcommittee will report their findings together with their recommendations at a convened meeting of the full IACUC. The IACUC will determine whether or not the allegation has merit. It may also ask the subcommittee to continue its investigation and gather further information and report back to the full committee before final disposition.

If the full IACUC determines that an allegation is without merit and cannot be substantiated, the responsible party and any UT officials who have been informed of the allegation will be so notified in writing.

If the full IACUC determines that the allegation has merit and has been substantiated, the IACUC will require the responsible party to rectify the situation and the matter may be referred to the appropriate UT officials for further action.

The IACUC may take a variety of actions. These may include but are not limited to:

- in cases in which the protocol deviation is justifiable, requirement for the submission of a protocol amendment or new protocol depending on the nature or extent of the change,
 - issuance of written reminders of IACUC rules,
 - notification of direct superiors and other UT officials,
 - monitoring of an investigator's research activities involving animal subjects,
 - suspension or termination of such activities,
 - reporting to the Office of Laboratory Animal Welfare (see *UT IACUC Guidelines for Reporting Serious Noncompliance to OLAW*), USDA, or funding agency,
 - referral of the matter to the UT Misconduct Committee.
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If the responsible party wishes formally to contest this finding, he will be referred to the Institutional Official, who has been delegated the obligation of enforcing UT's regulations pertaining to the use of animal subjects in research, as stated in the DHHS approved Assurance of Compliance filed by UT.

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