

IACUC POLICIES, PROCEDURES, and GUIDELINES

Evaluation and Investigation of Alleged Noncompliance, Deviations, and Concerns

128.1 Overview

The Institutional Animal Care and Use Committee (IACUC) investigates reports of alleged noncompliance or concerns regarding animal care and use at the University of Kentucky in accord with the United States Department of Agriculture (USDA) Animal Welfare Regulations, the National Institutes of Health Guide for the Care and Use of Laboratory Animals, Public Health Service (PHS) policy, and the University's PHS Assurance. At the direction of the Vice President for Research (VPR), the Division of Laboratory Animal Resources (DLAR) staff reports all potential incidents of protocol deviation to the IACUC for investigation.

This policy outlines the IACUC's procedure for investigating concerns and alleged noncompliance including deviations. A standing Investigative Subcommittee (IS) is appointed by the IACUC chair to evaluate and investigate reports of alleged noncompliance (e.g., deviations) and concerns. In certain instances, the IACUC chair may conduct an investigation of any alleged noncompliance using an *ad hoc* committee instead of the investigative subcommittee. Examples of concerns that may require an *ad hoc* committee include but are not limited to high profile incidents or programmatic deficiencies.

The IS or the *ad hoc* committee is responsible for: evaluating concerns, alleged noncompliance, and deviations; assessing the validity of the allegation, concern or deviation; if necessary, conducting an investigation; if appropriate, developing a recommendation for corrective action; determining if additional investigation or review is needed by the convened IACUC; reporting findings and making recommendations to the convened IACUC.

The IACUC has the option to further review the IS or *ad hoc* committee's findings and recommendations and, if appropriate, may make the final determination regarding whether: 1) an incident involved noncompliance; 2) potential sanctions or corrective actions are needed; 3) incident should be reported to Institutional Official, appropriate regulatory and/or funding agencies.

128.2 Incident Reporting

Concerns or deviations submitted by DLAR veterinarians and animal care staff are sent directly to the IS in accord with IACUC established reporting procedure. These reports should include at minimum the date the incident occurred, a brief description of what occurred, the relevant protocol number, the Principal Investigator (PI) name, and contact information.

Concerns submitted by other individuals may be reported to any IACUC member, DLAR or Office of Research Integrity (ORI) staff member. The allegations may be submitted through several existing mechanisms (e.g. telephone, e-mail, etc). The report should at a

minimum include the date the incident was noticed or occurred and a brief description of the incident.

Upon receipt of a concern, the individual who receives the information summarizes the incident/concern and submits it to the IS following established report mechanisms (e.g. e-mail).

128.3 Investigative Subcommittee (IS) Composition and Review Procedures

The IACUC chair appoints a standing IS of three individuals, at least one of which should be a DLAR staff veterinarian. Membership on the IS is open to all IACUC voting members and alternates. Membership is staggered so that the IS is not entirely comprised of all new members at any given time. An IS chair is appointed to lead the group.

The IS chair can serve more than once during his/her three year term on the IACUC. The IS chair is responsible for reporting to the IACUC chair and the Attending Veterinarian (AV) the following: any incident that places the animals at immediate jeopardy or harm; or any concern that needs immediate action by the IACUC or DLAR.

If an IS member has a conflict of interest involving any aspect of a report, then he/she is responsible for disclosing the conflict; the member in conflict does not participate in the review. An IS member, who is not a DLAR staff veterinarian, alternates with the IS chair as lead investigator for each case.

The lead investigator or designee is responsible for notifying the Principal Investigator (PI) whose protocol is subject to the allegation and for soliciting his/her input. Also, if appropriate, the lead investigator or his/her designee may review pertinent records, observe animals, obtain additional information from the complainant, DLAR staff, and /or protocol study personnel. Based upon the inquiry, the lead investigator prepares a brief summary report including a set of recommendations for IACUC action. If a member's term on the IS is ending and he/she is a lead investigator for a case, the member completes the ongoing investigation.

Each IS member has the right to request additional information. The IS may conduct its reviews through face-to-face meetings or via electronic communication. The IS makes a determination regarding whether the entire IACUC needs to conduct further review of the incident or concern at a convened IACUC meeting using the criteria listed below.

128.4 IS Criteria for Determination

Convened IACUC Review and Discussion of Investigation Report Required-This criteria includes incidents which resulted or could have resulted in harm to an animal(s), or other serious, repeated violations or those identified by National Institutes of Health Office of Laboratory Animal Welfare (OLAW) or USDA as being reportable.

Convened IACUC Discussion of Report Not Recommended Unless Requested by IACUC Member-This criteria includes incidents involving a deviation but animals were not or would not have been harmed and/or procedural/administrative issues with minimal consequences to animal welfare.

128.5 Convened IACUC Review

If convened IACUC review of the report and detailed discussion is not required, then the IS review including the protocol number is listed on an agenda for a convened IACUC meeting. Any IACUC member may request a copy of the summary report and request that the concern be discussed at the meeting.

If the incident requires convened IACUC review and discussion, ORI staff includes the investigation report in the agenda for a convened meeting of the IACUC. The report may include IS recommendations for corrective action. The IS or designee presents the report to the IACUC at the convened meeting.

The IACUC reviews the IS reports following standard operating procedures. Any IACUC member with an actual or perceived conflict of interest discloses the conflict and does not participate in the review or vote.

The IACUC determines appropriate course of action (e.g. dismissal of concern; corrective action; suspension or termination of IACUC approval; recommendations for sanction to VPR).

In addition, the IACUC makes a determination whether the incident is reportable to federal regulatory or funding agencies using the criteria for reporting outlined by OLAW and USDA.

The IACUC notifies the PI in writing of any action taken by the convened IACUC.

128.6 Record Keeping

The IS records deliberations are provided to the ORI by the IS using a variety of mechanisms (e.g. e-mail). The convened IACUC review of alleged noncompliance or concerns are maintained by the ORI following standard operating procedures.

128.7 Reporting to Federal Agencies

If the IACUC determines that the concern is reportable as required by OLAW or USDA, the IACUC, through the VPR, and with input from the Attending Veterinarian, promptly reports the serious or continuing noncompliance, or serious deviations, or suspension in accord with the agency's reporting requirements.

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