Investigation of Reported Alleged Deviations from Approved Activities or Practices, and Other Deficiencies that May Affect Animal Welfare

128.1 Overview

The Institutional Animal Care and Use Committee (IACUC) investigates reports of alleged noncompliances and deficiencies that raise animal welfare concerns 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.

This policy outlines the IACUC’s procedure for evaluating and investigating animal welfare concerns and alleged noncompliances, including deviations from approved activities and practices, and other deficiencies.

The IACUC chair appoints a standing Investigative Subcommittee (IS) to evaluate and investigate specific reports of alleged noncompliances, animal welfare concerns, and other deficiencies. The IS is responsible for: assessing the validity of the allegation; if necessary, conducting an investigation and if appropriate developing a recommendation for corrective action; determining if additional investigation or review is needed by the convened IACUC; and reporting findings and making recommendations to the convened IACUC.

The IACUC chair may also choose to appoint an *ad hoc* investigative committee or designee for certain events, for example, high profile incidents or programmatic deficiencies. Upon receipt of an allegation or animal welfare concern, the IACUC chair, the *ad hoc* committee or designee conducts a preliminary assessment to determine if the allegation provides sufficient information to suggest that a violation has occurred. If the allegation is found to be sufficiently specific and credible, for allegations that could lead to corrective action the Principal Investigator (PI) is informed as soon as appropriate in light of the nature of the allegations. Unless the PI agrees that the violation has occurred and agrees to correct it, an investigation is conducted as described in this document. For the protection of all parties, relevant records or research related information may need to be secured.

The IACUC may review the findings and recommendations from the IS, IACUC Chair or *ad hoc* committee, and determines whether: 1) a noncompliance occurred; 2) further information is needed; 3) potential sanctions or corrective actions are needed; 4) the incident should be reported to Institutional Official, appropriate regulatory and/or funding agencies.

128.2 Incident Reporting
Concerns or incident reports 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 the event, the relevant IACUC protocol number, the Principal Investigator’s (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 an incident report, the individual who receives the information submits a summary of the incident 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 or more individuals, including at least one scientific member, the Attending Veterinarian (or a veterinarian designated by the AV), and one ORI staff member. Membership in the IS is open to all IACUC regular and alternate members. Membership is staggered so that the IS is never comprised of all new members. 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. 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) any incident that places animals at immediate jeopardy or harm, and any concerns deemed to require immediate action by the IACUC or the Attending Veterinarian.

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. A scientific IS member may also serve as the lead investigator on a case, and may serve as an alternate to the IS chair.

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. The PI is informed as soon as appropriate, depending on the nature of the allegation. When notifying the PI of the allegation, the lead investigator shall advise of the nature of the allegations and the focus of the review and shall inform the PI of the opportunity to provide comments and other relevant information in response to the allegation.

In conducting the review, the lead investigator or his/her designee considers all relevant evidence, which may include a review of pertinent records, observation of animals, consultation with inside or outside experts, and obtaining additional information from the complainant, animal care staff, and/or protocol study personnel. Based upon the
inquiry, the lead investigator prepares a brief report including a description of the evidence reviewed, a summary of the findings, and a set of recommendations for IACUC action.

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 determines whether the entire IACUC needs to review the incident further 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 criterion 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.

This criterion may also include infrastructure deficiencies based on their severity and the degree to which they jeopardized animal care and health.

**Convened IACUC Discussion of Report Not Required Unless Requested by IACUC Member**-This criterion 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, IACUC Chair, or *ad hoc* committee 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, IACUC Chair, or *ad hoc* committee recommendations for corrective action. The IS, IACUC Chair, or designee presents the report to the IACUC at the convened meeting.

The IACUC reviews the 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 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.

In the case of infrastructure deficiencies, if the IACUC decides that the deficiencies may present a threat to animal welfare or safety, they are classified as “significant” and reported to the appropriate university officials with a reasonable and specific plan, including dates, for their correction.

Minor infrastructure deficiencies, those that do not pose a direct threat to animal health or wellbeing, are documented with a proposed correction schedule in the inspection report.

In determining the correction schedule, the IACUC considers the severity of the deficiency, the potential of the deficiency to adversely affect animal health, either directly or indirectly, and the logistical issues involved in the correction of the minor infrastructural deficiency.

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

128.6 Record Keeping

The IS, IACUC Chair, or ad hoc committee records and deliberations are provided to the ORI using a variety of mechanisms (e.g. e-mail). The convened IACUC investigation reviews are maintained by the ORI following standard operating procedures.

128.7 Reporting to Federal Agencies

If the IACUC determines that the incident 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.

128.8 Follow-Up

The IACUC staff sends an official letter to the PI or appropriate individual with an investigation summary, the committee’s determination and the committee’s action. The committee’s action may include training requirements, documentation of specific activities, counseling, etc. These actions are to be completed by the established dates reflected on the letter. Any items not completed by the established dates are brought back to the IACUC for further consideration. A formal motion may be brought forth by the Chair to the committee for vote. This motion may include additional sanctions including the potential for protocol suspension.
Any failure to adhere to the approved plan to resolve a significant deficiency shall be reported to the appropriate regulatory authorities (USDA, PHS-OLAW, AAALAC).