

## **Background**

Indiana University recognizes that it is a privilege to use animals in research and instruction, and is committed to protecting the welfare of animals. The Institutional Animal Care and Use Committee (IACUC) and Laboratory Animal Resources (LAR) expect and anticipate that those who work with research animals at the university will share this commitment. Thus, any time an IU employee has concerns with respect to animal welfare, care, or the use of animals at the institution, they are encouraged to report the situation immediately. These concerns may include but are not limited to incidents of non-compliance with the *NRC Guide for the Care and Use of Laboratory Animals*, *the Animal Welfare Act and Regulations*, *PHS Policy*, BIACUC policies, or a specific protocol.

Issues of non-compliance may also be detected by the IACUC and LAR during regularly scheduled semi-annual facility inspections or routine facility visits.

## **Policy**

The IACUC and LAR have established a formal process and set of procedures for reporting and following up on concerns of IU personnel about any aspect of animal care or use at the University.

### *1. Reports to the IACUC, LAR, or University hotline*

Individuals may report their concerns by phone, in writing, or email to the IACUC administrator, IACUC co-chairs or LAR veterinarians [[contact](#)]. Concerns may also be reported to the University Anonymous Reporting Hotline at 888-236-7542 or online by going to [www.indiana.edu/~iuaudit](http://www.indiana.edu/~iuaudit) and clicking on "Anonymous Reporting Hotline." These concerns are then gathered by the Institutional Official (IO) and the auditor. In the case of animal related issues, the IACUC co-chairs and administrator are immediately notified.

### *2. Identification of animal welfare concerns during inspections*

Compliance issues identified during semiannual facility inspections are resolved by the academic unit or the Laboratory Animal Resources at the request of the IACUC or the IO.

### *3. Investigation of reports of noncompliance*

In response to a report of noncompliance under (1) above, the IACUC co-chairs will convene an IACUC subcommittee to investigate the reported concern. The subcommittee will include an IACUC co-chair, a LAR veterinarian, and another IACUC member. The subcommittee will investigate the concern or issue by carefully reviewing the existing protocol and amendments, interviewing the principle investigator (PI) and personnel involved with the specific animals and protocol, and conducting any additional interviews and/or reviewing any additional information needed to determine whether or not a violation has occurred. If the subcommittee determines that a violation has occurred, the subcommittee will assess the significance of the violation. In particular, the subcommittee

will consider whether the violation involves harm to or mistreatment of animals or personnel. If there is evidence of harm to or mistreatment of animals the attending veterinarian may temporarily suspend that specific use of those animals and attend to their medical needs. An emergency full IACUC meeting may be called if severe welfare concerns are identified that require immediate action.

After the subcommittee has completed its investigation, the co-chair will develop a report for the IACUC. The IACUC co-Chair also may contact NIH's Office of Laboratory Animal Welfare (OLAW), to notify the agency of the ongoing investigation.

The co-chair will present the subcommittee report of the violation to the full IACUC at the next meeting. IACUC members will discuss the report and decide upon recommendations to be sent forward from the full committee to the Institutional Official (IO). The co-chair will draft a letter to the IO describing its investigation and findings with respect to the violation, and its recommendations for appropriate responsive action. Recommended actions may include, but are not limited to, requiring more frequent laboratory inspections and/or monitoring, requiring additional training, removing approval of certain individuals to use animals under a specific protocol, or suspending or terminating the protocol.

The IO will make a written determination regarding appropriate sanctions in response to a finding that a violation has occurred. The IO determines what specific actions will be required in the event of a violation. The IO has the authority to terminate a protocol. The IO will provide copies of its written decision to the PI, the PI's Departmental Chair, the IACUC and others as appropriate. Notification also will be provided to external agencies as required by law, which may include but is not limited to OLAW, USDA, relevant granting agencies, and other local, State, or federal government agencies.

4. Protocol Suspensions

- All suspensions and terminations based on noncompliance shall be reported to the Office of Laboratory Animal Welfare (OLAW) at the NIH and the federal granting agencies. If regulated species are involved in the research, then the USDA also shall be notified. The reports shall include the reasons for the suspension and the corrective action(s) taken.
- All animals housed under a suspended protocol will be disposed of in accordance with the original protocol or transferred to a LAR holding protocol. The PI (and his or her staff) will not be allowed to continue the research with these animals during the period of the suspension.
- The PI will be liable for continued housing per diems as well as any additional animal care costs incurred as a result of the transfer.