



INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

Noncompliance Event Reporting

FULL POLICY

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Additional Detail
Web Address

Effective: November 2015

Last Updated:--

Responsible University Officer:

*Dr. Fred H. Cate, Institutional Official
Vice President for Research*

Policy Owner:

***Bloomington Institutional Animal Care and Use
Committee***

Policy Contact:

IACUC Manager

Policy Statement

Protocol noncompliance is the failure to follow terms and conditions of an approved protocol including, but not limited to:

- Housing animals in unapproved facilities;
- Beginning research projects without IACUC approval;
- Wrongful/abusive physical or psychological treatment of an animal;
- Involvement of personnel not listed in an approved protocol;
- Changing analgesics or anesthetics without approval;
- Not following experimental timelines;
- Conducting unapproved procedures.

According to the 8th edition of the *Guide*:

BLOOMINGTON INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Bloomington, IN 47408

(812) 855-5138

Safeguarding the animal welfare is the responsibility of every individual associated with the Program. The institution must develop methods for reporting and investigating animal welfare concerns, and employees should be aware of the importance of and mechanisms for reporting animal welfare concerns. In the United States, responsibility for review and investigation of these concerns rests with the IO and the IACUC.

Procedures

Investigating reports of possible noncompliance:

- The IACUC investigates all concerns regarding the care, treatment, and use of animals for research at the university. Reporting concerns can be accomplished through using the IACUC e-mail or by calling the IACUC Chair, the Attending Veterinarian or IACUC Manager. Additionally, an individual may report a concern anonymously by calling the IU Anonymous Reporting Hotline at 1-888-236-7542.
- In response to a report of noncompliance, the IACUC Chair or designee(s) will determine if further investigation is needed.
 - If needed, the IACUC Chair will consult with other members of the IACUC to determine if further action is needed.
 - If no further action is needed, the report of possible noncompliance will be placed on the agenda for the next convened meeting. This will provide an opportunity for all IACUC members to review the determination by the Chair.
 - If further action is needed, the Chair, or designee, will convene an IACUC subcommittee to investigate the reported concern.
 - The subcommittee may include the IACUC Manager, a LAR/C veterinarian, and other IACUC members.
 - The concern or issue will be investigated by carefully reviewing the existing protocol and amendments, interviewing the principal 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 it is determined that noncompliance has occurred, the significance of the noncompliance will be assessed. Consideration will be given to whether or not the noncompliance involves harm to or mistreatment of animals or personnel.
 - If the IACUC Chair or Attending Veterinarian temporarily halts an activity involving animals, the reason for doing so will be discussed at a special meeting or the next scheduled meeting of a quorum of IACUC members. The IO, in consultation with the IACUC, will review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to the NIH Office for Lab Animal Welfare (OLAW), USDA and AAALAC, if applicable.
- After the investigation has been completed, the Chair or designee will develop a report for the IACUC.

- The subcommittee will report the findings to the IACUC at the next meeting. IACUC members will discuss the report and based upon the subcommittee's recommendations, and in consultation with the IO, decide what action(s) to take. The recommendations 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 IACUC Manager, on behalf of the Chair, will communicate, in writing, the results of the IACUC evaluation of a reported concern to responsible individuals. The communication will contain:
 - a summary of the concern,
 - the findings of the investigation,
 - determinations of the IACUC, and
 - the recommended corrective actions/sanctions.
- The letter will also inform the responsible individuals of his/her option to appeal the decision in writing to the IACUC Chair, within 10 days of receipt of this letter. An appeal must contain details for the basis of the petition.
- Notification of the noncompliance will also be provided to external agencies, by the IO, as required by law, which may include but is not limited to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.
 - If regulated species are involved in the research, then the USDA also shall be notified.
 - If the noncompliance involves a Veteran's Administration PI (VA PI), the IACUC will follow the VHA handbook 1058.01 for reporting noncompliance. If the noncompliance involves a suspension, then the report shall include the reason(s) and the corrective action(s) taken. The PI (and his/her staff) will not be allowed to continue animal-related research during the period of the suspension. Animals will be transferred to the AV's holding protocol and the PI will be responsible for continued housing per diems as well as any additional animal care costs incurred as a result of the transfer.

Suspension of Activities:

- The IACUC may suspend any activity if determined that the activity is not being conducted in accordance with applicable provisions of *the Guide*, Act, or *NIH* Assurance Statement.
 - The IACUC may suspend an activity only at a convened meeting of a quorum and with the vote of suspension by a majority of the quorum present. This is based on requirements in the AWR and PHS policy.

- If the IACUC suspends an activity involving animals, the Committee will review the reasons for suspension, take appropriate corrective action at a special meeting or the next scheduled meeting of the IACUC and report that action with a full explanation to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.

At any point during an investigation of possible non-compliance, if the health and welfare of animals are of an immediate concern, then the Attending Veterinarian, IACUC Chair, IACUC Manager, or a designee, will be notified to assess the circumstances and then resolve the issues as soon as possible. The IACUC Chair and Attending Veterinarian have the authority to immediately halt research activities if the health and welfare of animals are a concern.

Note: Pursuant to the Animal Welfare Act, FCR 2.32 (c) (4): *No facility employee, committee member, or laboratory personnel shall be discriminated against or be subjected to any reprisal for reporting violations of any regulation or standards under the Act.*

Indiana University Whistleblower Policy:

<https://policies.iu.edu/policies/ua-04-whistleblower/index.html>

Contacts

<i>Subject</i>	<i>Contact</i>	<i>Phone</i>	<i>Email</i>
<i>Noncompliance</i>	Attending Veterinarian	812-855-2356	LAR@Indiana.edu
<i>Noncompliance</i>	IACUC Manager	812-855-5138	BIACUC@Indiana.edu

Web Address for this Policy

http://researchcompliance.iu.edu/iacuc/iub/biacuc_policies.html