

TITLE:	Protocol Noncompliance
Policy Number:	2014-022
Responsible Department:	Institutional Animal Care and Use Committee
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Approval Date:	9/15/14
Reviewed:	10/26/16; 7/12/17
Revised:	10/26/16 (Modified section on major violations); 7/12/17 (revised reporting procedures; added links to Whistleblower Policy and red Report button on IACUC website)
Legislation:	Animal Welfare Act (Title 9 CFR Subchapter A, Part 2, Subpart C, § 2.31(c)(4) and (6) and (d)(6)-(7))

Purpose of Policy: To ensure the humane care and use of animals used in teaching and research by requiring that investigators comply with all regulations and policies governing the use of animals in teaching or research.

Policy Information: WesternU adheres to the principle espoused in the current edition of the [Guide for the Care and Use of Laboratory Animals](#) that “using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being.”

The [Animal Welfare Act](#) cited above and Sec. IV.B.4., IV.B.8. and IV.C.6-7 of the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) gives the Institutional Animal Care and Use Committee (IACUC) the authority to review and investigate concerns involving the care and use of animals under the jurisdiction of WesternU, including reports of noncompliance, and, if warranted, suspend part or all of the activities in a previously approved protocol. They also require that suspension of an approved protocol involving Public Health Service-funded activities be reported to the Office of Laboratory Animal Welfare (OLAW) and that cases involving United States Department of Agriculture (USDA)-covered species be reported to the USDA.

Serious noncompliance may include, but is not limited to,

- conducting research or teaching with animals without an approved protocol;
- violation of the methodologies, procedures, numbers, and conditions of the approved protocol;
- violation of requirements of the Animal Welfare Regulations or Public Health Service Policy on Humane Care and Use of Laboratory Animals;

- continuing protocol activities with animals beyond the expiration date of the protocol;
- increasing the invasiveness of a procedure without prior IACUC approval;
- changing animal species without prior IACUC approval;
- disregarding instructions of an Attending Veterinarian (AV);
- conduct of procedures by untrained or improperly trained personnel;
- housing animals in facilities not approved by the IACUC for such use;
- failure to provide adequate post-operative monitoring of animals;
- failure to provide adequate husbandry or veterinary care which seriously affects animal health or well-being;
- violation of WesternU IACUC policies or procedures.

Minor Violations: All protocol errors, regardless of magnitude, must be promptly reported to the IACUC. However, this policy addresses serious noncompliance issues, not small, inadvertent or isolated errors that do not attempt to circumvent appropriate requirements and regulations. Investigators are encouraged to immediately correct such simple and minor errors when they first become aware of them. Nevertheless, the IACUC reserves the right to determine if investigation and corrective actions are warranted. All reported violations or allegations of violations shall be reviewed and resolved at a convened meeting of the IACUC.

Major Violations: A known or suspected case of serious noncompliance shall immediately be brought to the attention of the IACUC Chair, the AV, the Director of Animal Resources or the Vice President for Research and Biotechnology, who is also the Institutional Official. The authority first notified shall inform the other three. Suspected cases may be reported via the IACUC's [Whistleblower Policy No. 2014-007](#) which provides mechanisms for anonymous reporting, such as the red [Report button](#) on the IACUC's website, and protects whistleblowers from reprisals. If the person filing the report identifies themselves in the report, every effort shall be made to protect their identity but absolute anonymity cannot be guaranteed. Every complaint shall be taken seriously and reviewed by the IACUC. In all cases, the IACUC shall use its judgment on whether or not the complaint is of sufficient substance to proceed further.

If a case of possible noncompliance presents a potential immediate risk to animal health or well-being, the AV shall be contacted immediately to assess the situation and take appropriate actions; these may include, but are not limited to, suspension of activities and confiscation of animals. The AV shall keep the IACUC informed about the situation as it develops.

Upon receipt of a report of possible serious noncompliance, the IACUC Chair shall inform all those involved, including the principal investigator (PI) and the Institutional Official (IO), that an instance of noncompliance has been alleged. The Chair shall invite the PI to respond to the allegations and, upon receipt of a response, shall bring the matter to a convened meeting of the IACUC. The IACUC Chair may, at his or her discretion, designate an individual or subcommittee to investigate allegations of mistreatment or noncompliance. Results of the investigation shall be documented and the IACUC shall inform all parties involved, in writing, of its findings and of the corrective actions and sanctions it has authorized. However, the IACUC reserves the privilege to keep committee discussions confidential. The PI has the right to ask the IACUC to reconsider its decisions.

In the event that the IACUC chooses to suspend some or all activities under the PI's protocol, the PI may resume the activities only after receiving written re-authorization from the IACUC.

The IO may choose to conduct an independent investigation and to take corrective actions or impose sanctions in addition to those taken by the IACUC. However, the IO may not weaken in any way the corrective action taken by the IACUC. The IO shall provide written notice of his determinations to the IACUC and to the PI. The IO's decisions are not subject to appeal.

If the activity is supported by PHS funds, the IACUC, through the IO, shall file a full report to the Office of Laboratory Animal Welfare.

Related Policies: IACUC Policy No. 2014-007, Whistleblower Policy; Policy No.2014-010, Adverse Event Reporting; Policy No. 2014-034, Mistreatment of Animals