



Institutional Animal Care & Use Noncompliance Policy

Purpose:

Montana State University's (MSU) Institutional Animal Care and Use Committee (IACUC) ensures that animals used for research, teaching, training, or testing are treated humanely and that research is performed with the highest scientific and ethical standards. This policy establishes guidelines to address instances of regulatory or policy noncompliance by individuals engaged in the care or use of animals used for research, testing, training, or teaching. This policy is intended to address compliance issues that in the determination of the IACUC and in some instances, the Institutional Official (IO), go beyond a minor oversight.

Research and Activity Requiring IACUC Oversight

Federal laws and regulations require that all research, teaching, training, or testing involving live vertebrate animals have oversight by MSU's IACUC. These animal related activities are subject to oversight by the United States Department of Agriculture (USDA) and the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and must meet the standards set forth by the USDA *Animal Welfare Act and Animal Welfare Regulations* and the NIH *Guide for the Care and Use of Laboratory Animals*.

Reporting Suspected Noncompliance

MSU is committed to operating with integrity and in full compliance with all university policies and federal regulations. Suspected noncompliance violations may be reported by Principal Investigators (PI), laboratory staff, support staff, or the general public. MSU provides a number of avenues to individuals reporting a suspected noncompliance violation involving animal related activities. The phone numbers of contact persons including the IACUC Chair, Attending Veterinarian, and Director of the Office of Research Compliance (ORC) are posted in all animal facilities. Also, MSU has selected a private contractor, [EthicsPoint](http://EthicsPoint.com), 855-753-0486, to provide an independent avenue for confidential reporting of a suspected noncompliance violation. All concerns will be treated as suspected noncompliance when initially reported, treated as confidential to protect all parties involved, and will be investigated promptly. MSU will not tolerate retaliation against individuals who report suspected noncompliance violations in good faith.

Examples of Noncompliance

Noncompliance with university policies or federal regulations can be classified as serious or moderate. Serious violations are the result of willful or malicious incidents relative to animal welfare, federal regulations, or violations that pose a real or potential threat to the health and welfare of animals. Moderate violations include instances where university policies are unclear, and which do not pose a threat to the health or welfare of animals.

Examples of violations include:

- Conduct animal-related activities without appropriate IACUC review and approval;
- Conditions that jeopardize the health or welfare of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- Failure to adhere to the standards set forth by the *USDA Animal Welfare Act and Animal Welfare Regulation* and the *NIH Guide for the Care and Use of Laboratory Animals*.

Investigation of Suspected Noncompliance

MSU will use the highest standards to investigate suspected noncompliance. Reported suspected noncompliance must be reported to the IACUC Chair and the ORC Director who will promptly initiate an investigation to gather facts to allow determination of the nature and extent of the concern, whether the issue presents a potential immediate animal health or welfare risk, and if the concern involves noncompliance with university policy or federal regulations. The involved individual(s) will be informed of the noncompliance investigation that is being conducted. If the IACUC Chair, in consultation with the ORC Director, concludes that the noncompliance is serious or complex, a subcommittee may be appointed to conduct the investigation. The following considerations are evaluated during the investigation of the suspected noncompliance:

- Whether the reported actions resulted in jeopardizing the health or welfare of animals;
- Whether the animal-related activities were conducted without appropriate IACUC review and approval;
- Whether the reported violations constitute serious or continuing noncompliance with university policies or federal regulations.

When the investigation deems that noncompliance has occurred with university policies or federal regulations, or that there is a past, present, or future threat to the health and well-being of animals, the noncompliance investigator(s) will provide a report to the IACUC, ORC Director, and the IO. The report shall include:

- A description of the noncompliance violation and whether the violation resulted in any adverse events.
- A summary of the records and evidence reviewed during the investigation.
- Identification of university policies or federal violations under which noncompliance occurred.
- Corrective actions that should be implemented to avoid noncompliance in the future and an appropriate date by which the corrective actions will be implemented.

Formal Determination of Noncompliance

When determination that a violation of university policy or federal regulation has occurred, the IACUC Chair will notify the involved individual(s) in writing of the noncompliance violation and corrective actions. In cases where the noncompliance is ongoing and presents risk to the health or well-being of the animal(s), the IACUC can suspend the research activity. If corrective actions are required, a timeline will be established in which the individual(s) must implement corrective actions. The individual(s) will have the opportunity to work with the IACUC, the AV, and the ORC Director to modify the corrective actions if deemed appropriate by the IACUC. The Office of the

Provost and the PI's Department Head, College Dean, and the Office of Sponsored Programs may be notified of the noncompliance violation.

Examples of Corrective Actions After Determination of Noncompliance

Most moderate noncompliance violations that are not a result of willful or malicious intent and that do not pose a threat to animal health or welfare or violate federal regulations can be resolved administratively. For serious noncompliance violations, the IACUC may mandate remedial corrective actions. Such corrective actions may include, but are not limited to:

- Requiring specific training or retraining of the individuals involved in the proper care and use of animals;
- Additional monitoring by the IACUC, AV, or animal care staff of the animal-related activities that pertain to the noncompliance violation;
- Requiring submission and approval of a IACUC protocol or a modification to an already approved IACUC protocol prior to continuation of the research for which noncompliance was reported;
- Restricting or limiting the scope of activities in which the individual(s) may engage;
- Suspending approval or terminating an approved IACUC protocol.

If any animal-related noncompliance is identified associated with an activity supported by the Public Health Service (PHS), the IACUC, through the IO, must promptly notify OLAW and the PHS funding agency, per PHS Policy, IV.F.3. Reporting guidelines can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.