1. Purpose

The Institutional Animal Care & Use Committee (IACUC) is required to provide ongoing oversight of animal activities conducted at Montana State University in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act and Animal Welfare Regulations.

1. Scope

The IACUC, in conjunction with the Office of Research Compliance, is responsible for reviewing concerns that involve the care and use of animals at MSU.

1. Definitions

Respondent: the person against whom an allegation is directed or who is the subject of an animal welfare or noncompliance proceeding.

Complainant: the person who initiates a formal animal welfare or noncompliance complaint.

Serious noncompliance: Serious noncompliance is any noncompliant event that has a negative impact on the welfare of an animal and/or human, and/or is in direct conflict with federal standards governing animal activities or university policies.

1. Allegations and Reports

Individual allegations and reports submitted to the IACUC for investigation through, for example, the Animal Care and Use Concern Form, Ethics Point, the Attending Veterinarian (AV), or the IACUC Chair, are routed to the Office of Research Compliance (ORC). The ORC and IACUC Chair, in consultation with relevant subject matter experts, will determine if an allegation is credible and meets the definition of serious noncompliance.

The IACUC Chair, ORC Director, and or the AV will take immediate action to ensure the welfare of any animal or human associated with the allegation. This action may include the immediate suspension of animal activities and or an individual’s ability to conduct animal activities until, at minimum, an investigation is conducted.

1. An inquiry process is initiated if:
	* + 1. The allegation was made in good faith
			2. The alleged conduct affects animal welfare and or meets the definition of serious noncompliance
			3. The allegation is sufficiently credible and specific to identify potential animal welfare issues and/or evidence of noncompliance.
2. If an inquiry is unwarranted, a summary of the findings and rationale is communicated to the IACUC.
3. Inquiry Process Animal Welfare Allegations and Concern

The purpose of the inquiry is not to reach a conclusion about whether animal welfare issues and or noncompliance occurred or who was responsible but is a process of gathering information and initial fact-finding to determine whether an allegation or animal welfare issue warrants an investigation. An investigation is warranted if (1) a reasonable basis for concluding that the allegation affects animal welfare and (2) preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The IACUC Chair may appoint a subcommittee to conduct the initial assessment of an allegation or Animal Welfare Concern. Members with direct involvement or conflict of interest with the reported incident will not be appointed.

1. Notification of Respondent

The IACUC Chair will inform the respondent that an allegation of animal welfare concern has been made against them, provide the respondent with a written summary of the allegation, and explain the investigation process for addressing the allegation. The IACUC Chair will make reasonable efforts to notify the respondent of the allegation in a face-to-face meeting, which generally will be attended by a representative of the dean’s office.

1. Investigation of Suspected Animal Welfare Concerns

If an investigation is warranted, the ORC and the IACUC Chair will investigate the concern and or appoint an IACUC subcommittee as an investigation team and an investigation team lead, as appropriate; members with direct involvement or conflict of interest with the reported incident will not be appointed

1. The investigation will include reviewing the initial concern documentation, interviewing involved personnel, observing the animals, housing and experimental environment, reviewing any pertinent records with appropriate subject matter experts, as applicable to the reported concern.
2. An investigation report will be prepared and submitted with findings and recommended corrective/preventative actions to the IACUC Chair. Recommended corrective/preventative actions will apply only operational processes and procedures. Personnel-related corrective action will not be captured through this procedure. In this case, Human Resources and or Legal Counsel will be contacted by the ORC Director. Upon acceptance of the investigation report, the IACUC Chair will review the report and recommended actions with the IACUC at a convened meeting. The report is finalized through a motion and a vote of a quorum.

When the investigation deems that animal welfare has been affected and or noncompliance has occurred with university policies or federal regulations, the report shall include:

1. A summary of the records and evidence reviewed during the investigation.
2. Identification of university policies or federal violations under which noncompliance occurred
3. A description of the noncompliance violation and whether the violation resulted in any adverse events.
4. Corrective actions that should be implemented to avoid animal welfare issues and or noncompliance in the future and a reasonable date by which the corrective actions will be implemented.
5. Formal Determination of Noncompliance Notification

When the IACUC determines that a violation of university policies or federal regulations has occurred, the IACUC Chair will notify the involved individual(s) in writing of the noncompliance violation and the corrective actions. In cases where the noncompliance is ongoing and represents an animal welfare or safety issue, the IACUC can suspend the research activity. If corrective actions are required, the individual(s) will have a timeline to implement the corrective actions. The individual(s) will have the opportunity to work with the IACUC and the IACUC Chair to modify the corrective actions if deemed appropriate by the IACUC. The Institutional Official, 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.

1. Reporting Noncompliance

ORC will provide a full explanation of the circumstance and actions to OLAW, USDA, and AAALAC as applicable.