MONTCLAIR
STATE UNIVERSITY

IACUC Policy on Reporting and Investigating Animal Welfare Concerns

Institutional Animal Care and Use Committee		**<u>Original Date</u>:** **12/17/2015** **<u>Minor Revisions</u>:** **April 2020** **May 2025**
Research Integrity and Compliance		
Approved by: **IACUC committee**	**Date:** **4/27/16** **4/29/20** **5/28/25**	
Approved by: **IACUC Office**	**Date:** **4/29/20** **5/28/25**	

I. Policy Statement and Scope

This document provides assistance to the Institutional Animal Care and Use Committee (IACUC) in responding to concerns raised regarding the care and use of laboratory animals used at the University or any facility that houses University-owned animals. The concerns may be raised by any University employee, student or member of the public. This guideline applies to all animal studies performed at the University.

II. Retaliation and Confidentiality

No employee within the University may intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any privacy right granted by this Policy. The IACUC process includes mechanisms for remaining anonymous, compliance with applicable whistleblower policies, nondiscrimination against the concerned/reporting party and protection from reprisals. The University may not require individuals to waive their privacy rights as a condition of any investigation. The University expects that reports will be made in good faith to address legitimate issues or concerns. In compliance with New Jersey's Conscientious Employee Protection Act (CEPA),or "Whistleblower Act"[1a], Montclair State will not retaliate against anyone for reporting or inquiring in good faith about potential policy breaches or for seeking guidance on how to handle suspected breaches. The Animal Welfare Act provides that, "No facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards under the Act." (9 CFR § 2.32(c)(4)[2a]).

III. Definitions

Animal - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

Animal Facility - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

IACUC – Montclair State University Institutional Animal Care and Use Committee[3]

Guide - Guide for the Care and Use of Laboratory Animals (8th edition)[4]

IV. Responsibilities

Institutional Official (IO) - The IO is the individual within the institution having the administrative and operational authority to commit institutional resources to ensure that the animal care and use program complies with requirements set forth in guidelines, policies and regulations. The IO is authorized to legally commit on behalf of the University with regards to the Animal Welfare Act and Regulations.

Principal Investigator (PI) - PI's are responsible for ensuring their studies remain in compliance with the approved protocols, policies and guidelines, as well as ensuring that their students and staff performing the studies are trained, capable and approved on the protocol.

IACUC Chair - The Chair works with the IACUC to oversee and evaluate the animal care and use program on an on-going basis. The Chair works with the Attending Veterinarian (AV) in making a determination of the legitimacy of the animal welfare concern as well as the appropriate dissemination of information.

Attending Veterinarian (AV) - The AV is given authority and responsibilities by the Animal Welfare Act and Regulations that integrate with IACUC functions and include authority to prevent, control, diagnose, and treat diseases and injuries, up to and including euthanasia.

V. Regulatory Background

In compliance with the Animal Welfare Act (9 CFR, Part 2, Subpart C, Section 2.31(c)(4)[2b]) the IACUC is required to "review and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees". Furthermore, in compliance with the Guide[4], "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". The IACUC and the IO are responsible for ensuring that all laboratory animals involved in research and testing at the University are treated and used humanely, in accordance with:

- The highest ethical standards
- The spirit and intent of all Federal and State laws and regulations governing animal welfare
- The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)[5]
- The Guide for the Care and Use of Laboratory Animals (Guide[4]).

VI. Procedures

The University expects that employees and non-employees doing business on its behalf, and who have a reasonable, good-faith belief that a workplace action or omission is unethical or in violation of University policy, values or standards, or applicable law, will promptly report such actions or omissions.

A. Reporting Concerns:

1. Employees and students are encouraged to first bring concerns or reports of potential noncompliance to the attention of their immediate supervisor, to the PI of the study, or to a veterinarian to resolve the concerns at the time of the event and with the individuals at a local level.

   If an employee or student is, for any reason, uncomfortable reporting the concern to his/her supervisor or institutional contact, or if such supervisor or institutional contact is the source of the concern, then the employee or student should address their concerns to a higher level of institutional management, to Human Resources, to RIC staff, to the General Counsel, or to the University Hotline.

   In the event concerns or reports can be resolved by direct communication through a supervisor or Principal Investigator (PI), the matter would not be escalated to the IACUC. However, if discussing the issue with their supervisor or the PI is not satisfactory, the employee may bring the concern or report of noncompliance to the attention of any IACUC member.

   Field Studies

   If a field animal experiences pain or distress requiring immediate attention, the PI should be promptly notified. The PI may optionally contact the Attending Veterinarian.

   Animals (on site) – Satellite facilities

   In cases where an animal experiences pain or distress requiring immediate attention, the PI and the Attending Veterinarian should be promptly notified. If this is not possible and depending upon the condition of the animal, the PI is authorized to take immediate action to alleviate pain and distress for animals, up to and including euthanasia.

   Animals (on site) - Vivarium

   In cases where an animal experiences pain or distress requiring immediate attention, the PI and the Attending Veterinarian, and Vivarium Director should be promptly notified. If the PI is not available, the Attending Veterinarian should be notified.

   If it is not possible to connect with the A/V or backup A/V and depending upon the condition of the animal, the Vivarium Director is authorized to take immediate action to alleviate pain and distress for vivarium animals, up to and including euthanasia.The Vivarium DirectorDirecor must report this to the A/V and IACUC immediately.

2. To facilitate communication, the names and phone numbers of contact persons, including IACUC Chair, Attending Veterinarian, and RIC staff must be posted in animal housing and procedural areas as well as on the IACUC website.

Reporting Animal Welfare Concerns posters (see Appendix A) are required to be posted in all animal facilities. Any University employee, student or member of the public who has animal welfare concerns regarding University In-vivo research is encouraged to do one of the following:

a. Scan the QR code on the poster to access the Reporting a Concern page of the IACUC website[3b] and submit the online form or print the Word document version of the form.
b. Report their concerns directly to the IACUC chairperson or any member of the IACUC via campus mail, e-mail,, in person or by telephone to the IACUC Office.
c. Additionally, animal welfare concerns may also channel through the following groups to the IACUC: the Research Integrity and Compliance Office (RIC), the IO, General Counsel, Human Resources, or the University Hotline.
d.

Note: If you, as the person filing the form, wish to be informed of the actions taken in response to the report, please include your contact information on the form. Otherwise, as stated earlier, you may remain anonymous. In all cases, your concern will be handled confidentially to the extent reasonably possible.

2. B. Review and Investigation of Concerns:

The responsibility for review and investigation of animal welfare concerns rests with the IACUC. The following procedure should be used to communicate concerns to the IACUC:

1. **IACUC Review:**
   Upon receipt of a concern, the informed individual shall immediately advise the IACUC Chair. The IACUC Chair, in consultation with the Attending Veterinarian, will review the concern and determine the legitimacy of the concern. If the concern is deemed legitimate, the IACUC Chair will inform the IACUC and the IO. Depending upon the significance of the incident, an IACUC investigation may occur and Human Resources and General Counsel may also be informed.

2. **IACUC Investigation:**

The IACUC will convene and review the concern to determine a course of action. If further investigation is warranted, the Chair will appoint an ad hoc committee consisting of at least two (2) IACUC members to investigate the concern. None of the ad hoc committee members should have a conflict of interest with the concern. The ad hoc committee will address the concern in a timely manner. The investigation should ensure compliance with all applicable federal and state laws and regulations, the standards of the Guide, and University animal welfare guidelines and policies. The IACUC may also engage additional non-committee members (RIC staff, veterinarians or Human Resources) to assist with the investigation.

The ad hoc committee's responsibility is to investigate and summarize their findings to the IACUC for review. The summary should include the issues and the results of the investigation.

3. **IACUC Investigation Response:**

   The IACUC reviews the summary and if warranted, develops a plan for corrective actions.

C. Corrective Actions:

1. **Major Animal Welfare Issues**

   Issues or concerns are deemed major if they pose a threat to the health, safety or wellbeing of animals. If the IACUC determines that the reported concern represents major or continuing noncompliance with federal or state regulations and/or IACUC policies or guidelines it may take one or more of the following actions:

   i. The AV or their designee will address the immediate health and wellbeing of the animals. If time permits, the PI and Chairperson should be consulted on the situation.

   ii. IACUC-mandated corrective action plans (e.g. education, retraining, additional monitoring and/or reporting, and protocol amendment(s), etc.) should remedy the current concern as well as prevent future recurrences of similar concerns.*

   iii. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Institutional Official, in conjunction with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and [for regulated

species] report that action with a full explanation to APHIS and any Federal agency funding that activity (if applicable).

iv. Communications may involve the PI's management on the IACUC's investigation and actions.

2. Minor Animal Welfare Issues

Issues or concerns are deemed minor if they do not immediately/directly affect the health, safety or well-being of animals. If the IACUC determines that the reported problem represents a minor noncompliance with federal or state regulations and/or IACUC policies or guidelines it may take one or more of the following actions:

i. Elect to make corrective action only.

ii. Communicate the concern to the PI and require the PI to provide a corrective action plan to the IACUC in a specified timeframe. Action plan(s) can include education, retraining, additional monitoring and/or reporting, formal communication (such as warning letter or memo) and protocol amendment(s).

iii. Communications may involve the PI's management on the IACUC's investigation and actions.

D. Follow-up Reporting

Any welfare issue, whether major or minor, that is reported to the IACUC, as well as any reports and updates related to the investigation should be submitted to the IO. All investigations shall be fully documented by the IACUC and such records shall be retained in confidential files in accordance with the requirements of the Federal Animal Welfare Act.

The IACUC is to report its finding(s) to the concerned individual(s), unless such concerns were brought forth anonymously. If the concern was received from outside of the University, senior management or the IO shall communicate with those individuals who expressed the concern, to advise them that the matter is being investigated or that it has been resolved. All such communications shall be reviewed and approved by General Counsel.

*If the violation results in the disciplinary action of a bargaining unit employee, bargaining unit procedures will be followed.

VII. References and website addresses

1. New Jersey's Conscientious Employee Protection Act (or "Whistleblower Act") N.J. Stat. § 34:19-1
    a. https://www.nj.gov/oag/cepa/pdfs/nj-cepa-poster.pdf

2. Animal Welfare Act and Regulations
    a. 9 CFR § 2.32 - Personnel Qualifications https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A/part-2/subpart-C/section-2.32
    b. 9 CFR, Part 2, Subpart C, Section 2.31 IACUC https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A/part-2/subpart-C/section-2.31

3. Montclair State University Institutional Animal Care and Use Committee
    a. https://www.montclair.edu/iacuc/
    b. https://www.montclair.edu/iacuc/reporting-a-concern/

4. Guide for the Care and Use of Laboratory Animals, 8th edition National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Washington (DC): National Academies Press (US); 2011
    a. https://olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf

5. The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) https://olaw.nih.gov/policies-laws/phs-policy.htm

Appendix A - Reporting a Concern Poster

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Reporting Animal Welfare Concerns

In compliance with Federal requirements and Montclair State University IACUC animal welfare policy, any employee or member of the public who has a concern involving the care, use or welfare of animals at this institution may have their concerns investigated. No person making such a report will be discriminated against or suffer reprisals or retaliation.

To report a concern you may submit information at this site:

http://www.montclair.edu/iacuc/reporting-a-concern/
or via phone
973-655-7781

Should you wish to remain anonymous, simply leave your name and contact information off the form linked above. If you decide to remain anonymous, please ensure that your concern is well detailed as the investigation team will be unable to reach out to you if they have any questions. The above link provides for reporting over the Internet, you can submit a report from your home, a neighbor's computer, or even the library as well as your workstation.

If you are uncertain about whether an incident or activity should be reported, please report it!