Policy for Reporting Noncompliance and/or Adverse Events

Background

The University of Rochester is strongly committed to the highest standard of animal care and compliance with all applicable regulations, policies and guidelines. Any concerns about animal care and use and/or adverse events can be reported to the University Committee on Animal Resources (UCAR) office directly, in writing using the Animal Concerns or Non-compliant Report Form (drop boxes are outside the UCAR offices), by phone: **anonymously** via the URMC Integrity Hotline at (585) 756-8888; UCAR Hotline at (585) 275-2055; Animal Resource Office at (585) 275-2651 or UCAR Office at (585) 275-1693. Reports may also be made through other academic integrity oversight offices as well, who may report the incident to UCAR. As per federal regulations, no University employee or student will be discriminated against, or be subject to any reprisal for reporting noncompliance.

Definitions

Animal use areas – All areas where animal are used including vivaria, satellite facilities, procedure rooms, lab and holding areas

Noncompliance – examples are in Supplemental Information (*C 3) below*. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Adverse Event - An adverse event is defined as an event, usually unanticipated, that impacts the welfare of an animal, leading to pain/distress, morbidity, and/or death of the animal. An adverse event may also have an impact on personnel health and safety.

If you observe or have knowledge of activities that you believe constitute inappropriate animal care and use, you are encouraged to report these activities so that they can be investigated.

1. Animal welfare concerns or non-compliance and/or adverse events, may be handled in one of three ways:

   a. If an **emergency situation exists**, contact the University Attending Veterinarian or designee immediately. Call the Division of Comparative Medicine (DCM) (585) 275-2651 or (585) 275- 2653. If after hours, voice mail (X5-2651) will provide emergency contact information or a message may be left. Emergency contact information is posted in each animal facility. An attempt will be made by the DCM veterinarian to contact the principal investigator (PI) prior to any action being taken. The DCM veterinarian will take any necessary action in the best interest of the animal and report to UCAR (Chair, Vice-Chair and/or Research and Training Coordinator (RTC).

   b. If the situation is not an emergency, the concern or complaint may be submitted to the UCAR office, the UCAR Chairperson, the RTC, DCM veterinary staff or the Institutional Official (IO). Contact information is posted in all animal facilities, satellites and laboratory areas ***and the UCAR website (www.urmc.rochester.edu/ucar)***.

   c. Less urgent matters can be reported via the Animal Concerns or Non-compliance Report Form. Providing a name on this form is optional. At any time, UCAR members or staff, DCM veterinarians and Vivarium supervisors can be approached with any concerns

regarding animal welfare. Written animal welfare concerns can be placed in drop boxes which are located outside the UCAR office and the Research and Training Coordinator's office.

2. Upon receipt of the reported concern, the UCAR Chair, Research and Training Coordinator and/or Designee will lead the investigation, to gather as much information as possible to inform the Committee of the relevant details. The UCAR Chair, will, at her or his discretion, involve a subcommittee of the Committee in the collection and review of the information. The initial report will ideally contain a description of the incident, including the species and the number of animals, potential infractions, corrective actions that were implemented or are in progress, and any follow up actions that may be required. This process may include consultation with the Principle Investigator (PI) and the research staff, members of the Veterinary staff, animal care staff and any other individuals who may have information pertinent to the incident. Information required by UCAR will vary depending on the circumstances, but may involve:

a. Interviewing complainants (if known), any persons against whom allegations were directed, members of the research team, veterinary staff, the PI's department head, and any other pertinent program officials;

b. Observing the animals and their environment;

c. Reviewing any pertinent records, (e.g., animal health records, protocols, and other documents); and

d. Consulting with appropriate experts.

3. The PI will be notified about the concern or suspected noncompliance once preliminary information has been gathered and before the matter is discussed by the Committee. A report will be prepared including the findings of the investigation, and the item will be put on the agenda for the next scheduled UCAR meeting. The Committee will determine what action will be taken to resolve the noncompliance.

4. The PI may respond in writing or by attending the next UCAR meeting to provide their point of view of the incident. UCAR will determine what further action will be taken.

- If that action is deemed reportable to the funding agency or if suspension of a protocol is warranted, a final report**,** with ***UCAR*** recommendations**,** will be sent to the Institutional Official, the PI's dean, the PI's departmental chair, and the PI. The Institutional Official will submit the report to the outside agency, based on the report received from UCAR.
- If the protocol is not supported by outside funds, or the agency does not require notification of noncompliance, then the report will be made to the Institutional Official, the PI's dean, the PI's departmental chair, and the PI.
- In either of the two scenarios above, UCAR may require actions that would have financial implications as part of the corrective action (e.g., hiring extra staff). In this case, those costs would be the responsibility of the PI.
- If UCAR does not vote to report the incident, any internal action, requests for information or outcome from the Committee discussion will be reflected in the meeting minutes and communicated to the PI.

All reports will be filed in the UCAR Office for documentation of the incident and the investigation.

5. UCAR may suspend an unapproved activity or an activity which was previously approved, if it determines that the activity is not being conducted as described in the approved protocol.

Suspension of Protocol

As indicated above, the UCAR is empowered to suspend a protocol if it finds violations of the PHS Policy, Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the UCAR, and with a vote for suspension from a majority of the quorum present. In addition, the PI may (and in appropriate cases will be encouraged to) agree to voluntarily suspend the protocol pending review by the UCAR. If the UCAR suspends an activity involving animals, the Institutional Official, in consultation with the UCAR, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW and any federal agency funding that activity. At the time of suspension of a protocol, the UCAR will vote on terms for reactivation of the protocol. The PI's dean and chair will also be notified of the noncompliance prior to UCAR's formal vote to suspend.

Reporting noncompliance, Adverse Events and deviations from the Guide and protocol suspensions

Circumstances that must be reported to OLAW by the Institutional Official, are: serious or continuing noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals ("the PHS Policy"); serious deviations from the ILAR's Guide for the Care and Use of Laboratory Animals ("the Guide"); and suspensions of protocols by the UCAR. Issues may be reported to OLAW.

Reporting to AAALAC

AAALAC Rules of Accreditation, Section 2, Standards, Point f.

In addition, the accredited unit shall promptly notify AAALAC of adverse events relating to animal care and use program. Examples include investigations by the USDA or OLAW, as well as other serious incidents or concerns that negatively impact animal well-being.

Allowable charges to NIH grants during periods of non- compliance

"The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges." Therefore, if the incident relates to conduct of non-approved procedures on a protocol being funded with NIH funds, charges to the grant related to the animal activities related to the incident will require removal. The PI will need to work with the vivarium administration to determine the amount of the charges.

Supplemental information - Regulatory Mandates and Guidelines

Our animal care and use program is governed by Federal Guidelines for the care and use of animals for research and teaching. The University Committee on Animal Resources oversees the entire program and reviews and approves all animal teaching and research activities. The animal care and use program at U of R is inspected by the United States Department of Agriculture (USDA), New York State Department of Health and is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC. Int.). The Institutional Animal Care and Use program is based on the Animal Welfare Act and Regulations, the Guide, and the institution's Letter of Assurance with the Public Health Service (National Institutes of Health).

A. Federal Requirements Regarding the Reporting of Animal Care and Use Concerns: USDA – Animal Welfare (9 CFR Ch.1)

1. Part 2 - Subpart C 2.31 (c) UCAR Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall:

- *(4) 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;*

2. *2.31 (d)*

- *(6) The IACUC may suspend an activity that it previously approved if it determines that an 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;*
- *(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity.*
- *2.32 Training and Instruction of personnel must include (4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care are treatment reported by any employee of the facility. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or standards under the Act.*

4. *2.33*

- *(2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use. (USDA provides the authority and responsibility to the attending veterinarian to temporarily suspend an activity involving animals.)*

B. Public Health Service (Implementation of Public Law 99-158)

1. B. Functions of the IACUC
   - *4. Review concerns involving the care and use of animals at the Institution;*
2. C. IACUC Review of PHS-conducted or Supported Research Projects

   - *6. The IACUC may suspend an activity that it previously approved if it determines that*

the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.l.a-g of this Policy. The IACUC may suspend an activity only after a 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.

- *7. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW*

3. F. Reporting Requirements

- *3. The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy; b. any serious deviation from the provisions of the Guide; c. any suspension of an activity by the IACUC.*

C. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

1. http://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html

2. Examples of reportable situations:

- *conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;*
- *conduct of animal-related activities without appropriate IACUC review and approval;*
- *failure to adhere to IACUC-approved protocols;*
- *implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;*
- *conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);*
- *conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;*
- *conduct of official IACUC business during a period of time that the Committee is improperly constituted;*
- *failure to correct deficiencies identified during the semiannual evaluation in a timely manner;*
- *chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;*
- *participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;*
- *failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);*

- *failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);*
- *failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO 2);*
- *failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or*
- *IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.*

3. OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the Guide. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the UCAR. Examples of situations not normally required to be reported:

- *death of animals that have reached the end of their natural life spans;*
- *death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;*
- *animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;*
- *animal death or injuries related to manipulations that fall within parameters described in the UCAR-approved protocol; or*
- *infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).*

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