

University of Pennsylvania School of Medicine
Policy and Procedure Manual

Management of Significant Non-Compliance in Animal Research

RESEARCH ADMINISTRATION
Policy Number: RA-ANML-007
Date Approved: February 4, 2009

I. PURPOSE

The purpose of this policy is to describe the procedures at the University of Pennsylvania School of Medicine (SOM) for reporting, investigating, and sanctioning instances of significant non-compliance with animal research regulations, practices, policies, and procedures.

This policy is designed to support 1) the synchrony between the authority, policies, and procedures of the Institutional Animal Care and Use Committee at the University of Pennsylvania (IACUC) and the SOM in matters of non-compliance with IACUC-related animal research regulations, and 2) the process in the SOM for overseeing incidents in which individuals are alleged to deviate significantly from SOM or University (non-IACUC) animal research practices, policies, or procedures.

This policy is the official SOM position for responding to and managing significant animal research non-compliance in the SOM. The procedures outlined in this policy are intended to ensure a standard, transparent, and fair approach to the management of all such instances of significant non-compliance in animal research in the SOM. This policy is essential to ensuring that all individuals in the SOM adhere to the highest standards of humane, responsible animal care and use.

This policy is not intended to cover allegations of scientific misconduct for which separate policies exist: "III.C. Procedures Regarding Misconduct in Research" in the "Handbook for Faculty and Academic Administrators" [link: http://www.upenn.edu/assoc-provost/handbook/iii_c.html] and "Procedures Regarding Misconduct in Research for Nonfaculty Members of the Research Community" [<http://www.upenn.edu/almanac/volumes/v51/n01/OR-research.html>].

II. DEFINITIONS

Non-compliance with IACUC-related regulations (IACUC-related non-compliance):
An animal research action that warrants an IACUC investigation because it does not comply with the Animal Welfare Act and Regulations, the Public Health Service Policy,

the *Guide for the Care and Use of Laboratory Animals* and/or University policies and guidelines governing animal research.

Examples include but are not limited to:

- Performing procedures not approved by the IACUC
- Unapproved deviations from IACUC protocols
- Absent recordkeeping of animal use and care
- Inadequate post-procedure monitoring
- Failure to abide by ULAR veterinarians' orders

Other significant animal research non-compliance (other non-compliance): An animal research action that does not satisfy the criteria warranting an IACUC investigation but that nonetheless significantly deviates from accepted SOM research practices or approved SOM or University (non-IACUC) procedures and policies.

Examples include but are not limited to:

- A violation of accepted SOM animal research practices or approved SOM or University procedures or policies that is committed intentionally, knowingly, repeatedly, or recklessly
- A violation of accepted SOM animal research practices or approved SOM or University procedures or policies that creates significant risk or damage to the SOM or University research community. Further examples include but are not limited to:
 - Violations of SOM policies governing quarantine in SOM facilities
 - Violations of SOM policies governing relocation of rodents between rooms, suites, and facilities
 - Violations of SOM policies governing housing or use of animals in non School of Medicine sites
 - Violations of other SOM and/ or University procedures or policies

III. WHO DOES THIS POLICY APPLY TO?

This Policy applies to all SOM faculty, staff, students, and trainees, and also any individual engaged in animal research activities in the SOM.

IV. POLICY STATEMENT

The IACUC is the authority in identifying, investigating, and sanctioning all instances of IACUC-related non-compliance as defined by the "Standard Operating Procedures and Policies of the University of Pennsylvania Institutional Animal Care and Use Committee

(IACUC),” [link: <http://www.upenn.edu/regulatoryaffairs/IACUCguides.html>]. The IACUC is charged with assuring that all activities involving animals at the University of Pennsylvania meet the ethical and legal requirements for the humane care and use of animals.

The SOM Dean’s Office is the authority in identifying, reviewing, and sanctioning all instances of other non-compliance with accepted SOM practices or approved SOM or University (non-IACUC) animal research procedures and policies.

The SOM has identified three key areas where it can contribute to the promotion of compliance and good conduct in animal research:

- Creating an environment in the SOM in which incidents of potentially significant IACUC-related non-compliance are promptly reported to the IACUC in order to initiate an IACUC review and, if warranted, investigation.
- Where appropriate with IACUC and University policies, and charged by the SOM Dean’s Office, the SOMARC can support the maintenance of appropriate conduct in animal research by reviewing alleged instances of other non-compliance with SOM or University (non-IACUC) practices, policies, or procedures.
- Based on such an SOM-based review, and where appropriate with University policies, the SOMARC may recommend to the SOM Dean’s Office that SOM-based sanctions be imposed. For faculty, this process is governed by “II.E.16. Procedure Governing Sanctions Taken Against Members of the Faculty” in the “Handbook for Faculty and Academic Administrators” [link: http://www.upenn.edu/assoc-provost/handbook/ii_e_16.html], and, for staff, this process is governed by the relevant University Human Resources policies.

V. WHO SHOULD KNOW THIS POLICY?

- Dean
- Executive Vice Dean and Chief Scientific Officer (EVD/CSO)
- Associate Dean for Animal Research (ADAR)
- School of Medicine Animal Research Committee (SOMARC)
- SOM faculty and lab personnel engaged in animal research
- University Laboratory Animal Research (ULAR) staff
- IACUC Chair
- Office of Regulatory Affairs Animal Welfare Staff
- University Vice Provost for Research

VI. POLICY AND PROCEDURES

Reporting IACUC-Related Non-Compliance to the IACUC

The IACUC identifies instances of significant IACUC-related non-compliance through various methods, including through IACUC semi-annual inspections of animal facilities, random visits by IACUC compliance monitors, and reports from individuals who have witnessed non-compliance. It is through this last method, in which individuals report potential IACUC-related non-compliance directly to the IACUC, where the SOM can further assist the IACUC in reinforcing the expectation that SOM faculty and staff assist in assuring compliance.

All members of the SOM — including faculty, staff, students, and trainees — are expected to promptly report to the IACUC any potential incidents of significant IACUC-related non-compliance. These concerns can be reported in writing, by telephone, or in person, and can be made anonymously.

Significant IACUC-related non-compliance should be reported to any one of the following University offices:

- Animal Welfare Compliance, Office of Regulatory Affairs
 - e-mail: felsburg@exchange.upenn.edu (IACUC Chair)
thallman@upenn.edu (Director of Animal Welfare)
deyanira@upenn.edu (Assoc. Dir. of Animal Welfare)
 - telephone #: (215) 898-2614
 - address: 3624 Market Street, Suite 301 S
Philadelphia, PA 19104-6006

- Corporate Compliance Office
 - telephone #: (888) 236-8477 or 888-BEN-TIPS

Once a report is made, the IACUC will review and, if warranted, will initiate its investigation process.

If, upon investigation, the IACUC recommends to the SOM that it undertake a preliminary inquiry for misconduct in research, the IACUC will contact the ADAR as representative of the SOM Dean's Office with this recommendation.

The SOM Dean's Office, and ultimately the Office of the Provost, is the authority in adjudicating instances of misconduct in the SOM as defined in "III.C. Procedures Regarding Misconduct in Research" in the "Handbook for Faculty and Academic Administrators" [link: http://www.upenn.edu/assoc-provost/handbook/iii_c.html] and "Procedures Regarding Misconduct in Research for Nonfaculty Members of the Research Community" [<http://www.upenn.edu/almanac/volumes/v51/n01/OR-research.html>].

Overseeing Other Non-Compliance with SOM or University (non-IACUC) Animal Research Practices, Policies, or Procedures in the SOM

The SOM identifies alleged instances of other non-compliance in animal research in the SOM through the submission of an SOM Animal Research Incident Report Form (link) by mail, e-mail, or in person to the Associate Dean for Animal Research, who represents the SOM Dean's Office. In order to prompt a review for other non-compliance in the SOM, this Form or an e-mail or letter containing the following information:

- Contact Information: Name, Department, Phone Number and Email Address
- Facility in which the incident occurred
- Date of incident
- Description of Incident

must be completed and submitted to the Associate Dean for Animal Research. Here is the contact information:

- Thomas N. Ferraro, Ph.D., Associate Dean for Animal Research
 - tnf@mail.med.upenn.edu
 - 2209 Translation Research Laboratories
125 S. 31st Street
Philadelphia, PA 19104-3403

Using this method, all members of the SOM — including faculty, staff, students, and trainees — are expected to promptly report to the SOM Dean's Office any potential incidents of other non-compliance in animal research in the SOM.

If the allegation of other non-compliance arises from within the ULAR staff, this allegation must be discussed with the Director of ULAR. Based on the discretion of the Director of ULAR, the Director of ULAR may choose to then contact the Associate Dean for Animal Research following the process described above.

If the SOM Dean's Office determines that an SOM-based review is necessary, the SOM Dean's Office through the ADAR may charge a faculty committee (3 – 4 faculty members) to conduct a review and to make a recommendation to the SOM Dean's Office regarding 1) whether or not other significant non-compliance with SOM or University (non-IACUC) animal research practices, policies, or procedures has occurred, and 2) whether or not SOM sanctions are recommended.

The members of this committee must not share the same department, collaborate with, or have a conflict of interest with the individual under review. This review will be

thorough, but expeditious, with a goal of generating recommendations within 15 working days from its inception.

Here are the necessary procedural steps in this review:

- The individual under review will be informed in writing that the SOM Dean's Office is reviewing their conduct, and that they will have an opportunity to formally respond to this review.
- The committee will gather all information deemed necessary to a thorough review, including materials aiding assessment of the risk or the damage the alleged violation created for the SOM and University research community.
- Within 15 working days, the committee will submit a written document to the SOM Dean's Office (ADAR and EVD/CSO), with a copy to the individual under review, that is detailed and specific regarding the evidence reviewed, a summary of the process of inquiry, and any dissenting opinions within the committee. This document must recommend whether or not:
 - There has been significant non-compliance with SOM or University (non-IACUC) animal research practices, policies, or procedures;
 - SOM sanctions should be imposed and, if relevant, the nature of these additional sanctions; for faculty, this process is governed by "II.E.16. Procedure Governing Sanctions Taken Against Members of the Faculty" in the "Handbook for Faculty and Academic Administrators" [link: http://www.upenn.edu/assoc-provost/handbook/ii_e_16.html] and for staff, this process is governed by the relevant University Human Resources policies.
- Following the submission of the committee's written recommendation, those individuals whose actions are under review will be given 15 working days to respond in writing to the committee's document and deliver this response to the SOM Dean's Office (ADAR and EVD/CSO).

If the committee recommends the imposition of SOM-based sanctions, the ADAR and EVD/CSO will discuss this recommendation with SOMARC as soon as possible after the 15 day response period in order to develop the most appropriate final action.

The SOM Dean's Office has final discretion over whether or not to impose sanctions. Once the SOM Dean's Office decision is finalized, the SOM faculty member, staff, student, or trainee under review will be informed in writing of the decision of the SOM.

VII. CONTACTS

Executive Vice Dean and Chief Scientific Officer of the School of Medicine

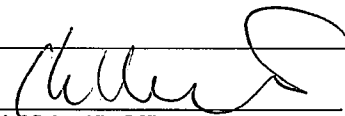
Phone: (215) 898-2874

Fax: (215) 573-7945

Associate Dean for Animal Research

Phone: (215) 573-4581

E-mail: tnf@mail.med.upenn.edu

Supersedes: None – New Policy	APPROVED:  Executive Vice Dean/Chief Scientific Officer, School of Medicine Date 2/4/9
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School of Medicine Animal Research Incident Report Form

Name: _____

Department: _____

Phone: _____

E-mail: _____

Facility in which incident occurred: _____

Date on which incident occurred: _____

Description of incident (use additional page if necessary): _____

Signature: _____

Date: _____