

**HACKENSACK UNIVERSITY MEDICAL CENTER**  
**Research Department Policy Manual**

**Name: The Institutional Animal Care and Use Committee (IACUC) Handling of Reports of Research Misconduct or Suspected Endangerment of Animal Welfare**

**Policy # IACUC 126**

**Effective Date: 3/2013**

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**GENERAL**

**Purpose:** Define the handling of reports of Research Misconduct or Suspected Endangerment of Animal Welfare (Whistleblower Policy)

**Administration:** The Institutional Official (IO) in conjunction with the IACUC are responsible for the review and revision of this policy.

**Policy:** Upon receipt of an allegation of research misconduct or suspected endangerment of animal welfare, HackensackUMC's IACUC will conduct an investigation of the alleged misconduct. The Chairperson will notify the IO and Risk Management.

Any Member of the IACUC who may be involved with the alleged misconduct or who may have a conflict of interest will have to recuse him or herself from the investigation or any vote on disposition of the investigation or protocol. The IACUC may invite other members of HackensackUMC to be part of the investigation for their expertise (example: scientist with expertise in the field, risk management, legal).

The Committee will make a determination of appropriate actions which may include appropriate steps to correct the research record (also see chart below);

- verbal and/or written reprimand;
- suspension or termination of procedures or the protocol until assurance of compliance with appropriate standards;
- suspension or termination of employment;
- reporting of results to the federal agency responsible for oversight;
- referral to law enforcement when criminal activity is involved.

HackensackUMC employees who are subjects of allegations will receive appropriate protections including

- review of allegations by objective individuals with appropriate expertise;
- timely investigation, arbitration, and appeal;
- confidentiality to the extent possible and consistent with a fair and thorough investigation;

- Reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct or endangered animal welfare but against whom no finding is made.

HackensackUMC employees may not retaliate in any way against complainants or witnesses. Individuals should immediately report any alleged or apparent retaliation to the Institutional Compliance Officer, who will review the matter and take appropriate action.

## **REFERENCES**

Public Health Service Policy on Humane Care and Use of Laboratory Animals:  
National Institutes of Health, Office of Laboratory Animal Welfare. Public Health Service: *Policy on Humane Care and Use of Laboratory Animals* (8/7/02). Section IV: Implementation by Institutions. Retrieved from <http://grants.nih.gov/grants/olaw/references/phspol.htm#AnimalWelfareAssurance>

Committee for the Update of the Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, Division on Earth and Life Studies, National Research Council of the National Academies. (c2011). Animal Care and Use Program. In *Guide for the Care and Use of Laboratory Animals*, 8<sup>th</sup> ed. (Chapter 2). Retrieved from: <http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-Laboratory-animals.pdf>

Code of Federal Regulations, Title 9 (Animals and Animal Products), Subchapter A - Animal Welfare, Part 2 - Regulations, (3/22/13). Retrieved from [http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title09/9cfr2\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title09/9cfr2_main_02.tpl)  
Revised 3/2013

Silverman, J. (2006) Animal Mistreatment and Protocol Noncompliance. In J. Silverman, M.A. Suckow & S. Murthy (Eds.), *The IACUC Handbook* (pp. 543-570). Boca Raton: CRC Press.

## Procedures to Handle Reported Deviation or Violations:

Time Frame	IACUC Action Taken	If Principal Investigator Responds	If Principal Investigator Doesn't Respond
First Notification	<p>IACUC Administrator contacts the PI via email or phone in order to inquire about the protocol changes.</p> <p>The PI must submit a revised application and other related documents within one week of the email or phone call.</p>	Case resolved	Action Progresses
1 Week – Following Notification	<p>The PI receives written notification from the Institutional Official</p> <p>This written notification is mailed to the PI, Chairperson of the IACUC and Placed in the PI's IACUC File</p> <p>The notification letter will contain a request to meet in-person in order to reach a resolution.</p>	An in-person meeting will be held in order to provide clarity on procedures and requirements to the PI. The PI must submit any changes within 2 business days.	Action Progresses
2 Weeks – Following Notification	The IACUC will review the revision submitted by the PI	Case resolved (if the revisions are approved)	Action Progresses
3 Weeks – Following Notification	If the revisions require a full review, it is brought to the next IACUC meeting for a vote to suspend the research. If the study is an expedited review, it is sent to the reviewers for a decision to suspend the research.	Case resolved (if the revisions are approved)	Action Progresses
Suspension of Research	<p>The PI receives a Notification of Suspension from the Institutional Official.</p> <p><i>This notice will be mailed to the PI and other institutional entities that are affected by the research including applicable federal agencies.</i></p> <p>Research may not resume until the required documents are submitted and administrative approval is obtained.</p>	Case resolved (if the revisions are approved)	Termination