

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

Name: Protocol Submission to the Institutional Animal Care and Use Committee (IACUC) Policy# IACUC 101

Effective Date: August, 2009 / Modified December, 2009 Page 1 of 4

GENERAL

Purpose: To ensure that timely consideration can be given to each proposal to use animals for research at Hackensack University Medical Center (HackensackUMC).

Administration: The IACUC is responsible for the review and revision of this policy

Policy: Every Principal Investigator (PI) working with live animals must have a protocol approved by the IACUC.

Purpose: To ensure that timely consideration can be given to each proposal to use animals for research at HackensackUMC.

PROCEDURE:

Receiving Protocol Number and Application:

1. A memo from the PI is sent to the IACUC Administrator requesting a protocol number. This memo must contain:
 - Names of PI and Co-Investigators
 - Title of the proposed protocol:
 - Species / strain of animal required.

2. Once the memo is received, a protocol number and the Protocol Application Packet will be transmitted electronically to the investigator. The packet contains:
 - Protocol application
 - Submission due dates for the current year
 - Occupational Medicine forms and policy
 - Training requirements and procedure
 - Conflict of interest form

Note: The Occupational Medicine, Training and Conflict of Interest requirements must be completed before submission of the application

3. The Protocol application must be filled out in its entirety and submitted to the IACUC Administrator in **BOTH** electronic and signed paper format. The paper format MUST be signed and dated based on the submission date. The PI has 90 days to return the completed protocol application. After that time, the protocol number will be cancelled.
4. All new submissions for review must be received by the IACUC Administrator by the due date included in the application. Late submissions will not be reviewed until the following month's meeting.
5. The protocol application will be distributed to the members of the IACUC for review at that month's meeting. The protocol will then be assigned into one of the following categories:
 - Approval
 - Modifications Required to Secure Approval – small changes required for clarity.
 - Withhold Approval – Requiring major clarifications or corrections
 - Denied
6. Once a decision is made by the IACUC, the PI will be notified of that decision in written and electronic format.
 - Approval: The PI will receive a letter indicating protocol approval from the IACUC; the Institutional Official (IO) will also receive copy of the letter. The IO will confirm the availability of funds to carry out the proposed work, and will notify the Manager of the Department of Biological Resources that work on this protocol can begin. No work may commence without the approval of the IO.
 - Modifications Required to Secure Approval or Withhold Approval: The PI will receive a letter outlining the issues and questions raised by the IACUC in response to the protocol. The PI must submit within the next 30 days; a) a written response that addresses all the concerns outlined in the IACUC critique and; b) and

revised protocol that incorporates the changes recommended by the IACUC. All text changes/additions made to the protocol should be demarcated in **bold-underlined type**.

- Denied: The PI will receive a letter outlining the issues that called for protocol denial.
7. Protocol approval is valid for up to 3 calendar years from the approval date. The PI must submit a Renewal form annually in order to keep the protocol active. At the end of the third year the PI must submit a complete resubmission of the protocol for full committee review (refer to Policy #IACUC 108 for more details).
 8. As long as the protocol remains active, a new protocol number is not required.
 9. Protocol renewal notifications are sent electronically at 90, 60 and 30 days prior to the due date.

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*, 8th 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
Revised 3/2013

Laber, K., & Smith A. (2006). Submission and Maintenance of IACUC Protocols. In J. Silverman, M.A. Suckow & S. Murthy (Eds.), *The IACUC Handbook* (pp. 93-112). Boca Raton: CRC Press.

Prentice, E.D. & Oki, G.S.F (2006) General Concepts of Protocol Review. In J. Silverman, M.A. Suckow & S. Murthy (Eds.), *The IACUC Handbook* (pp. 113-138). Boca Raton: CRC Press.

Revised 12/2009
4/2013