

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

**Name: Amendment Submission to the Institutional  
Animal Care and Use Committee (IACUC)**

**Policy # IACUC 106**

**Effective Date: August, 2009 / Modified December, 2009 Page 1 of 3**

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**GENERAL**

**Purpose:** To ensure that timely consideration can be given to each change (amendment) to protocols using animals for research at HackensackUMC.

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

**Policy:** Every Principal Investigator (PI) submitting changes to current IACUC protocols must complete the following:

All changes are protocol specific.

**PROCEDURE**

**Procedure:**

1. A memo is sent to the IACUC Administrator requesting an amendment form.
2. The amendment form must be filled out in its entirety.
3. All amendments must be received by the IACUC Administrator no later than the first Friday of each month in order to be reviewed at that month's IACUC meeting.
4. Proposed protocol is distributed to members of the IACUC for review. At the following month's meeting, a decision will be made as to its disposition.
  - a. Approval
  - b. Modifications Required to Secure Approval
  - c. Withhold Approval
  - d. Denied
5. Once a decision by the Committee is made, notification in writing will be sent to the PI of record.
  - a. If Approved, the PI will receive signed confirmation from the IACUC. The Institutional Official (IO) will also receive a copy of the letter.
  - b. For any other disposition, including Modifications Required to Secure Approval, Withhold Approval or Denied, the PI will

receive a letter outlining the problems, questions and/or concerns of the IACUC with regard to the submitted protocol. The Institutional Official (IO) will also receive a copy of the letter. The PI must satisfactorily address all concerns and questions of the IACUC in order to receive an approval. Corrected copies must be sent in **BOTH** electronic and paper format (signed and dated) to the IACUC Administrator; who will send to the appropriate parties for review.

6. Any amendment made to the protocol must be incorporated into the third year resubmission of the protocol.

**Timing for Responses/Clarifications/Corrections:**

1. IACUC decisions on protocol status will be communicated in writing within seven business days after the meeting - no verbal responses will be forthcoming.
2. The PI has up to 20 business days from dated notification to respond to IACUC comments. If resubmission is necessary, the response must be received in time to meet the following month's deadline or it will be held over for the following months meeting. If the PI needs additional time to get the information needed, the PI may write a letter to the IACUC stating the reason for the delay and the proposed date the protocol will be resubmitted.
3. Deadline for rebuttal for Denied amendment changes to Protocol is 30 business days. If no response is received at the end of the 30 business day period, this amendment will be considered closed.

**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>

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