

HACKENSACK UNIVERSITY MEDICAL CENTER
Research Department Policy Manual

**Name: Institutional Animal Care and Use
Committee (IACUC) – Reviewing Protocols**

Policy# IACUC 116

Effective Date: November, 2012

Page 1 of 5

GENERAL

Purpose: Guidelines for reviewing and approving protocols for research activities involving the use of animals.

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

Policy: In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals.

PROCEDURE:

The IACUC procedures for protocol review are as follows:

All protocols shall reflect requirements of the Animal Welfare Act, PHS policy and other federal regulations. The Principal Investigator (PI), prior to protocol submission, drafts a memo stating the following: Title of protocol, species, and PI.

At that time, the protocol will be assigned a protocol number for the PI to use for that particular protocol. All correspondence for any protocol should include the PI's name, and the protocol title and number.

Protocols with protocol number shall be submitted to the IACUC Administrator as a hard copy and electronic copy.

Upon receipt of a new protocol, the IACUC Administrator emails each IACUC member a list of proposed research projects to be reviewed and attaches each protocol to the email. Any member of the IACUC may obtain, upon request, full committee review of those research projects. This allows the IACUC to pre-review the protocol prior to the convened meeting. Comments and recommendations submitted by IACUC members are returned to the IACUC Administrator. The IACUC Administrator will then compile the comments and recommendations into one spreadsheet to be shown at the next convened meeting. All new protocols are reviewed by the full committee at a convened meeting with a quorum present. A majority vote of the quorum present is required to approve, require modifications in order to secure approval, or withhold approval of a protocol. The Designated Member

Review process is not used by the IACUC for the initial review.

Comments and category placed on the protocols will be returned to the IACUC Administrator.

The PI will be given the comments in writing to make necessary changes if needed. A copy of the decision will also be given to the Institutional Official. If there are any questions or concerns about the comments, the PI should address them to the IACUC Chairperson. Once necessary changes are made, final review will be done by the primary reviewers and the protocol will be placed in one of the following categories:

1) Approve: The IACUC has given approval based on the fact that the protocol conforms with the Institution's Assurance and that it meets the requirements a-e listed above and as stated in IV. D.1. of the PHS Policy. Approval of a new protocol may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. The PI may only conduct work on animals that has been approved by the IACUC.

2) Modifications requested in order to secure approval:
The IACUC sends a request to the PI requesting modifications via a detailed letter, which states point by point what modifications are needed before the IACUC will grant approval. The PI is required to respond via letter to the IACUC's request. The PI's response must address each point listed in the IACUC request as well as in the protocol itself. Designated Member Review (DMR(s)) is generally used to review and approve, request additional modifications in, or return to full committee the modifications submitted by the investigator as a result of the initial review conducted by Full Committee Review (FCR). After the initial review of the protocol at a convened meeting where the quorum present voted that modifications were required in order to secure approval, the quorum voted to send the subsequently modified protocol to DMR for final review and approval. After the meeting, the IACUC Administrator sends an email with the title of the protocol and the modifications requested by the quorum present at the meeting to all committee members to allow them the opportunity to call for FCR prior to

implementing DMR. If no member requests FCR of the modified protocol after 5 business days, then DMR is implemented by the Chairperson who selects one or more members to serve as the designated reviewers. Any member can make the decision to send the protocol (s) and/or amendments to full committee review at any time during the time designated for providing this opportunity. The designated reviewer(s) act on behalf of the entire IACUC to approve the protocol, request additional information from the PI before approval may be granted, or refer it for FCR. The designated reviewer(s) does/do not have the power to withhold approval. The PI may not order animals nor begin any research described in the protocol until they receive an approval letter from the IACUC. The approval letter is not sent until all modifications have satisfied the IACUC's questions and are approved using either FCR or DMR.

3) **Withhold approval:** In this case the PI has failed to show the committee, that their research protocol has met the guidelines followed by the Institution, the PHS Policy, The Guide or The Animal Welfare Act. If a protocol has approval withheld, a letter is sent to the PI stating the reason(s) why the decision was made. A copy of the letter also goes to the Institutional Official. The PI has 30 days to reply to the letter and must address the IACUC's concerns in writing, as well as having the opportunity to appear before the IACUC in person, upon request.

Once protocols have been reviewed, there will be a memo addressed to the PI stating the status of the protocol. Based on which category the protocol is placed will determine the PI's next steps as described above.

IACUC meetings will be at least once a month. If an unscheduled meeting is necessary, the IACUC Administrator will make arrangements. A majority of the committee members need to attend to discuss any issues in which a vote is necessary. Final approval will fall on the IACUC Chairperson, the Clinical Veterinarian, and /or other IACUC members assigned by the Chairperson.

In cases of an expedited review process, all IACUC members will be given a copy of the proposed protocol and have 48-72 hours to respond from time of receipt to discuss any issues. The approval will otherwise be in the hands of the reviewers

assigned by the Chairperson, as mentioned above.

Note: All members are notified about upcoming protocols and are given a copy of each protocol for review. If any member has questions or concerns, they have the option to request a full committee review.

Protocol modifications and significant changes:

The IACUC reviews and approves, require modifications in (to secure approval), or withholds approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C.

The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Amendments to protocols in progress with the use of animals will follow guidelines set by the Animal Welfare Act, PHS Policy and SOP's of the Institution.

A PI should send in writing the nature of the change, the justification of the change, and any preliminary data or literature search to support the change in the protocol.

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
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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

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