

**SEATTLE CHILDREN'S RESEARCH INSTITUTE  
OPERATING POLICIES / PROCEDURES**

<b>DEPARTMENT:</b>	Institutional Animal Care and Use Committee
<b>POLICY NUMBER:</b>	IACUC-004
<b>REPLACES:</b>	
<b>EFFECTIVE DATE:</b>	June 10, 2005
<b>REVISION DATE:</b>	March 4, 2011

**TITLE:** Protocol Review And Approval Process

**SUMMARY:**

The purpose of this policy is to describe the process used by the Institutional Animal Care and Use Committee (IACUC) to review animal care and use protocols to ensure that the criteria established in Public Health Service (PHS) policy and Animal Welfare Regulations (AWRs) are implemented. The primary goal is to facilitate compliance with applicable laws, regulations, and policies consistent with the performance of appropriate and productive scientific endeavors.

**POLICY/PROCEDURE:**

## 004-1 Content

004-1.1 Investigators must submit a complete "New Project Application Form" application to the IACUC Administrator. The application must include all requested information, including that outlined in PHS Policy IV.D.1 & 2 as follows:

004-1.1.1 Identification of the species and approximate number of animals to be used;

004-1.1.2 Rationale for involving animals, and for the appropriateness of the species and number used; the rationale shall be written in lay language. Lay language refers to language that is understandable to a non-scientist;

004-1.1.3 A complete description of the proposed use of the animals written in lay language;

004-1.1.4 A complete description of the procedures used so that reviewers can assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

004-1.1.5 A description of euthanasia methods to be used.

## 004-2 Full Committee Review

004-2.1 IACUC meetings are held on the first Tuesday of every month. Exceptions to this may be allowed at the discretion of the IACUC Chair for scheduling purposes.

004-2.2 All New Project Applications (NPAs) and modifications or annual renewals with significant changes not qualifying for Designated Member Review (DMR) as per IACUC 003-1.2 will be reviewed by Full Committee Review (FCR). Applications just described must be received no later than the end of business of the Friday occurring six business days prior to the next scheduled meeting) in order to receive IACUC review at that meeting. Applications missing this deadline will be placed on the IACUC agenda for the following month. Exceptions can be granted by the IACUC Chair on a case-by-case basis in response to funding or programmatic needs.

004-2.3 Procedures for protocol review are initiated through the IACUC Administrator. IACUC members are provided with submitted documents, via e-mail, to provide all committee members with the opportunity to review material prior to the next scheduled meeting in accordance with the PHS Policy at IV.C.2.

004-2.4 FCR must be conducted by a quorum (more than half of committee members). One member, selected by the IACUC Chair with the IACUC Administrator, leads the discussion of the submission. Following discussion, the committee will vote on the protocol. A majority of the quorum present must vote in favor for a motion to pass. Protocols requiring modifications to secure approval may be reviewed by DMR subsequent to FCR, if the members present agree by unanimous vote. Approval is granted only after all concerns are satisfied. A letter of approval, signed by the IACUC Chair, is then provided to the principal investigator.

004-2.5 The IACUC shall review any grant application associated with a funded animal research protocol. The committee member leading the

discussion of the submission shall compare the funded application with any approved or pending IACUC protocol to ensure uniformity in design and conduct.

#### 004-3 Designated Member Review

004-3.1 The IACUC may use the designated member review procedure for:

004-3.1.1 Review of protocol amendments with no significant changes in accordance with IACUC- 003, and;

004-3.1.2 Annual renewal protocols with no significant changes as described in IACUC policy 003-3.

004-3.1.3 Annual renewal protocols and protocol amendments with significant changes that are deemed to be eligible for designated member review as per IACUC 003-1.2.

004-3.2 Under the DMR procedure, all voting members are provided with a notification of the submission and a copy of the completed application form;

004-3.3 All members are provided with the opportunity to request FCR.

004-3.4 If no member calls for FCR, the Chair designates one or more qualified members to review the submission.

004-3.4.1 Under DMR, the IACUC Chair or designated member assigned by the Chair, reviews the protocol amendment or annual renewal. The reviewer may exercise all of the authorities of the IACUC except disapproval. A protocol amendment or annual renewal may be disapproved only after review in accordance with Full Review procedures (004-2.2).

004-3.5 All designated member approvals will be reported at the next convened IACUC meeting.

004-3.6 Any IACUC member may request that an activity which has been approved under the DMR procedure be reviewed by the full committee. A vote of the members shall be taken concerning the request which may be: (1) for more information, (2) requiring modification, or (3) disapproving the project.

#### 004-4 Committee Actions

004-4.1 **Approval.** All review criteria, based on the PHS Policy and AWRs, have been adequately addressed by the investigator. Animals may be

purchased and used in the approved protocol only. Approval is given for three years, with a requirement for annual review.

004-4.2 **Modifications required to secure approval.** In some cases, the IACUC may require specific modifications to the protocol before granting approval. At the conclusion of the committee meeting, the IACUC Coordinator will prepare a letter outlining the specific concerns presented by the committee. These concerns must be addressed to the satisfaction of the IACUC chairperson (or designated reviewer) within 30 days of receipt. No animals may be ordered and no work may begin until the final approval is received by the investigator.

004-4.3 **Tabled.** Tabled protocols are neither approved nor disapproved. A protocol may be tabled for reasons including the IACUC's need for clarifications and/or revisions/additions in order to properly assess the proposed research or the IACUC's wish to seek external consultation. The investigator may be asked to submit significant additional information or a new protocol. No animals may be ordered and no work may begin until the final approval is received by the investigator.

004-4.4 **Approval Withheld.** The Committee did not approve the protocol. A new revised protocol must be submitted for review based on the observations/recommendations/criticisms of the IACUC.

#### 004-5 Approval Period

004-5.1 Protocols are approved for up to three years, after which the protocol must be rewritten and resubmitted as a new protocol. The re-submission must include an updated review of the available literature and a synopsis of the status of the study.

004-5.2 The IACUC will initiate a full review of the re-submitted application in accordance with 004-2.

#### 004-6 Annual Review and Renewal

004-6.1 All approved protocols must be reviewed at least every 12 months.

004-6.1.1 The IACUC Administrator will advise the investigator of renewal one month before the expiration date;

004-6.1.2 The investigator shall submit a "Renewal Application/Modification Request Form" to the IACUC, for each ongoing study, no later than two weeks before the expiration date.

004-6.2 Annual review with no significant changes included will employ the Designated Member Review Process.

#### REFERENCES:

ARENA / OLAW, "The Institutional Animal Care and Use Committee Guidebook", 2<sup>nd</sup> Ed. NIH. Bethesda, MD. 2002.

OLAW, "Public Health Service Policy on Humane Care and Use of Laboratory Animals", Office of Laboratory Animal Welfare, NIH, Amended August, 2002.

Submitting Office: Office of Institutional Assurances

Approved by:

\s\ Anne Clancy, IACUC Chairperson, 3/24/2011

\s\ William R. Morton, VMD, Attending Veterinarian, 3/30/2011

\s\ Mason Craig Bailey, Manager/Office of Animal Care, 3/24/2011