

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

<b>DEPARTMENT:</b>	Institutional Animal Care and Use Committee
<b>POLICY NUMBER:</b>	IACUC-003
<b>REPLACES:</b>	
<b>EFFECTIVE DATE:</b>	June 10, 2005
<b>REVISION DATE:</b>	March 4, 2011
<b>POSTED FROM:</b>	

**TITLE:** Protocol Amendments

**SUMMARY:**

The purpose of this policy is to describe administrative procedures for review of amendments to approved animal protocols.

**POLICY/PROCEDURE:**

- 003-1 Modifications to approved protocols may occur during the course of experimentation and must be submitted for Institutional Animal Care and Use Committee (IACUC) review and approval prior to any change in experimental procedure.
- 003-1.1 Modification requests are submitted on the "Renewal Application/Modification Request Form" to the IACUC Administrator.
- 003-1.2 Modifications that constitute a significant change are typically scheduled for full committee review per protocol review policy 004-2 but may be reviewed by designated member review as outlined in §003-2. The decision to review a significant change by designated member review will be made by the IACUC Chair in consultation with the Attending Veterinarian.
- 003-1.2.1 A "significant change" shall include, but is not limited to:
- (a) changes in the objectives or purpose of a study;
  - (b) increases in the pain, distress, or discomfort experienced by an animal;
  - (c) changes in the degree of invasiveness of a procedure;
  - (d) change from non-survival to survival surgery;

- (e) addition of a surgical procedure that results in multiple major survival surgery in an animal;
- (d) change of animal species;
- (e) addition of USDA-regulated species;
- (f) a >10% change in the number of rodents approved;
- (g) any additional number of USDA species;
- (g) use of different anesthetic agents;
- (h) change in analgesics or withholding of analgesics;
- (i) change in method of euthanasia
- (j) prolonged restraint of animals (this does not include brief restraint for the purpose of performing approved routine clinical or experimental procedures);
- (k) food or fluid restriction;
- (l) change in principal investigator.

003-2 Other changes may be reviewed by designated member review, using the following process:

003-2.1 All voting members are provided with a notification of the proposed modification and a copy of the completed modification request form;

003-2.2 All members are provided with the opportunity to request full committee review.

003-2.3 If no member calls for full committee review, the Chair designates one or more qualified members to review the proposed amendment. For changes that are not significant, the Chair typically acts as the designated member reviewer.

003-2.4 Designated member review shall be used for other changes that include, but are not limited to, the following:

- (a) addition of new animal procedures that have been approved in advance by the veterinarian;
- (b) changes in frequency or number of procedures performed on the same animal approved in advance by the veterinarian;
- (c)  $\leq 10\%$  change in the number of mice/rats used;
- (d) addition of new personnel involved in animal procedures;
- (e) addition of strains of mice/rats unless the phenotype raises the potential pain and distress category of the protocol, or if the addition includes  $\geq 10\%$  change in animals.

003-3 Any proposed change that, in the judgment of the IACUC Chair, is too extensive to be addressed by amendment shall be returned to the investigator for submission as a new protocol. The occasion may arise where multiple amendments have been submitted to an existing protocol during the course of

the approval period. If, in the judgment of the IACUC Chair, additional changes requested to an existing protocol make monitoring and review of the existing protocol too complex, the investigator may be requested to submit a new protocol.

003-5 Copies of all approved amendments will be maintained in the OAC to assure proper tracking of animal numbers and procedures by the Manager.

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