



## IACUC POLICY AND PROCEDURE STATEMENT

**Policy/Procedure:** Definitions

**Policy/Procedure ID:** 05-02-001      **Effective:** February 18, 2005

### A. Background

A Committee functions more effectively when everyone (members, researchers and administrators) “speaks the same language”. Therefore, definitions of specific, commonly used terms are provided in order to create consistency and common understanding.

### B. Policy

**Clarification / Modification** – A change to, or provision of additional information for, a submission that is required before final approval can be granted. The Committee determines at their discretion whether the requested items can be reviewed by designated review or requires review by the full committee.

**Designated Review** – Review of a protocol or proposed change to an approved protocol by less than the full IACUC in a convened meeting. In accordance with PHS Policy (IV.C.2) and the Animal Welfare Regulations (9 CFR 2.31(d)(2)), the review may only be done after each Committee member has been given a list of proposed activities to be reviewed and had opportunity to request full Committee review. In the absence of such a request, at least one member, designated by the Chair and qualified to perform the review, reviews the proposed activities and has authority to approve, require modifications (to secure approval), or request full Committee review. Often erroneously called “Expedited Review”.

**Primary Reviewer(s)** – The Committee member(s) responsible for thoroughly reviewing a submission in advance of the convened meeting and “presenting” the submission at the convened meeting. The Primary Reviewer is responsible for identifying areas of potential confusion or insufficient information in the submission and contacting the PI for clarification/additional information. No Committee member is allowed to serve as the Primary Reviewer of a protocol for which s/he is the PI or a member of the research team.

**Significant Changes** – Changes to approved protocols that require IACUC review and approval before they are implemented. As a result of the great diversity of research performed at assured institutions, the Office of Laboratory Animal Welfare (OLAW) has not provided a general definition of what constitutes a significant change. OLAW has, however, identified several kinds of significant changes to serve as examples. They are:

- Changes in the objectives of a study



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- Proposals to switch from non-survival to survival surgery
- Changes in the degree of invasiveness of a procedure or discomfort to an animal
- Changes in species or in the approximate number (greater than 5%) of animals used
- Changes in the Principal Investigator (see below for information regarding other personnel changes)
- The addition of hazardous agents in animal procedures
- Changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia

Changes in the duration, frequency, or number of procedures performed on an animal may be considered significant depending upon the nature of the change. Certain personnel additions may require IACUC review depending upon the nature of the work the individual is to perform and the level of training required in order to perform the work.

**Minor Changes** – Minor changes are changes that are not deemed significant and do not require IACUC review. Implementation of these changes should be accompanied by notification to the Office of Research Compliance in order for ORC to keep the protocol file up to date.