University of Colorado at Boulder; Office of Research Integrity; Institutional Animal Care and Use Committee			
SOP # 5	**Title: Review of Changes to a Protocol**		
Date: 01/18/2012	**Revision:** first	**Effective Date: 11/17/2010**	**Pages: 2**

1. PURPOSE

To describe how changes to a protocol are handled by the IACUC[1].

2. DEFINITIONS

2.1. **Addendum:** A form used for submitting protocol changes to the IACUC.

2.2. **Significant changes:** include but are not limited to the addition of new procedures; changes in the species; in approximate number of animals used; in Principal Investigator; in addition or deletion of a drug in anesthetic agent(s) or the use or withholding of analgesics; in the method of euthanasia; and in the duration, frequency, or number of procedures performed on an animal;.

2.3. **Administrative changes:** non-significant changes, include changes in the funding source, in personnel (other than the PI), in the use of a different UCB building location for animal housing, and in protocol title (changes in procedures due to a new grant requires an addendum).

2.4. **Qualified member who can conduct reviews**: a voting member of the IACUC who does not have a conflict of interest[2].

3. PROCEDURES

3.1. An addendum can be submitted at any time.

3.2. Changes to an IACUC protocol require submission of an addendum form for review and approval by the IACUC before the changes can be implemented.

3.3. Addenda with the following elements may be reviewed through a designated member review as long as no member requests a full committee review and at least three members conduct the designated member review of the addendum:

- major survival surgery
- death as an endpoint
- unrelieved pain and distress

3.4. Change in the purpose of the study usually requires a new protocol. Other substantial changes to the protocol may also require submission of a new protocol if deemed necessary by the committee.

3.5. Review of Administrative Changes: Amendments that contain administrative changes can be reviewed and approved by the IACUC Administrator.

3.6. Review of other significant changes: If amendments contain significant changes other than the criteria outlined above, amendments are assigned to a designated member review. The reviewer must be qualified to conduct a review.

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[1] PHS Policy IV, B: "As an agent of the Institution, the IACUC shall with respect to PHS-conducted or supported activities:… 7. review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities…"

[2] PHS Policy IV, C, 2: "No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC…"

- A list of amendments containing significant changes is provided to all IACUC members, and full committee review can be requested at any time for any such amendments submitted to the IACUC office for review.
- If full committee review is not requested, at a minimum, one qualified IACUC member will review the changes. The designated reviewers can approve or require modification in order to approve the amendment, or request full-board review. Designated members cannot disapprove an addendum.
- If full committee review is requested, the addendum must be reviewed at a convened meeting and approved by a majority of a quorum present.

4. Outcomes of IACUC Actions Concerning Amendments:

4.1. If the protocol is approved, the approval letter and approved addendum will be sent to the investigator indicating that animals may be ordered and research covered by the protocol may begin.

4.2. If the protocol is approved pending modification:

- A request for modifications will be sent to the investigator and she or he will be asked to respond by a prescribed time.
- Upon receipt of the modifications, the designated member(s) will review the responses and either verify that it is adequate and approve, or require further modifications.

Overview of changes:

	Major Significant changes	**Other Significant Changes**	**Administrative Change**
Review Type	Full Board or designated member review; may require a new protocol	Designated member review	IACUC Administrator, and other as necessary
Average Turn-around Time	Next IACUC meeting For deadlines see: http://www.colorado.edu/VCResearch/integrity/animalcare/Protocols.html For DMR: 3-14 days	3-10 days	1-2 days