

UCI IACUC PROTOCOL MODIFICATION INSTRUCTIONS

SUBMISSION REQUIREMENTS AND PROCEDURES:

1. An original Request for IACUC Protocol Modification form, completed and signed by the Lead Researcher and Faculty Sponsor (if required).
2. A brief narrative summary attached to the Modification Request form which summarizes the proposed change, the rationale for making the change, and a discussion of any potential impact of the proposed modification on animal well-being.
3. A revised version of the entire approved protocol, in which the proposed modification has been **incorporated and highlighted** to ensure that the additions and/or changes are clear to IACUC reviewers. NOTE: Lead Researchers and their staff are responsible for maintaining the current approved version of all animal protocols.
4. For designated and full committee review, submit **one signed original** of the Modification Request Form and Narrative, plus an updated protocol narrative with the changes clearly highlighted to the IACUC Administrative Office. Modification requests received before 3:00 p.m. Friday may be eligible for subcommittee review the following Friday. The Lead Researcher will be notified once the required level of review is determined, and may be contacted for additional information or clarification as necessary. Modifications that are submitted for designated review but require full committee review will be reviewed according to the posted deadlines on the Web
5. For minor changes such as the addition of a funding source or new research personnel, submit the original modification form only, along with a narrative explanation of the change and an updated/highlighted protocol narrative. For additional personnel, be sure to include a description of what role/responsibility each person will fulfill on the project and a description their relevant experience and/or training in the appropriate section of the updated protocol.
6. Requests to modify approved IACUC protocols cannot be submitted via the web portal at this time. Modification requests may be submitted via email attachment by sending them directly to the IACUC administrative mailbox at IACUC@uci.edu or they can be delivered in hard copy via personal delivery or campus mail to the Office of Research Administration , 300 University Tower, zot code 7600.

LEVEL OF REVIEW

Many factors may contribute to the level of review a protocol modification receives from the IACUC. In general, addition of a new species, or addition of a new procedure that increases the invasiveness or the amount of pain or distress an animal experiences requires a full committee review. However, if the study objective changes significantly, a new protocol may be required. Consultation with a ULAR Veterinarian (824-5271, -0569 or -4666) or the IACUC Administrator (824-8170) is **strongly recommended** before submission of any modification.

Less significant changes to an approved protocol (e.g., addition of a non-invasive procedure and changes in drug dosages) may be eligible for Designated Review by an IACUC subcommittee that meets weekly. However, all modifications may require full committee review if any committee member requests it. Please refer to the IACUC Website <http://www.rgs.uci.edu/ora/rp/acup/protocolmodification.htm> for a more in-depth discussion of the different levels of review.

HOW TO INCORPORATE AND HIGHLIGHT CHANGES

Effective June 1, 2007, all requests to modify existing IACUC protocols must be accompanied by an updated copy of the complete protocol with the modification incorporated and highlighted. To do this:

- Open the current version of the approved protocol (which has been saved and labeled as described in the application instructions under Part 2, Conditions of Approval - LEAD RESEARCHER RECORD-KEEPING RESPONSIBILITIES (<http://www.rgs.uci.edu/ora/forms/iacuc/instructions.htm#part2>)).
- Set the "Track Changes" feature in Microsoft Word®.
- Revise each section of the protocol application affected by the proposed change.
- Save the modified protocol (**do not** click "Accept Change" at this time, as that will make the highlighting disappear).
- Submit the protocol with the changes incorporated and highlighted, along with the Modification Request Form and narrative.
- Click here to see a sample [original protocol](#) and a [revised/highlighted](#) one. [Prot2007-9999Updated4-1-07.doc].

Once approved, the changes will be accepted by the IACUC Administrative Office and a clean copy will be returned to you, to be saved as the currently approved version.

NOTE: Lead Researchers are responsible for keeping accurate and complete protocol records, and for ensuring that all members of the laboratory staff are familiar with the protocol and all approved procedures.