

Protocol Review & Facility Assessment

Item 4 - Protocol Amendment (Addendum)

Institutional Animal Care and Use Committee (IACUC) review of all procedures using animals in research or teaching is required by law. Before any significant changes to animal use in existing protocols can be performed, a protocol addendum form must be completed (available from the IACUC Office or online at <http://www.upstate.edu/iacuc/forms.php>) and submitted to the [IACUC Office](#) for approval.

The IACUC has designated that the addendum will be reviewed by the AV (or Clinical Veterinarian if the AV is not available or there is a conflict of interest) and the original primary reviewer of the protocol. These individuals are designated to evaluate and review all activities related to the care and use of animals and determine if the proposed activities are in accordance with federal regulations. If the primary reviewer is no longer available to conduct the review, the Chairperson will designate a new reviewer.

Significant changes that would require the submission of an addendum and IACUC review include, but are not limited to: changes in animal numbers, addition or deletion of new anesthetics or drug, the addition or deletion of a new phase of the study or principal investigator change.

Non-significant changes to an existing protocol (i.e. new personnel, title change, room number change, strain change, change in sex - depending on species and how the change will affect the animal) do not require the submission of an addendum. Non-significant changes should be submitted in writing to the IACUC Office.

A new protocol form must be completed if there is a change in the research objective being investigated or if there is a significant change in the procedures to be used.

Process

1. IACUC administrator will route the addendum form to the Attending Veterinarian (AV).
2. If the AV determines that the proposed change **meets the criteria** for Veterinary Verification and Consultation (VVC), the addendum will be processed according to IACUC-approved policy, [Item 5 – Veterinary Verification and Consultation](#).
3. If the AV determines that proposed change **does not meet the criteria** for VVC, the addendum will be processed for review as follows:
 - a. The addendum will be sent to the designated reviewers for review and to all other members to provide comments and/or call for full committee review. All members will be given 7 days to review the document and respond back to the designated reviewers or the IACUC Office with comments, questions or call for full committee review.
 - b. If full committee review is requested, the addendum will be discussed at the next scheduled IACUC meeting.
 - c. If full committee review is not requested, the original primary reviewer (or member designated) and AV will review the addendum and decide on one of the following actions:
 - 1) approve as written, or
 - 2) require modifications to secure approval
 - d. If modifications are required in order to secure approval, the principal investigator should address them in a revised addendum. However, an email response from the principal investigator may be accepted at the reviewers' discretion.
 - e. When all questions/concerns have been resolved, the reviewers will confirm approval with the IACUC administrator.
 - f. The IACUC administrator will verify personnel training for any added procedures.
 - g. The IACUC administrator will notify the PI of approval.
4. Approval of an addendum must occur within six months of submission date or the addendum will be withdrawn from further consideration.

Adopted: 3/29/1999

Revised: 2/20/2017