

## CHANGES TO APPROVED ANIMAL USE PROTOCOLS (AMENDMENTS)

The Animal Welfare Regulations (9<sup>th</sup> CFR USDA Regulations) and the Public Health Service Policy require that the Institutional Animal Care and Use Committee (IACUC) review and approve any proposed significant change to an Animal Use Protocol (AUP). Proposed changes to an AUP must be reviewed and approved by the IACUC. A proposed change to AUP at The Ohio State University (OSU) may not be initiated until notification of IACUC approval has been received.

Investigators who wish to propose a change to a currently active AUP should submit a request using the eProtocol system. The requested amendment must fit with the objectives, purpose, or aims stated in the original protocol. If this requirement is not met, then the IACUC will require submission of a new protocol. After completeness of an Amendment Request is verified, the amendment is scheduled for the appropriate review based on the review criteria outlined below.

### A. Amendments are considered significant (major) when they include (but are not limited to):

1. change in species
2. addition of animal numbers >10% larger than the approved number of rodents
3. any additional number of USDA species
4. housing > 12 hours in a non-ULAR facility for USDA species, >24 hours for non-USDA species
5. non-survival to survival surgery
6. addition of a surgical procedure that results in multiple major survival surgery in any animal\*
7. change in type of survival surgery in USDA species
8. change in degree of invasiveness of a procedure
9. any procedure that would fall in the USDA pain category E\*
10. increase in the duration of pain, discomfort or distress to an animal
11. restraint of animals for > 1 hour\*
12. hazardous agents administered to animals
13. Principal Investigator (PI) change
14. addition of neuromuscular blocking agents
15. change in euthanasia procedures
16. any procedures other than observation only studies involving non-human primates\*
17. unrelieved pain/ distress\*
18. any change in anesthetic or analgesic drug regimens
19. addition of sample collection times

\*Changes that automatically require review at a convened committee meeting.

### B. Amendments may be considered minor when there are changes in:

1. addition of humane endpoints which result in less pain/distress
2. increase in numbers of rodents less than 10% of the approved numbers
3. addition of non-invasive sampling/analysis
4. addition of another strain/stock of the same animal species

5. addition or removal of personnel other than the PI to or from a protocol
6. change in animal use location

For requests that do not clearly fall into any category, the IACUC Chair will determine whether the amendment request is considered minor or significant.

**C. Review Process for Significant Amendments**

Amendment Requests proposing significant activities or changes as outlined above will be evaluated by the standard IACUC review process.

**D. Review Process for Minor Amendments**

Amendment involving minor changes will be reviewed by a ULAR Clinical Veterinarian (or designee) and the IACUC Chair (or designee). The amendment will be considered approved once the IACUC Chair has voted for approval within the eProtocol system. Notification of all minor amendments will be sent to the IACUC the week in which the minor amendment was approved. Any IACUC member can request further review of a minor amendment.

Proposed change requests that only involve adding or removing personnel other than the Principal Investigator on an AUP should be submitted to the IACUC utilizing the propose and submit study team change activities in the eProtocol system. Changes in personnel cannot be submitted until all training requirements and registration in the Occupational Health registry is up to date for all individuals listed on the protocol. Such changes will be considered approved when the IACUC support staff verifies the training narrative is complete for any additional personnel.