

## Guidelines on Amendments to IACUC Approved Animal Use Protocols

This resource is meant to provide guidance to principal investigators at James Madison University on what constitutes a major vs minor amendment (change) to a protocol.

- Significant amendments a protocol require IACUC review.
  - Examples of significant amendments include:
    - Change in purpose or specific aim of study
    - Change of principal investigator
    - Change of species
    - Addition of species
    - 20% or more increase in animal numbers over the number approved on the initial protocol and any subsequent committee reviewed amendments
    - Addition of a survival surgery
    - Addition of a painful procedure
    - Unanticipated marked increase in clinical signs or proportion of animal deaths
    - Addition or change of anesthetic or analgesic agent or a change in dosage
- Minor amendments are processed through the IACUC office as administrative changes or through Designated Member Review (DMR).
  - Examples of minor amendments include:
    - Changes to contact information of the PI or study personnel
    - Changes to training updates of the PI or study personnel
    - Addition or deletion of study personnel
    - Addition of faculty collaborator
    - Addition of another strain of the same species
    - Change of sex in the animal to be used
    - <10% increase in animal numbers over the number approved on the initial protocol and any subsequent committee reviewed amendments
    - Addition of sample collection times (if not exceeding standard limits - with veterinary consult as needed)
    - Additional non-invasive sampling (if not exceeding standard limits - with veterinary consult as needed)
    - Reducing or eliminating previously approved water or feed restrictions
    - Addition of or change in dosage of an experimental drug in the same class as one previously approved
    - Addition or deletion of animal usage location