

Name: Minor Amendment Request
Number: FSU-SOP- 190.01
Category: General Procedures

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Revised: --
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1.0 Purpose

IACUC protocols are typically approved for three years. It is the expectation that any protocols approved are implemented as written; however, there may be occasions where minor revisions must be made to an approved protocol. This SOP describes the procedures for submitting requests for approval of a Minor Amendment, and outlines what constitutes a minor revision. It is the responsibility of the PI to carefully read and follow this SOP as a condition of approval.

2.0 Policy

- 2.1 Any protocol contained in an application approved by the IACUC is to be implemented as written. Protocols are typically approved for a three-year period, with the expectation of annual review.
 - 2.1.1 If the PI desires to change any of the procedures that have been approved in the application, these changes must be formally submitted to the Chair of the IACUC prior to implementing these changes. These changes will be subject to the approval of the IACUC, which may include approval from the Chair or Vice Chair. If after reviewing the request the Chair or Vice Chair deems it necessary, a Designated Member Review or a full committee review may be conducted.
 - 2.1.2 Any implementation of procedures that deviate from those contained in the approved application, which have not been approved by the committee, would constitute implementing a non-approved procedure.
- 2.2 Any time there is a need for a Minor Amendment, this request should be submitted to the Chair of the IACUC at iacuc@fitchburgstate.edu prior to implementing the changes sought.
 - 2.2.1 Examples of changes that could be approved via Minor Amendment include:
 - 2.2.1.1 Small change (less than or equal to 50%) in animal numbers used for research or teaching activities
 - 2.2.1.2 Change in acclimation period
 - 2.2.1.3 Change in diet
 - 2.2.1.4 Addition/deletion of procedure that is less invasive than the approved protocol
 - 2.2.1.5 Addition of minor procedure (causes minimal or less pain or distress)
 - 2.2.1.6 Addition of sample collection times
 - 2.2.1.7 Addition of noninvasive sampling
 - 2.2.1.8 Change in age of animals
 - 2.2.1.9 Change in housing conditions

- 2.2.1.10 Change in strain of animal species
- 2.2.1.11 Change in sex of animal
- 2.2.1.12 Change in species of animal, provided that the new species is a comparable alternate species to that originally proposed
- 2.2.1.13 Addition or deletion of a faculty collaborator
- 2.2.1.14 Addition or deletion of student researcher
- 2.2.1.15 Change in protocol title
- 2.2.1.16 Transfer of animals to another PI (if same strains are approved for both PIs)
- 2.2.2 Changes should be made on the original submission, with the changed text highlighted throughout the protocol
- 2.2.3 The revised/highlighted protocol should be submitted along with a cover letter which explains the reason(s) for the minor amendment, and describes the changes to the protocol that accompany each of the reason(s)
- 2.2.4 If new personnel are added, please also be sure to submit proof of completed training on all required training (e.g. Responsible Conduct of Research, IACUC-required training modules, etc.) along with the revised/highlighted protocol, as necessary
- 2.2.5 Any non-emergency protocol changes must be approved by the IACUC BEFORE these changes are implemented. An emergency would constitute any event that impacts, or has the potential to impact, the health and/or welfare of the animals. If you are uncertain if your change is an emergency, please contact the Chair of the IACUC.
- 2.2.6 Failure to request approval for changes, and to gain this approval, may require all animal use activity under this protocol to stop and a new protocol application to be submitted and approved by the IACUC.

VERSION #	APPROVED	DETAILS
190.01	5/26/2022	Authored by R.Shapiro, D.Welsh