

Document Number: ANP040	PROCEDURES FOR RECORDING AMENDMENTS TO EXISTING ANIMAL PROTOCOLS <i>CONFIDENTIAL INFORMATION</i> MOLECULAR MEDICINE RESEARCH INSTITUTE	Effective Date: January 2005
Section: Animal Research		Supersedes Date:
Subsection: Facility		Page: 1 of 2

1.0 OBJECTIVE

- 1.1 The objective of this procedure is to describe the procedures for amending designated experimental animal protocols at the MMRI Animal Research Facility.

2.0 SCOPE

- 2.1 This procedure applies to study protocols for animals used for experimentation.

3.0 POLICY

- 3.1 It is the policy of MMRI to establish written and approved procedures to ensure that the health and well being of employees is protected, and that potentially hazardous procedures are performed in a safe manner.
- 3.2 Minor changes to an Animal Care and Use Protocol can be submitted in the form of an amendment; a new protocol is required for major changes. Major changes include a substantial change in a study procedure.
- 3.3 Amendment review will require a meeting of three members of the IACUC body including the institutional veterinarian, the IACUC chair, and one other member of the committee.
- 3.4 OLAW guidelines allow the IACUC scope to decide upon institutional definitions of minor and major changes to existing animal study protocols.

4.0 RESPONSIBILITIES

- 4.1 It is the responsibility of Manager of Animal Research or designated alternate to implement this procedure and revise it when necessary.

5.0 REFERENCES

- 5.1 OLAW Guidelines
- 5.2 MMRI IACUC guidelines
- 5.3 MMRI Amendment Form

6.0 PROCEDURE

- 6.1 If any of the following changes are made to an existing animal study protocol, an amendment is required: name changes, addition or deletion of personnel, addition of closely related species, new drug or agent, dosages, or, minor changes in procedures.

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6.2 An amendment will be in the form of a memo with the following format:

Date:

To: Animal Use and Care Committee, c/o Director of Animal Research

From: Principal Investigator (and signed by the PI)

Re: Amendment to Protocol # _____

The amendment will include the following information:

a. Proposed Changes: Briefly state what you would like to amend on your protocol, then describe the change(s) in detail (who, what, when, where, why and how, if applicable). Does this change require any increase (decrease) in the number of animals or does it only apply to the animals already approved?

Examples of information that should be included with a proposed change:

i. Addition of personnel: Include name, title and if person(s) will have significant animal contact.

ii. Addition of species or increased (decreased) numbers: include how many of each species requested and provide a justification.

iii. Addition of physical, chemical or biological agents: include dose, route and frequency. (The method of anesthesia should be included for each new species.)

b. Justification of requested amendment (the reason why the amendment is needed).

c. Signature: The Principal Investigator must sign or initial the amendment and the amendment must be complete. If the amendment is not clear and complete, it will often be tabled and approval will be delayed.