

SOP:	105.7 Animal Use Protocol (AUP) Modifications and Renewals		
Version Date:	10-2024		
Review By:	10-2027		
Subject:	To describe the submission and approval process for modifications to AUPs		
	and animal protocol renewals.		
Related Documents	SOPs 100, 103		

Modifications

1. Modifications to previously approved protocols must be approved by the AREB prior to their implementation.

Minor Modifications

- 1. A minor protocol change is defined as a change that does not have a significant effect on the safety or well-being of animals. Minor modifications include, but are not limited to: changes in personnel, the addition of a small number of animals (less than 10% of total animals (other than zebrafish) and less than 20% of total zebrafish), changing housing or procedure location, and minor procedural changes that do not result in increased pain and/or distress to the animals associated with the AUP. Determining whether a modification should be considered minor will be up to the discretion of the AREB chair.
- 2. Minor modifications to approved projects must be submitted through the online application system using the appropriate form(s) and must outline, minimally: the nature of the proposed changes, the reason(s) for the request, and an assessment of any potential harmful implications to the animals arising from the request.
- 3. Minor modifications are reviewed and approved by the AREB Chair, in consultation with Animal Care & Ethics Staff.
- 4. In cases where the AREB Chair is named as an investigator, co-investigator, supervisor, or has a relationship with the investigator resulting in a real or perceived conflict of interest, the AREB Vice-Chair, or delegate, in consultation with Animal Care & Ethics Staff, may approve minor modifications.
- 5. Minor modifications will typically be addressed within five (5) business days of receipt.

Major Modifications

1. A major modification is defined as a change that significantly alters the approved protocol, including, but not limited to: a substantial increase in the number of animals required for use, a change of species, the use of more invasive or more frequent procedures, the use of entirely new procedures, procedural changes that may result in increased pain and/or distress to the animals, or

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any other changes that do not fall within the definition of minor modifications.

2. Major modification requests will require the submission of a new AUP and be subject to full AREB review, as per SOP 100.

Annual Renewals

- 1. All AREB approved protocols continuing past twelve (12) months of the original date of approval by the AREB require annual renewal prior to expiration (expiration date is one year following approval), to a maximum of three (3) renewals.
- 2. Requests for renewals must be submitted through the online application system using the appropriate form(s). If minor modifications are to be made at this time, a modification request form must also be submitted. If major modifications are to be made at this time, a new AUP must be submitted, as per SOP 100.

CCAC Category of Invasiveness A, B, or C

1. Annual review of renewals for ongoing protocols that are CCAC Category of Invasiveness "A", "B" or "C" and that are not proposing major changes to the protocol will be reviewed by a subcommittee of the AREB, consisting minimally of the AREB Chair or Vice-Chair; the Consulting Veterinarian; one (1) community representative; and one (1) member with relevant expertise. At any time, any of the subcommittee members may stipulate that the protocol should go to full AREB Review.

CCAC Category of Invasiveness D or E

1. Annual review of renewals for ongoing protocols that are CCAC Category of Invasiveness "D" or "E" will undergo full board review at the next scheduled AREB meeting.

Previous Versions

SOP Number	Date Effective	Summary of Changes
105.0	07-2010	
105.1	12-2011	
105.2	05-2012	
105.3	11-2013	
105.4	11-2016	Minor administrative edits.
105.5	10-2019	Minor updates to the submission process.
105.6	10-2021	Staff position terms updated
105.7	10-2024	Vice-Chair position, ROMEO removal.

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