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| **SOP:** | **105.5** | **Animal Use Protocol (AUP) Modifications and Renewals** |
| **Version Date:** | 10-2019 |
| **Review By:** | 10-2022 |
| **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 and less than 20% of total fish), 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 or not 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 ROMEO 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 the Research Ethics Officer.
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 the Research Ethics Officer, 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 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 ROMEO 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 designate; 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**

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| **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 (Current) | 10-2019 | Minor updates to submission process. |