AEEC Standard Operating Procedure
SOP for Protocol Amendment

Objective	To provide standard review and approval process for amendment requests to AEEC approved protocols
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Approved	25 May 2023
Version	1

Introduction

The AEEC recognises that animal experimentation is dynamic and amendment to approved projects is often necessary during the validity period. The purpose of this Standard Operating Procedure (SOP) is to describe the review and approval processes for amendment request to approved research and teaching protocols.

The validity of research and teaching protocols are 5 years and 3 years respectively from the date of approval. The approval is for the species, procedures, personnel and locations described in the protocol and any variation of these requires additional endorsement or approval from the AEEC. Any variances must be approved before implementation.

The following amendments will not be processed:

- Change in the animal species used
- Adding procedures that do not logically relate to the specific aims of the original protocol
- Unrelated change in the scientific aims of the original protocol application
- Switching from non-survival to survival surgery
- Switching from single to multiple survival surgeries on the same animal

A new protocol application must be submitted to incorporate any of the above changes, as the new issues arising related to animal welfare will need to be reviewed.

NOTE: Investigators may use fewer animals than approved. This does not require AEEC approval, notification, consultation, or administrative handling.

Amendment Category & Process

1. Administrative Review

Changes that are handled administratively by the AEEC Secretariat Office are:

1. Update on Animal Licence issued by the Department of Health.
2. Changes in personnel, other than the PI.
3. Correction of typographical or grammatical errors.

Changes that are handled administratively by the AEEC Secretariat Office and approve by AEEC Chair are:

1. Changes in protocol titles, provided that congruency has been confirmed and other modifications are not necessary.
2. Transfer of protocol from one PI to another PI.
3. Extension of protocol for up to 1 year.
4. Transfer of animals to another protocol where animals (same stock/strain) are already approved on that study

2. Amendments eligible for Veterinary Verification & Consultation (VVC)

The AEEC interprets "minor" changes to an animal study protocol as those that do not have a substantial impact on the health and well-being of research animals or that may decrease the potential for pain or distress (i.e. a refinement).

The following are changes regarded as "minor" and require only the Attending Veterinarian (AV), Animal Ethics & Welfare Officer (AEO) and AEEC Chair's approval:

1. Adding or changing the location where animal procedures are conducted
2. Addition of animals (10% or less than the original approved number)
3. Changes in euthanasia procedures
4. Changes in anaesthesia methods
5. Changes in animal monitoring and analgesic plan
6. Changes in strain or gender of animal, provided that the strain does not have potential health problems related to phenotype
7. Changes in duration, frequency, type (e.g. blood collection site or volumes, route of administration, volumes, and dosages) performed on an animal contingent upon them not exceeding published guidelines
8. Minor changes in surgical procedures, e.g. from midline to frank approach

The request would be approved, required modifications in (to secure approval), or be requested Full Committee Review (FCR) by AV or AEO.

3. Amendments not eligible for Veterinary Verification & Consultation (VVC)

All other changes not falling under administrative or VVC categories would require Designated Member Review (DMR) or Full Committee Review (FCR), as agreed by the AEEC Chair.

Designated Member Review (DMR)

The request would be reviewed by AV and at least one member of the AEEC, appointed by the Chair and qualified to conduct the review. The request would be approved, required modifications (to secure approval), or be requested Full Committee Review (FCR).

Full Committee Review (FCR)

The request would be reviewed and discussed during the monthly AEEC meeting. The decision for approval, reviewed by designed members or approval withheld would depend upon the vote of a majority of the quorum present in the meeting.

PI will be notified in writing the result of the amendment request.

Amendment submission

Applications that are made on the Tick@lab portal should submit amendment request using the amendment function on Tick@lab. Applications that are made on paper forms should submit the required documents as listed in the Appendix to the Secretariat Office via the online platform.

If the protocol changes involve the use of a hazardous agent (e.g. radioisotope, toxic chemical, biological agent, or genetically modified material), an updated risk assessment and Safety Approval from the University Safety Office is required.

Appendix - Amendment Documentation Checklist

	Required documents	**Supporting documents** (where applicable)
Minor Amendments (Administrative or AAV)		
Project Title	• AEEC form cover page	• Grant allocation letter
Animal License	• Valid Animal licence (with at least 2 months validity)	
Personnel involved in experimental procedures (Add/remove users)	• Personnel amendment cover page with PI and new users' signatures • Valid Animal license (with at least 2 months validity)	• Training record
Extension of Project	• Justification letter from PI	
Change PI	• Letter from PI • AEEC form with PI and Department Chair or School Director's signature	
Location for research	• Relevant experimental forms • Valid Animal license with new location listed (with at least 2 months validity)	• Animal movement arrangement • Approval from facility manager
Animal strain/Quota (<10%)	• Relevant experimental forms • Valid Animal license (with at least 2 months validity)	• Supporting literature • Current findings • Power calculations • Any adverse events
Humane endpoint/analgesic anaesthesia method	• Relevant experimental forms	• Discussion with vet • Supporting literature • Current findings • Any adverse events
Minor changes in experimental Procedures	• Relevant experimental forms	• Supporting literature • Current findings • Power calculations • Any adverse events
Major Amendments (DMR or FCR)		
Major changes in experimental procedures	• Relevant experimental forms	• Supporting literature • Current findings • Power calculations • Any adverse events
Additional procedures	• New experimental forms • Valid Animal license with new procedures (with at least 2 months validity)	• Supporting literature • Current findings • Power calculations • Any adverse events
Animal quota (>10%)	• Relevant experimental forms • Valid Animal license (with at least 2 months validity)	• Supporting literature • Current findings • Power calculations • Any adverse events
Food or fluid restriction	• Relevant experimental forms	• Supporting literature • Current findings • Any adverse events
Physical restraint	• Relevant experimental forms	• Supporting literature • Current findings • Any adverse events
Change in the use of hazardous agents	• Relevant experimental forms	• Supporting literature • Current findings • Any adverse event • Safety Approval memo