

## **Review and process of amendments to approved AEC projects**

This document is to provide an overview of the concept of amendment to existing approved protocols, and a guidance for La Trobe animal users to understand the amendment request review process.

### **1. Review and approval of minor amendments**

- 1.1. Minor amendments may be approved by the Executive Committee of the Animal Ethics Committee (AEC). All minor amendments approved by the Executive on behalf of the AEC must be ratified by the full committee at the next meeting (the Code 2.2.23 (ii)).
- 1.2. Animal Welfare Victoria guidelines for the conduct of AECs require that AEC procedures provide guidance on the type of activity that would be considered a minor amendment and could therefore be approved by the AEC Executive. The essential criterion that must be met is provided in Section 2.2.23 (ii) of the Code, which states that “a minor amendment may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress”.

### **2. Evaluation of amendments to AEC approved projects**

- 2.1. When determining whether an amendment is minor the welfare of the animals must be considered. Amendments that have potentially high animal welfare impact (for example justification for inducing pain in the absence of analgesia, single housing for social species, queries as to why valid alternatives are not used) must be considered by a quorate meeting of the AEC.
- 2.2. Examples of minor amendments provided in the Animal Welfare Victoria guidelines are:
  - addition of suitably experienced personnel
  - minor changes to procedures: where “minor” is defined as any change that has little or no impact on the wellbeing of the animals involved in the project; for example, verifying dose rates for drugs, needle sizes, routes of administration where the impact to the animals is the same or less than originally approved
  - opportunistic diagnostic or veterinary activities intended to benefit the animals
  - re-activation of paused projects.
- 2.3. To the above, the following change can be included:

- removal of personnel
- time extension (provided all approved activities still meet best practice standards)
- change to the number of animals required to ensure that results are statistically significant (for example, because planned breeding produced too few of a required strain) or to replace animals whose results cannot be included (perhaps as the result of an adverse event)
- performance of a procedure already approved for the project on one strain of animal to a different strain, provided the change of strain has no impact on the outcome of the procedure
- addition of a new strain to a breeding application where no resultant changes are needed to the monitoring or to procedures that may need to be performed on the animals
- addition of a new collaborator
- update to the list of procedures to be performed by an investigator named on the project, where that investigator is listed on TRACR as competent in the additional procedure(s)
- a person's competence to perform a procedure where no exercise of judgement is required (for example, competency is confirmed by an authorized person at another institution or a trainer confirms that a person has met AEC-approved assessment criteria for the performance of a procedure). The following rules apply:
  - Competency Assessments based on satisfactory completion of an AEC-approved Training & Assessment Plan do not need to be reviewed and approved by the AEC.
  - Confirmations of competency from another institution with its own AEC (received on the AEC-approved Confirmation of Competency form) do not need to be reviewed and approved by the AEC.
  - Competencies claimed by La Trobe staff and students and external personnel, other than those covered by 1 and 2 above, need to be reviewed and approved by the AEC.
- phenotype reports, where the phenotype requires no new measures to be introduced than have already been approved for the associated project(s).

The above list is not meant to be exhaustive. In cases not covered by the above, the AEC Chair will refer requests for amendment to the AEC Executive based on an assessment of the likely pain and distress in accordance with Section 2.2.23 (ii) of the Code.

**References:**

1. The Australian code for the care and use of animals for scientific purposes 2013
2. The Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits
3. Guidelines for conduct of AECs Feb2018 FINAL (Agriculture Victoria)