



‘Death as an endpoint’ scientific procedures

Guidance note

Introduction

Death as an endpoint (DAEP) scientific procedures are rare, very high-impact animal procedures where death of the subject animal is a deliberate measure in the procedure and where there will be no intervention to kill the animal humanely before death occurs in the course of the procedure or procedures.

Such procedures are prohibited in Victoria unless:

- the objective of the procedure or procedures cannot be achieved by any other scientific means; **and**
- the procedure or procedures are approved by the Minister for Agriculture and are carried out in accordance with approval and any conditions determined by the Minister.

DAEP does not include the death of an animal due to unexpected adverse events, the humane killing of an animal as planned in an Animal Ethics Committee (AEC) approved project or due to the condition of the animal.

This guidance note will assist investigators prepare an application for Ministerial approval to undertake such procedures and provide guidance to the responsible AEC.

DAEP scientific procedures requires ministerial approval

The Minister may only grant approval when the scientific procedure is related to:

- potentially life-saving treatment for animals or human beings; or
- research in connection with cancer in animals or human beings; or
- development and assessment of the humaneness of lethal vertebrate pest control agents; or
- investigation of environmental contaminants.

Steps to obtain approval for DAEP scientific procedures

Project preparation

The principal investigator must determine that the proposed project satisfies the criteria defined by the *Prevention of Cruelty to Animals Act 1986* (POCTA Act) and associated Regulations (see above).

The principal investigator may then prepare a project application using the institution’s internal procedures for applying to the AEC.

The application to the AEC must comply with the POCTA Act and associated Regulations including the *Australian code for the care and use of animals for scientific purposes 2013* (Australian code). Animal Welfare Victoria (AWV) recommends that applicants review the list of reasons a project may require revision and resubmission, prior to submission to the AEC, see section C of this guidance note.

Death as an endpoint must be replaced with early experimental and humane endpoints whenever possible. Where DAEP is essential for the aim(s) of the project and cannot be avoided:

- the project must be designed to minimise the number of animals that will die; and
- steps to avoid or minimise pain and distress, including early experimental and humane endpoints, must be considered, implemented, and reviewed at all stages of the project.

AWV expects implementation of the governing principles of the Australian code be incorporated into project planning and the application to the AEC. For example, data collection using suitable biomarkers to identify earlier endpoints and allow recalculation of the number of animals required.

AEC review and approval

The AEC must be informed that the proposed project includes DAEP scientific procedures.

The AEC reviews the project application and, when it is satisfied that the project fully complies with the licence conditions including the Australian code, may approve the project.

The project must not commence until Ministerial approval is obtained. AWV recommends the AEC apply a condition of approval reflecting the requirement to obtain Ministerial approval prior to project commencement.

Submission of an application

The project principal investigator named on the AEC approved project may apply to the Minister for Agriculture via the Manager, Licensing and Audit team, AWV, Department of Jobs, Precincts and Regions. Email sp.licensing@ecodev.vic.gov.au for the application form.

The applicant must ensure all information as specified within the application form is included. The licence nominee must endorse submission of the application.

Animal Welfare Victoria assessment and recommendations to the Minister

The Licensing and Audit team, AWV, will assess the application for Ministerial approval based on the application provided to the AEC, any referenced standard operating procedures (SOPs), associated AEC comments and communication, and any other relevant information.

If the criteria under which the Minister may approve DAEP scientific procedures are not satisfied, the application will not be approved and AWV will communicate the reason(s). If the principal investigator wishes to resubmit the application, they should obtain independent legal advice prior to doing so.

The application for Ministerial approval, the AEC-approved project and any associated SOPs must comply with the POCTA Act, associated Regulations and the Australian code. Should the Licensing and Audit team's assessment determine that the project broadly satisfies the criteria for Ministerial approval but does not fully comply, it will be returned to the principal investigator for revision. Depending on the nature of the revision the AEC may need to reconsider an amendment to the project at a quorate meeting prior to resubmission for Ministerial approval.

Reasons projects may require revision and resubmission include:

- failure to ensure project design is consistent with 'current best practice';
- failure to include a step-by-step description of what will happen to each animal, or group of animals, for the duration of the project;
- failure to implement earlier endpoints due to advancement in knowledge or technology;
- inadequate application of the principles of replacement, reduction, and refinement (3Rs);
- inadequate justification for failing to fully apply the 3Rs or current best practice – note: justification that includes insufficient resources, equipment, or competency is not acceptable;
- referencing of SOPs does not comply with the Australian code;
- poorly defined humane and/or scientific endpoints;
- inconsistencies between various parts of the AEC project and/or referenced SOPs;
- inconsistencies between the AEC project application and the application for Ministerial approval;
- errors in calculations of group sizes and number of animals requested;
- inclusion of information unrelated to the proposed project – for example cut and paste errors.

Upon receipt of a compliant application with evidence of AEC approval, the Licensing and Audit team will make recommendations to the Minister.

The Minister's decision will be communicated to the principal investigator by the Licensing and Audit team. The project must not commence until written notification of Ministerial approval is received.

The process of project assessment and consideration by the Minister may take up to two months after receipt of a compliant application. Where the project involves novel techniques or procedures legal advice may be sought by AWW. This may result in delayed consideration by the Minister.

Amending an already approved DAEP project

The process for amending an already approved project will depend on the nature of the proposed change.

Minor amendments

In accordance with the Australian code, a minor amendment is considered 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.

Amendment of an approved project that is considered minor, must be communicated to the Licensing and Audit team in writing, after approval by the AEC. The notification must include the reason for amendment, the amended AEC approved project, and evidence of AEC approval.

If found compliant and consistent with a minor amendment, the Licensing and Audit team will acknowledge the notification of amendment.

The amendment must not be implemented until such acknowledgement is received. Investigators should allow at least four weeks for such acknowledgement.

Amendments requiring Ministerial approval

The Minister must approve all other (non-minor amendments). For the purpose of assessment of DAEP applications this is considered to include an increase in animal number, change in principal investigator or extension of duration of approval.

A written submission to amend an approved project, including the reason for amendment, the amended AEC approved project, and evidence of AEC approval, must be provided to the Licensing and Audit team.

The Licensing and Audit team will assess the proposed amendment and make recommendations to the Minister.

The Minister's decision will be communicated to the applicant by the Licensing and Audit team. The amendment must not be implemented until written notification of Ministerial approval is received, which may take up to two months, or longer depending on the complexity of the proposal.

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