



RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House

PROJECT APPLICATIONS

Statement of Intent and Outcomes

The St Vincent's Hospital (Melbourne) Animal Ethics Committee (AEC) is committed to fulfilling the governing principles of the *Australian code for the care and use of animals for scientific purposes*, 8th Edition (2013) by ensuring that any research and teaching activity that involves animals are clearly defined, and subject to a competent and timely ethical review.

Definitions

Activity: any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee.

Animal: any live non-human vertebrate (that is fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.

Application: a request for approval from an animal ethics committee to carry out a project or activity. An application may be for commencement of a project or activity, or an amendment to an approved project or activity.

Project: an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose

Procedure

All information provided in project applications must be sufficient to satisfy the AEC that the project has scientific or educational merit, and has potential benefit for humans, animals or the environment. It must be demonstrated that the use of animals is essential to achieve the stated aims and suitable alternatives to replace the use of animals (and still achieve the stated aims) is not available. The project must involve the minimum number of animals required to obtain valid data with the minimum adverse impact on the wellbeing of the animals involved. The AEC must be satisfied that there is sufficient evidence to support the proposed use of animals and that it is justified. An essential component of assessing the ethical acceptability of the proposed use of animals is the application of the 3Rs (Replacement, Reduction and Refinement) as specified within the Code.

Project applications must be completed using plain English (lay language) throughout the entire application so that all AEC members are provided with sufficient information to participate effectively in the assessment of the application. Where the use of scientific

language is deemed unavoidable, it must be supported by a suitable lay definition, or a glossary of terms.

The application form must contain the following information:

Information Required	Explanation of Requirement
Project title	To explain and identify the project
Research team details including names of all personnel involved in the project, their proposed role, and details of their experience or required training.	To ensure researchers have the necessary skills and/or supervision to undertake the work
Source of animals, animal housing location and where procedures will be performed	To confirm the appropriate use of animals and suitable facilities
Project summary, aims and potential benefits	To assist in justifying the use of animals in the project and determining its merit.
Reduction: Describe efforts made to minimise the total number of animals requested	To ensure the number of animals used in a project is the minimum necessary to achieve the proposed aims/s and to satisfy good statistical design.
Replacement: Justify why animals are required to achieve the aims. Include alternatives considered and how they are used. Explain why human alternatives or <i>in vitro</i> options are not suitable.	To ensure that animals are approved only for those studies where an alternative is unsuitable. This decision must be based on a detailed and relevant explanation.
Refinement: Identify known and potential impacts on the wellbeing of animals. Include how such impacts will be avoided or minimised.	To ensure that steps are taken at all times to support and safeguard animal wellbeing.
Experimental Procedures and Monitoring: Provide clear step by step description of procedures to be carried out on each animal or group of animals, in relation to aims of the project. Include details of how the wellbeing of animals will be monitored and assessed.	To ensure current best practice is in-place and that animal wellbeing is maintained and supported at all stages during the project.
Justification: A justification must be provided for the use of animals as well as the total number of animals requested.	The AEC need to assess and balance whether the potential benefits justify the potential effects on the wellbeing of the animals involved.
Declaration: The researchers must formally declare that they are familiar with, and will comply with the relevant legislations, and the requirements of the Code.	To ensure compliance and that researchers are aware of their responsibilities.

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Standard Operating Procedures

Clinical and Husbandry Standard Operating Procedures (SOPs) that are current and have been reviewed and approved by the AEC may be referenced by researchers within applications to reduce the repetitious explanation of procedural techniques.

SOPs can be written and revised by any research staff but must be submitted and approved by the AEC before implementation. SOP's must include the title and the date on which they were last approved or reviewed by the AEC (at least once every three years) and AEC members must have access to copies of all current SOPs. If a variation to a SOP is proposed, the entire procedure must be comprehensively detailed in the application for review and approval.

Approval

Only scientific and teaching activities that conform to the requirements of all relevant sections of the Code may be approved. Project applications must be considered and approved only at quorate meetings of the AEC.

The AEC must advise Principal Investigators of their decisions in writing as promptly as possible. Projects must not commence until written final approval has been received.

Project applications are approved for a period of three years only, with the opportunity to seek an additional time extension at the completion of this period. If further time is required for either experimentation or breeding, a new application must be submitted for full AEC review.

Associated Procedures/Instructions

2.1 – New Project Applications

2.7 – Standard Operating Procedures (SOPs)

Reference Documents

- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2018)
- Prevention of Cruelty to Animals Act (1986)
- Prevention of Cruelty to Animals Regulations (2008)

Authorized by:



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