



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

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## NEW PROJECT APPLICATIONS

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### 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*, 8<sup>th</sup> Edition (2013) by ensuring competent, fair, consistent and timely review of applications and reports related to the care and use of animals.

### 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.

**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.

**Investigator:** any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys

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

### Procedure

The AEC must consider and approve applications for new projects and activities only at quorate meetings of the AEC. The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of 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 description, or a glossary of terms.

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.

Decisions by the AEC should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

### **Standard Operating Procedures**

Husbandry and Clinical Standard Operating Procedures (SOPs) which are current may be referenced by investigators within applications to reduce the repetitious explanation of procedural techniques.

Clinical SOPs can be written and revised by any research staff but must be submitted and approved by the AEC before implementation. If a variation to an SOP is proposed, the entire procedure must be comprehensively detailed in the application for review and approval.

Husbandry SOPs are written by animal facility staff with input from relevant research staff and must be submitted and approved by the AEC before implementation. If a variation to an SOP is proposed, the entire procedure must be comprehensively detailed in the application for review and approval.

### **Submission process**

All new project applications must be submitted using the current version of the St Vincent's Hospital (Melbourne) AEC Project Application Form; no other formats will be accepted.

The original signed application plus 8 hard copies must be submitted to the Research Governance Unit by close of business on the closing date of each scheduled AEC meeting. Closing and meeting dates are available on the Research Governance Unit website. No exceptions will be made to this closing date, unless previously negotiated with the AEC Secretary. A word document (not pdf) of the project application must also be emailed to [research.ethics@svhm.org.au](mailto:research.ethics@svhm.org.au) An AEC Fee form must be submitted with the project application to ensure fee payments are processed prior to project review at the scheduled AEC meeting.

Once the submission and fee form is received by the AEC Secretary an acknowledgement email will be sent to the Principal Investigator confirming the application has been received and the AEC Reference Number which has been assigned to the project.

All documentation which is superfluous to record keeping requirements will be destroyed by the Research Governance Unit, via confidential shredding services used by the hospital.

### **Project presentation at meeting**

The Principal Investigator (or senior member of the research team) has the opportunity to present the proposed project to the AEC by giving a brief (5-10 minute) overview outlining the project and procedures, which may be followed by answering questions from the Committee. This process is recommended but not mandatory with an invitation included in the submission acknowledgement email.

### **Review outcomes**

The AEC may decide that an application to commence a project or activity is approved with or without conditions, deferred subject to modification, or not approved. The AEC must advise investigators of their decisions in writing as promptly as possible. Projects must not commence until written final approval has been received.

#### Rejection:

The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of the Code. The Principal Investigator will be notified in writing and may respond to the decision to reject an application; however, unless the ethical issues can be resolved, the AEC reserves the right to reject any requests for reconsideration.

#### Re-Submission:

A full re-submission is required if the AEC determines the application to be inadequate. The Principal Investigator will be notified in writing and then must submit a revised application as per the new project submission process.

#### Conditional Approval:

The AEC may identify projects which have merit and integrity, but fail to meet the requirements of the Code or include insufficient information. If the AEC agrees that such deficiencies can be resolved by refining techniques/methods, or providing additional information/clarification, conditional approval is granted. A conditional approval letter is sent to the Principal Investigator stating each of the issues and requesting an appropriate response. Research must not commence until written final approval is obtained.

The Investigator must respond to the AEC by providing a cover letter of response, which addresses each of the issues identified, and a revised project application, with revisions highlighted in bold or strikethrough text. A signed hard copy (with Principal Investigator signature only) must be submitted to the Research Governance Unit and a word document (not pdf) of the project application must also be emailed to [research.ethics@svhm.org.au](mailto:research.ethics@svhm.org.au)

Responses to conditional approval may be reviewed by Spokespersons, Executive, Chair or AEC Secretary which is delegated at the AEC meeting and recorded in the meeting minutes. If it is determined that all ethical issues are resolved, delegated members may grant final approval. However, the delegates retain the right to request additional information, or defer consideration to the full AEC as required. All out of session approvals must be ratified by the AEC at the next scheduled quorate meeting.

#### Final Approval:

Project applications that conform to the requirements of the Code, are ethically acceptable and the AEC do not require any clarification may receive final approval at the AEC

meeting. An approval letter is sent to the Principal Investigator and research may commence.

Project applications are approved for a period of three years only, with the opportunity to request 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**

2.4 – Project Time Extensions

2.7 – Standard Operating Procedures (SOPs)

4.7 – Making and Communicating Decisions

**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:



Dr Megan Robertson  
Director of Research

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