



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

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## PROJECT AMENDMENTS

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### Statement of Intent and Outcomes

The St Vincent's Hospital (Melbourne) Animal Ethics Committee is committed to fulfilling the governing principles of the *Australian code for the care and use of animals for scientific purposes* (2013), by ensuring competent, fair, consistent and timely review of amendments.

### Definitions

**Amendment:** any proposed change to a current approved project

**Minor Change:** an amendment which does not raise any ethical issues

**Modification:** an amendment which raises ethical issues

### Procedure

The AEC acknowledges that projects require amendment, for the purposes of reduction, refinement and replacement, and to account for any unexpected circumstances which impact upon the research. Investigators must apply for and obtain written approval from the AEC before implementing any amendments to a current approved project. To facilitate a process of efficient and timely review, project amendments may be submitted as a minor change or a modification.

### **Minor change amendments**

A minor change is an amendment which does not raise any ethical issues, for example, different strain of animals, substitution of agents, or a change in procedure/technique provided it doesn't increase BAW impact. Due to the low risk associated with minor changes, submissions are reviewed by the AEC Executive out of session. Minor change requests that involve additional animals will be reviewed on a case-by-case basis by the AEC Executive and referred to the full AEC for review if deemed necessary.

### Submission process

All minor change amendments must be submitted using the St Vincent's Hospital (Melbourne) AEC Application for Amendment to Approved Project form; no other formats will be accepted. The amendment form must be submitted with a revised project application and the proposed changes highlighted in bold or strikethrough text.

Copies are not required and only the signed original applications (Principal Investigator signature only on revised project) are required for submission. A word document (not pdf) of the revised 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 minor change application to ensure fee payments are processed at the time of review. There are no closing dates for minor change requests, they can be submitted anytime.

Once the submission is received by the AEC Secretary an acknowledgement email will be sent to the Principal Investigator.

#### Review outcomes

The submitted amendment form and revised project are emailed to the AEC Executive for review. The AEC Executive retains the right to request clarification or additional information, or defer consideration to the full AEC as required. The Principal Investigator will be notified of the outcome in writing. A copy of correspondence must be retained on file by the Research Governance Unit. All minor changes are ratified by the AEC at the next scheduled quorate meeting.

#### **Modification amendments**

A modification is an amendment which raises ethical issues, for example, additional animals, changes in procedure/technique which increases impact on animals, additional procedure/s, or any proposed change that increases risks or impacts animal wellbeing. All modification amendments are reviewed by the AEC at a quorate meeting.

#### Submission process

The original signed amendment application (plus 8 copies) and revised project application (with Principal Investigator signature only plus one copy) must be submitted to the Research Governance Unit by close of business on the closing date of each scheduled AEC meeting. Applicants must ensure that all relevant information is included in the Amendment Form as not all AEC members will have access to a copy of the revised project application. 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 revised 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 modification application to ensure fee payments are processed prior to review.

Once the submission is received by the AEC Secretary an acknowledgement email will be sent to the Principal Investigator.

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.

#### Review outcomes

The AEC may decide that an application to amend an approved 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. Amendments to approved projects must not commence until written final approval has been received.

#### Conditional Approval:

The AEC may identify amendments 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.

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 Spokesperson, 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:

Amendment 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 the amendment can be implemented.

A copy of correspondence must be retained on file by the Research Governance Unit.

Associated Procedures/Instructions

- 4.5 – Committee Executive
- 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

<b>Author:</b> Research Governance Unit	
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