



**ST VINCENT'S
HOSPITAL**
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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

RECORD MANAGEMENT

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) and complying with the *Prevention of Cruelty to Animals Act 1986*, by ensuring a high standard of documentation and record management.

Definitions

Nil

Procedure

Animal Ethics Committees

Institutions must ensure that records related to the AEC business are maintained including a register of all applications to the AEC, including the outcomes of deliberations, minutes that record decisions and other aspects of AEC's operation and records of inspections conducted by the AEC. Where appropriate, the institution, in consultation with the AEC, should ensure that animal carers have access to records of approved projects and activities.

The Research Governance Unit must maintain a database to record submission and review of project applications, including but not limited to:

- Name of the institution and SPPL to which the research approval is provided
- Project identification number
- Name of Principal Researcher and Research Team members
- Project title
- Project approval status
- Project period of approval
- Annual reporting requirements
- Fieldwork Notifications

The Research Governance Unit should retain a hard copy file for each project including all documents and correspondence related to the project. Files are kept in the Research Governance Unit and once projects are closed files will be transferred to an offsite confidential archive facility. Project files will be kept for a minimum 5 years (commencing at project expiry), with all AEC minutes and associated documents retained indefinitely. In addition to hard copy files electronic versions will be maintained and kept indefinitely. Access to all files is restricted to Research Governance Unit staff, with supervised access granted at the discretion of the Executive Officer.

The agenda and submission documents are distributed in a timely manner to AEC members, at least one week in advance of a meeting, to enable members to be fully informed. All documents must be returned to the AEC Secretary at the end of the meeting for appropriate filing or disposal.

At each AEC meeting minutes will be taken by the AEC Secretary to record decisions and other aspects of the AEC's operation. Minutes will be finalised in a timely manner following a meeting, approved by the Chair and then emailed to AEC members.

Documentation will also be communicated via the Research Governance Unit website, to ensure documents are publicly available. This includes all template application forms, Terms of Reference and Standard Operating Procedures (Clinical and Husbandry SOPs are password protected).

Investigators

Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers.

Investigators must ensure that records of monitoring and assessment of animals are in accordance with the following;

Methods for monitoring and assessment of animal wellbeing should include:

- (i) the criteria that will be used to assess wellbeing
- (ii) the level and frequency of monitoring to ensure that any changes in an animal's condition are detected early
- (iii) the criteria that will be used to determine when action is required
- (iv) actions that will be taken so that adverse impacts on animal wellbeing, including predicted effects and unforeseen complications, are addressed rapidly and effectively
- (v) the methods for recording observations, treatments and actions
- (vi) flexibility to ensure a rapid and effective response to changes during the course of the project or activity

Records of the monitoring and assessment of animal wellbeing must be:

- (i) sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse event as a basis for future prevention strategies
- (ii) accessible to all people involved in the care of the animal
- (iii) available for audit by the institution, the AEC and authorised external reviewers

Investigators must ensure that records include:

- (i) the origin/source of the animals and provisions for the animals at the conclusion of their use
- (ii) the number of animals used
- (iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes
- (iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result
- (v) any additional information requested by the AEC
- (vi) names of people performing the procedures and entering the records

- (vii) names and contact details of people responsible for monitoring and emergency incidents.

When activities involved genetically modified animals records must also include the number of animals used for the creation and maintenance of genetically modified animals as well as the lineage and health status of the animals.

Animal Carers

Animal carers must maintain records of the care and monitoring of animals and, for breeding facilities, the health status and breeding performance of animals. Records of the monitoring and assessment of animal wellbeing must be sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies. These records must be accessible to all people involved in the care of the animal and available for audit by the institution, the AEC and authorised external reviewers. Animal carers must make these records available to the institution, the AEC, authorised external reviewers and, if relevant, investigators.

Animal carers should ensure that records relating to health status and breeding performance include:

- (i) the source, care, supply, movement between locations and the use of the animals
- (ii) details of all diseases in the facility
- (iii) the fertility, fecundity, morbidity and mortality rates of breeding colonies
- (iv) The health status, genetic constitution and physical environment of the animals

Associated Procedures/Instructions

- 1.4 – Investigator Record Management
- 3.2 – Adverse Events
- 3.6 – Post-Approval Monitoring
- 3.9 – Facility Inspections
- 4.7 – Making and Communication 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)

Authorized by:



Dr Megan Robertson
Director of Research

Author: Research Governance Unit	
Date Issued: 2011	Next Review: 2022
Date Revised: 2016, 2019	Filepath: