

RESEARCH GOVERNANCE UNIT

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

INVESTIGATOR RECORD MANAGEMENT

Statement of Intent and Outcomes

The St Vincent's Hospital (Melbourne) Animal Ethics Committee (AEC) is committed to fulfilling governing principles of the *Australian code for the care and use of animals for scientific purposes* 8th Edition (2013), by ensuring investigators are aware of their roles and responsibilities in the retainment of information via good record management.

Definitions

Investigator: is 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

Procedure

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

Investigators must ensure that the records include:

- AEC project number
- origin/source of the animals and provisions for the animals at the conclusion of their use,
- the number of animals used,
- details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes,
- the condition of the animals, any adverse impact on animals wellbeing and actions taken as a result
- any additional information requested by the AEC
- names of people performing the procedures and entering the records
- names and contact details of people responsible for monitoring and emergency incidents

When activities involve genetically modified animals, records must include:

- the number of animals used for the creation and maintenance of genetically modified animals
- the lineage and health status of the animals

Monitoring and assessment records should include the criteria that will be used to assess wellbeing, level and frequency of monitoring to ensure that any changes in animal's condition is detected early, the criteria that will be used to determine when action is

required, methods for recording observations, treatments and actions and actions that will be taken so that adverse impacts on animal's wellbeing are addressed rapidly and effectively. The monitoring records must be sufficient to enable verification that the wellbeing of animals has been monitored as approved in a project application and accessible to all people involved in the care of the animals.

Training records must be maintained to track technique training for investigators listed as not competent in AEC approved projects. Training records must include name of person being trained and trainer, date of training session and technique/procedure being trained, competency details (assessed as competent or not competent because further training is required) and signature of trainer.

Each project should have a study file in which all documentation is kept including, but not limited to, the approved project, all AEC related correspondence, training records, animal use records and monitoring and assessment records.

All research related documentation should be retained by the Principal Investigator for a minimum of 5 years.

Associated Procedures/Instructions

1.1 – Responsibilities of Investigators

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

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