

#### **RESEARCH GOVERNANCE UNIT**

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

# **RESPONSIBILITIES OF INVESTIGATORS**

# **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 researchers fulfil their roles and responsibilities specific to ethics. Refer to Section 2.4 of the Code for comprehensive information.

#### **Definitions**

3Rs: are Replacement, Reduction and Refinement

**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.

**AEC** (**Animal Ethics Committee**): a committee constituted in accordance with the terms of reference and membership laid down in the Code

**Competent:** the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and kill to new situations and environments

**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

**Person with ultimate responsibility:** person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified.

**Wellbeing:** an animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health and of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions

## **Procedure**

Investigators have personal responsibility for all matters that relate to the wellbeing of animals they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the Animal Ethics Committee (AEC) until provisions are made for the animal at the conclusion of their use.

Investigators must only consider using animals when they are satisfied that a case can be made that the proposed use is ethically acceptable, based on whether such use demonstrates the governing principles of the Code (Clause 1.1) and balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

Investigators should seek advice and information from relevant experts, including other experienced scientists, veterinarians, animal care staff, or specialists in laboratory animals, livestock or wildlife, when necessary.

#### Investigators must:

- apply the principles of the Code (Section 1) in all aspects of the care and use of animals, including planning, conducting and reviewing projects,
- follow relevant policies and procedures established by St Vincent's Hospital (Melbourne) and the AEC,
- apply for and obtain written approval from AEC before commencing a project that involves the use of animals, or an amendment to an approved project,
- conduct the project in accordance with the conditions and requirements of the AEC approval and cease the project if approval from the AEC is suspended or withdrawn,
- undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures,
- ensure that procedures using animals are performed competently,
- maintain records of the care and use of animals,
- report to the AEC as required

A person must be identified who has ultimate responsibility for the care and use of animals in a project; in the AEC Project Application form this person is specified as the Principal Investigator. This person must ensure that all people involved in the project understand and accept their roles and responsibilities and that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities and be competent with respect to the wellbeing of animals used in the project. This person does no relieve the individual responsibility of each investigator working with animals in the project.

When planning projects investigators must only consider using animals when the use of animals is justified, high standards of scientific integrity are applied, the 3Rs are applied at all stages of the project, measures are taken to ensure the animals' environment and management are appropriate for the species and support the animals' wellbeing, the project is designed to minimise harm (including pain and distress) and all people involved in the care and use of animals in the project understand and accept their roles and responsibilities.

Investigators must notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution.

Investigators must maintain records of the care and use of animals and make these records available to institution, AEC or authorised external reviewers. See Procedures 1.4 *Investigator Record Management* and 3.6 *Post-Approval Monitoring* for more details.

Investigators must provide an annual report for each approved project, promptly notify the AEC of any unexpected adverse events and submit a final report on outcomes as soon as practicable after completion or discontinuation of a project.

# Associated Procedures/Instructions

- 1.4 Investigator Record Management
- 3.1 Annual and Final Reports
- 3.2 Adverse Events
- 3.6 Post-Approval Monitoring

### 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)

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