



ST VINCENT'S  
HOSPITAL  
MELBOURNE

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

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## NON-COMPLIANCE

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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 providing a framework to investigate and handle alleged non-compliance appropriately.

### Definitions

**Animal 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.

**Code:** the *Australian code for the care and use of animals for scientific purposes*

**Compliance:** acting in accordance with the Code and AEC project approval

**Institution:** any organisation or agency involved in the care and use of animals for scientific purposes, including universities, hospitals, research institute, government departments, teaching organisations (including schools and colleges), vocational training organisations, agricultural organisations, commercial companies, and organisations involved in animal breeding and supply.

**Scientific purposes:** all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

### Procedure

Non-compliance is a breach of one or more of the following:

- *Prevention of Cruelty to Animals Act*
- *Australian code for the care and use of animals for scientific research*
- St Vincent's Hospital (Melbourne) AEC SOPs
- St Vincent's Hospital (Melbourne) AEC project approval

Non-compliance may be identified during post-approval monitoring and annual facility inspections. Reports of non-compliance may come from internal and external sources and can be reported to AEC Chair, AEC Secretary, Animal Facility Managers/Veterinarian or Research Directorate. All alleged incidents of non-compliance should be directed to the AEC Secretary to co-ordinate the non-compliance process.

When projects or activities that are in breach of the Code are detected, the AEC must ensure that:

- (i) actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project or activity
- (ii) actions are taken to address the issues in consultation with the person(s) involved
- (iii) when considered necessary, such matters are referred to the institution (e.g. Licence Nominee) for action
- (iv) non-compliance receives appropriate follow-up.

The Veterinarian and/or Animal Facility Manager is responsible for assessing animal wellbeing and determining whether immediate action is required to relieve any suffering or distress in an animal. The Category A AEC member may also be consulted during this process.

The AEC Chair in consultation with Category A AEC Member and based on advice from Animal Facility Manager, Veterinarian and AEC Secretary is responsible for reviewing Non-Compliance Reports and determining the non-compliance category and recommended actions.

#### **Non-compliance categories**

##### Minor:

- Failure to submit annual and final reports at a satisfactory standard

##### Moderate:

- Failure to submit annual and final reports within 3 months after due date
- Failure to maintain satisfactory animal use records
- Failure to maintain satisfactory health monitoring records
- Failure to maintain adequate training records
- Change of animal strain without AEC approval
- Refinement of procedure or technique that reduces the impact on animals without AEC approval
- Health monitoring, anaesthesia, analgesia or euthanasia not performed according to AEC approval but not resulting in impact on animal wellbeing
- Animal use for a project or procedure that has conditional approval commencing before written final approval is issued

##### Major:

- Failure to submit annual and final reports within 9 months after due date
- Change to procedure or technique that increases impact on animals without AEC approval

- Health monitoring, anaesthesia, analgesia or euthanasia not being performed according to AEC approval which results in impact on animal wellbeing
- Animal use for a project or procedure without obtaining AEC approval
- Not-competent research team members performing procedures without appropriate supervision
- Animal use continued after AEC approval has expired
- Using more animals than approved
- Procedure performed by investigator not approved by the AEC to work on the project
- Change of animal species without AEC approval
- Failure to report Adverse Events

### **Non-Compliance Process**

1. Alleged incident or complaint is reported and details forwarded to AEC Secretary
  - a. Minor:
    - i. Principal Investigator informed and requested to submit Non-Compliance Report form
    - ii. Non-Compliance Report forwarded to AEC Chair to determine non-compliance category and recommended actions
    - iii. Principal Investigator notified of recommended actions
    - iv. Non-Compliance Report included in next scheduled AEC meeting agenda.

If minor non-compliance is repeated it may be upgraded to a higher category.

- b. Moderate:
  - i. Principal Investigator informed and requested to submit Non-Compliance Report form
  - ii. Licence Nominee may be notified
  - iii. Non-Compliance Report forwarded to AEC Chair to determine non-compliance category and recommended actions
  - iv. Animal Facility Manager and/or Veterinarian to confirm that there was no impact on animal wellbeing
  - v. Principal Investigator notified of recommended actions
  - vi. AEC Chair may request meeting with Principal Investigator and/or Licence Nominee
  - vii. Non-Compliance Report included in next scheduled AEC meeting agenda.

If moderate non-compliance is repeated it may be upgraded to a major category.

- c. Major:
  - i. Principal Investigator informed and requested to submit Non-Compliance Report form
  - ii. Licence Nominee is notified
  - iii. Non-Compliance Report forwarded to AEC Chair to determine non-compliance category and recommended actions. Immediate action will be undertaken by Executive if the matter is considered sufficiently serious.
  - iv. Animal Facility Manager and/or Veterinarian to advise if any action was required to relieve suffering or distress in an animal

- v. Principal Investigator notified of recommended actions
- vi. AEC Chair must request meeting with Principal Investigator and/or Licence Nominee and relevant research team members
- vii. Non-Compliance Report included in next scheduled AEC meeting agenda.

**Recommended Actions**

- Written warning
- Submit project amendment
- Revise and submit SOPs
- Suspension or withdrawal of AEC project approval
- Attendance at relevant training sessions
- Recommend disciplinary action to Licence Nominee

Relevant state or territory government authorities will be advised of alleged breaches of legislation that had a significant impact on animal wellbeing

A Non-Compliance Register will be maintained by the AEC Secretary that includes details of all non-compliance incidents reported to the AEC. Non-Compliance incidents will also be included in the AEC Annual Report.

**Associated Procedures/Instructions**

Non-Compliance Report form

**Reference Documents**

- Prevention of Cruelty to Animals Act (1986)
- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2007)

Authorised by:



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