

RESEARCH GOVERNANCE UNIT

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

COMPLAINTS HANDLING

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 process complaints.

Definitions

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

EOR: Executive Officer Research

RGU: Research Governance Unit

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.

SPPL: Scientific Procedures Premises Licence

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

Institutions must have procedures for addressing complaints relating to the care and use of animals for scientific purposes including:

- complaints concerning the care and use of animals by the institution
- complaints concerning the AEC process of review of an application or report and decisions of the AEC
- disagreements between AEC members, between the AEC and investigators and between the AEC and institution/s

Complaints may come from internal and external sources and could be reported to AEC Chair, AEC Secretary, Animal Facility Managers/Veterinarian or Research Directorate.

Once received, all complaints should be directed to the Executive Officer Research (EOR) to initiate the complaints process in consultation with the AEC Chair, AEC Secretary, or any other relevant AEC members and, where necessary, the Director of Research. All complaints must be handled promptly in a timely manner, sensitively and confidentially.

Complaints will be recorded on the AEC Complaints Register, held in the Research Governance Unit (RGU). The register includes information to track the progress of the complaint, provide a history of all referrals and action taken, as well as dates of receipt and resolution of the complaint.

Complaints concerning the care and use of animals

The complaints process must give priority consideration to the wellbeing of animals and ensure that activities with the potential to adversely affect animal wellbeing cease immediately. The Veterinarian and/or Animal Facility Manager/s must be consulted regarding complaints involving the care and use of animas as they are responsible for assessing animal wellbeing and determining actions required to relieve any suffering or distress in an animal, the Category A AEC member may also be consulted.

Once the EOR receives a complaint concerning the care and use of animals the AEC Chair will be consulted. If it is determined there are grounds for concern the complaint will be investigated and recommendations provided to the EOR for consideration. Project approval or approval for procedures may be suspended pending investigation. The EOR and AEC Chair will determine how the complaint will be investigated which may involve the AEC Chair, AEC Chair in consultation with Veterinarian and/or Animal Facility Manager/s or delegated members of the AEC. The investigation should include discussions with investigators and relevant research staff and review of records, inspection of animals/facility/laboratories if required. A report should be provided to the EOR in a timely manner which outlines recommendations for action which may include that no further action is required, the project or procedures require modification, suspension of approval, additional approval conditions or disciplinary action to be considered by institution/SPPL holder. The EOR and AEC Chair will consider the complaint, report and any other relevant documents or information and may accept, modify or reject the recommendations. The AEC and relevant parties will be informed accordingly.

Complaints concerning the AEC process of review or decisions

Complaints from researchers about any aspect of the review of a submission or management of their research project by the RGU or AEC should be directed in the first instance to the EOR. The EOR, in consultation with the AEC Chair, will liaise with the Principal Investigator and, where necessary, the committee itself to resolve the matter. Serious complaints which cannot be resolved using this process will be referred to the Director of Research and, if necessary, the St Vincent's Hospital Melbourne Chief Medical Officer or Chief Executive Officer. In some circumstances, external independent advisors may be consulted to provide assistance and advice.

Disagreements between AEC members, or the AEC and investigators or between the AEC and institution/s

Decisions by the AEC should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further

discussion. The Chair should resolve other disagreements between AEC members. If unable to be resolved, or if the Chair is involved, the disagreement should be referred to the EOR.

Disagreements between the AEC and investigators should be directed in the first instance to the EOR. The EOR, in consultation with AEC Chair, will endeavour to resolve the problem directly with the complainant and/or the Principal Investigator (as applicable)

In circumstances involving disagreements between the AEC and the institution/s or licence nominees, external independent advisors may be consulted to provide assistance and advice.

For projects involving more than one institution and/or AEC the St Vincent's Hospital (Melbourne) AEC Secretary is the first point of contact regarding complaints and non-compliance. The AEC Secretary will liaise with the EOR to co-ordinate the required process and to report between the relevant institutions and AEC's.

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

Associated Procedures/Instructions

3.8 – Non-Compliance

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 (2018)

Authorised by:

Dr Megan Robertson Director of Research

Author: Research Governance Unit	
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