



## **St Vincent's Hospital (Melbourne) Animal Ethics Committee (AEC)**

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### **TERMS OF REFERENCE**

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#### **Introduction**

The Animal Ethics Committee (AEC) is a committee of St Vincent's Hospital (Melbourne). The Committee has been formed in line with the requirements of the *'Australian code for the care and use of animals for scientific purposes'*, 8<sup>th</sup> Edition 2013 (the Code) under the *'Prevention of Cruelty to Animals Act'* (1986).

The St Vincent's Hospital AEC, under the responsibility of the Director of Research, is responsible for the review, approval and ongoing monitoring of research and teaching involving animals on the St Vincent's Hospital Campus.

The St Vincent's Hospital AEC is a nominated Animal Ethics Committee, and listed on the Scientific Procedures Premises Licence (SPPL), for St Vincent's Institute, Bionics Institute, University of Melbourne at St Vincent's Health, Centre for Eye Research Australia and University of Melbourne at RVEEH.

The St Vincent's Hospital AEC may also act as a delegated AEC for external organisations, including but not limited to, overseeing animal housing, animal monitoring and scientific procedures taking place in its premises when approval has been issued by the external organisation's nominated AEC.

#### **Purpose**

The St Vincent's Hospital AEC is responsible for ensuring that all activities relating to the care and use of animals are conducted in compliance with the Code.

#### **Function**

The St Vincent's Hospital (Melbourne) AEC will ensure that the governing principles of the Code are met and adhered to at all times by:

- Reviewing animal research and breeding applications in line with the Code and approving projects that demonstrate the use of animals is essential to achieve the stated aims and which conform to the governing principles of the Code and any applicable Institutional Policies and/or Procedures.
- Reviewing clinical and husbandry Standard Operating Procedures (SOP's) and approving those that ensure current best practice, support the animal's wellbeing and conform to the governing principles of the Code.

- Conducting post-approval monitoring interviews to establish that animal use within a project is being conducted as approved by the AEC and to assist investigators with compliance with the Code. This process includes review of records relating to animal use, procedures and monitoring, training and competency, adverse events, annual reports and may also include observation of animals.
- Monitoring the acquisition, transportation, production, housing, care, use and fate of all animals used for research (including those used for breeding purposes).
- All premises listed on a scientific procedures premises licence (animal housing and laboratory facilities) are inspected at least annually. Frequency of inspections may be influenced by the number and accessibility of sites, the number and types of projects and activities and whether inspections can be combined with scheduled AEC meetings. The AEC may also decide that certain projects or activities require more frequent inspection than others. Facility inspections may be announced or unannounced.
- Ensuring that all persons involved in animal care and/or animal use have the appropriate competency or are under the direct supervision of a person who is competent.
- Withdrawing or suspending the ethical approval for any project where the impact on the continued ethical acceptability of the project is brought into question.
- Ensuring that adequate records of animal use (including regular monitoring) are maintained.
- Maintaining a register of all research projects which use animals for the purposes of research, breeding and/or teaching.
- Maintaining a register of all reported Adverse Events which occur during the conduction of approved projects which use animals for the purposes of research and/or teaching. Representatives from the AEC may also audit the records of researchers to monitor the incidence of all Adverse Events which occur during the conduction of approved projects.
- Ensuring that the requirements of all relevant Federal and State legislation are adhered to, and that all incidents of non-compliance are investigated and actioned as appropriate.
- Comply with the reporting requirements of St Vincent's Hospital (Melbourne) and the Code.
- Ensuring that all business of the AEC is treated as confidential.
- Ensuring an efficient and effective complaint handling process is developed and monitored, in line with the institutional policies and procedures of St Vincent's Hospital (Melbourne).
- Making recommendations to the Director of Research, regarding any measures needed to ensure that the standards of the Code are maintained.

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When the St Vincent's Hospital AEC is nominated on the SPPL of an external organisation and an agreement is not yet formalised:

- Licence holder nominates the AEC to oversee the conduct of the organisation's care and use of animals for scientific purposes.
- The AEC Secretary is the primary point of contact.
- Undertaking by the organisation, their investigators and other relevant personnel to abide by the directions of the AEC.
- Undertaking by the organisation to abide by the AEC Admin SOPs and other relevant policies and procedures in regards to governance, reporting and non-compliance.
- To ensure communication between the AEC and external organisation the AEC Annual Report will be distributed to licence nominee with an invitation to meet with the Director of Research and/or AEC Chair if requested.
- A representative from the organisation may be appointed as a Category B member of the AEC, where possible, whilst ensuring balance of membership is compliant with the Code.

### **Membership**

The Chief Executive Officer of St Vincent's Hospital (Melbourne) will confirm the appointment of members to the AEC. Members are appointed for an initial one year period, with the opportunity to extend appointment for subsequent terms, as applicable. Extended terms of appointment will occur at the discretion of the Director of Research and AEC Chair, and must take into consideration any actual, perceived or potential conflicts of interest.

The appointment of any member may be terminated, in writing at any time, by the Institution via the Director of Research, if they believe it is necessary for the effective functioning of the AEC, if the person has failed to carry out their duties or if the member has not complied with the Terms of Reference.

A member can resign in writing to the AEC Secretary at any time during their term, if possible 4 weeks' notice is requested, to allow for recruitment of a replacement member.

All AEC members must follow relevant institutional policies and procedures relating to the operation and functioning of the AEC. All matters and activities of the AEC are to be treated as confidential at all times.

All members of the AEC must acknowledge their acceptance of the AEC Terms of Reference and any requirements for confidentiality required by St Vincent's Hospital (Melbourne). St Vincent's Hospital (Melbourne) should ensure that all members undergo appropriate induction, and have access to appropriate education programs and resources.

The AEC must maintain a minimum membership of at least four persons, with at least one member in each of the following categories:

Category A: A person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to St Vincent's Hospital (Melbourne) activities or the ability to acquire relevant knowledge.

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Category B: A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to St Vincent's Hospital (Melbourne) and the business of the AEC. This must include possession of a higher degree in research or equivalent experience.

Category C: A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with St Vincent's Hospital (Melbourne), and who is not involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.

Category D: A person not employed by or otherwise associated with St Vincent's Hospital (Melbourne) and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other category.

Additional Members: Person(s) responsible for the routine care of animals within St Vincent's Hospital (Melbourne).

Chairperson: A person who holds a senior position at St Vincent's Hospital (Melbourne) and who possesses the skills to manage the business of the AEC including the ability to resolve conflict. The chairperson should have an understanding of the ethical and animal welfare issues involved in the use of animals for scientific purposes and is responsible for guiding the operation of the AEC. A deputy chairperson may also be appointed from the existing membership.

In Attendance members: The membership may also include representation from the Director of Research, St Vincent's Hospital (Ex-officio, non-voting) and Executive Officer Research Directorate, St Vincent's Hospital (Ex-officio, non-voting).

The AEC may seek expertise from people with skills and backgrounds of value, as required.

The AEC may invite researchers, or any other persons deemed appropriate, to attend an AEC meeting.

An executive sub-group of the AEC exists to expedite the approval of minor changes to projects. The executive sub-group is composed of the Chair, at least one member from Category A or B, and at least one member from Category C or D. Any decisions by the executive must be ratified by the AEC at the next meeting. The AEC Executive will not approve new applications.

## **Meetings**

The frequency of meetings should be sufficient to allow for effective functioning of the AEC. The St Vincent's Hospital (Melbourne) AEC shall meet at least nine times per calendar year. Meetings may be held either in-person or virtual depending on St Vincent's Hospital policy relating to pandemic regulations.

At each meeting, the Research Governance Unit at St Vincent's Hospital (Melbourne) shall be responsible for providing an agenda, recording minutes, and communicating decisions to researchers in a timely manner, as per the Admin Standard Operating Procedures.

At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for conduct of a meeting, and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present.

Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by AEC members, and should be made only by those present throughout the discussion. Decisions should be made on the basis of consensus.

All AEC members must declare all perceived, potential or actual conflict of interest if it arises. This member can answer questions relating to their research project but must leave the meeting while any decisions relating to the research are discussed by the AEC.

All AEC members must maintain confidentiality regarding the content of applications and the deliberations of the AEC, in accordance with applicable Institutional Policies and/or Procedures.

AEC documentation and proceedings will be treated as confidential. Communication with external organisations will only be conducted via the AEC Chair or AEC Secretary, to ensure confidentiality is maintained.

## **Reporting**

### Annual Report

The AEC will formally report to the Director of Research on an annual basis, including a summary of activities, the number and types of projects approved a summary of the physical facilities for the care and use of animals within the institution, training, and any other administrative matters that may affect compliance. The AEC Annual Report will be distributed to licence holders that nominate the St Vincent's Hospital AEC as their Animal Ethics Committee.

### Animal Use Return

Animal Welfare Victoria conduct an annual report on the number of animals used for science each year in Victoria. This is to obtain annual statistics to direct policy and compliance programs and to inform the community about the nature and purpose of the animals used each year.

The Animal Use Return is composed of up to 3 parts that together provide the required information on animal use under a licence. Animal Use Return details animals assigned to or used in projects and Specified Animal Breeding Colonies, Statement and Declaration incorporates a declaration by the institution that the details of the return are correct, summarises animal use by the licence, and details compliance with the principles of the 3Rs and the Death as an Endpoint form must be completed to report any Death as an Endpoint Procedures conducted under the licence.

The AEC Secretary co-ordinates and compiles the Annual Animal Use Return, in consultation with Principal Investigators, completes the Statement and Declaration form, arranges for Licence Nominee signature and submits all Annual Animal Use Return forms to Animal Welfare Victoria via email with the Licence Nominee cc'd.

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Additional annual reporting on the status and progress of AEC protocols will be submitted to Animal Welfare Victoria, and any other bodies as required.

#### **Indemnification**

Members of the AEC are indemnified by the Professional Indemnity Insurance Policies held by St Vincent's Hospital (Melbourne), in respect of liabilities that may arise in the course of the conduct of AEC member's duties.

#### **Administrative Management**

The Research Governance Unit will be responsible for the administrative management of the AEC, including the collation and distribution of applications to Committee members, taking the minutes of all AEC meetings, writing correspondence on behalf of the AEC, managing ongoing documentation and records, and develop and maintain administrative Standard Operating Procedures, Institutional Policies and Procedures, and any other administrative function required by the AEC and/or Institution.

#### **Approved by:**



Dr Megan Robertson  
Director of Research  
St Vincent's Hospital (Melbourne)