



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

MAKING AND COMMUNICATING DECISIONS

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* (2013), by ensuring efficient and transparent processes are followed when making and communicating decisions.

Definitions

Consensus: the outcome of a decision-making process whereby the legitimate concerns of members of the animal ethics committee are addressed and, as a result, all members accept the final decision, even though it may not be an individual's preferred option.

Procedure

The AEC must provide competent, fair, consistent and timely review of applications and make a judgement based on whether the proposed use, or continued use, of animals is ethically acceptable. This judgement must be based on information provided by the applicant that demonstrates the application of principles outlined in Section 1 of the Code and balance out whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits. The AEC may only approve those projects and activities that are ethically acceptable and conform to the requirements of the Code. Applications for new projects and activities and the ongoing approval for existing projects and activities must be considered and approved only at quorate meetings of the AEC.

The AEC must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant, and may use information in addition to that obtained from the applicant. The AEC may decide that an application to commence a project or activity, or amend an approved project or activity is approved with or without conditions, deferred subject to modification or not approved. Following review of the annual report for an approved project or activity and possible consultation with the applicant, the approval for project or activity is continued, suspended, modified or discontinued. Approval can also be suspended or withdrawn.

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

For decision making, members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum as defined in the Code that is one member from each of the membership categories A, B, C and D with Categories C and D together representing at least one-third of the members present.

Decisions of the AEC must be made as promptly as possible.

Pilot studies, where proposed, should be regarded as integral to the overall project, especially to enable assessment of the feasibility of the project and the potential for refinement and reduction. They must be assessed by the AEC according to the criteria applied to project approval.

When considering approval for the reuse of animals, the AEC must take into account:

- the pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions
- the time allowed for recovery of the animals between activities
- whether an animal has fully recovered from the previous activities
- the pain and distress likely to be caused by the next and subsequent activities
- the total time over which an animal will be used

The Principal Investigator (or senior member of the research team) has the opportunity to present the proposed project to the AEC by giving a brief (5-10 minute) overview outlining the project and procedures, which may be followed by answering questions from the Committee. This process is recommended but not mandatory with an invitation included in the submission acknowledgement email.

All AEC meetings must be recorded and the minutes are prepared and distributed by the AEC Secretary. These minutes must contain the outcomes of AEC deliberations including clarification points for submissions and a final decision regarding approval, amendment or rejection of applications.

The AEC must also decide if the response should be reviewed at the next meeting, or whether authority is delegated to the Chair, Spokesperson/s, Secretary or Executive for review out of session. Delegated authority must be recorded in the minutes. The time taken to review and / or approve these documents is at the discretion of the AEC Secretary and delegated authority, but must remain timely.

As soon as possible after the completion of the meeting, the Principal Investigator of each project will be notified in writing, regarding the decisions made by the AEC. This correspondence must include any queries raised by the AEC during review, and any other governance related issues.

When a decision is delayed, the reasons will be recorded in the minutes and the investigator will be notified in writing of the reasons for the delay.

Responses to AEC queries from the investigator/s must be in writing and should include a cover letter and revised application with revisions highlighted.

Projects and amendments that receive final approval out of session will be recorded and ratified at the following AEC meeting.

When a decision is made to terminate or suspend a previously approved protocol, the reasons will be recorded in the minutes and the investigator will be notified in writing of the reasons for the decision and actions that can be taken to discuss the situation further.

A copy of correspondence must be retained on file by the Research Governance Unit.

Associated Procedures/Instructions

- 2.1 – New Project Applications
- 2.2 – Project Amendments
- 3.7 – Complaints Handling
- 4.5 – Committee Executive
- 4.6 – Delegation of Authority
- 4.8 – Conflicts of Interest

Reference Documents

- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2018)

Authorized by:



Dr Megan Robertson
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