



ST VINCENT'S
HOSPITAL
MELBOURNE

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

POST-APPROVAL MONITORING

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 ensuring that all AEC approved projects are monitored appropriately.

Definitions

Monitoring is measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the code. Monitoring occurs at different levels (including those of investigators, animal carers and animal ethics committees).

Project is an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose

Scientific purposes are 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

The AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC. The AEC must ensure identified problems and issues receive appropriate follow-up and, if necessary, refer suspected breaches of the Code to the institution.

The AEC should monitor activities that are likely to cause pain and distress at an early phase during the conduct of the activity. This requirement should be a condition of approval for the project or activity. These activities could include the study of pain, responses to stressors, models of human and animal diseases, or attempts to change behaviour by physical or chemical means.

The level of project monitoring required by the AEC will be dependent on each individual AEC approved project. Low impact projects or projects that the Committee have experience and excellent understanding of will require a lower level of monitoring compared to a high impact project or a project that the Committee (or investigator, animal facility manager, veterinarian) have limited experience in or knowledge of. Low level monitoring includes review of annual reports whereas higher level monitoring may include review of researcher records, pilot study and procedure progress reports and adverse event reports. If the AEC

agree that a high level monitoring is required this will be stipulated as a condition of approval for the project and kept on record by the Research Governance Unit.

The AEC monitors the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records, adverse event reports and annual progress reports.

The AEC Secretary will monitor governance compliance of current AEC approved projects by conducting a desktop audit on randomly selected projects. The purpose of the desktop audit is to ensure that the project file kept in the Research Governance Unit is current and up to date and correlates with Principal Investigator records. Documentation audited will include current project version number, research team lists, training records, animal use, adverse events, annual reports, GBNML approvals and IBC approvals. The 'AEC Desktop Audit Checklist' will be forwarded to the Principal Investigator to complete this process. A Desktop Audit Register will be maintained by the AEC Secretary that includes details of the audits conducted and outcomes, which will be reported to the AEC at a quorate meeting.

Delegated members of the AEC will conduct post-approval monitoring interviews with Principal Investigators and/or senior research team members of randomly selected projects. The purpose of post-approval monitoring is to establish that animal use within a project is being conducted as approved in the current version of the project and to assist investigators with compliance with the Code. Post-approval monitoring interviews will include review of records relating to animal use, procedures and monitoring, training and competency, adverse events, annual reports and may also include observation of animals.

Associated Procedures/Instructions

- 3.1 – Annual and Final Reports
- 3.2 – Adverse Events
- 3.5 – Record Management
- 3.7 – Institutional Audits
- 3.9 – Facility Inspections

Reference Documents

- Australian code for the care and use of animals for scientific purposes (2013)
- Australian Code for the Responsible Conduct of Research (2007)

Authorized by:



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