ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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

ADVERSE EVENTS

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 adverse events are reported and managed appropriately.

Definitions

Adverse events: are any events that have a negative effect on the wellbeing of an animal.

Unexpected adverse events: are any events that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

Procedure

Investigators must take steps at all times to safeguard the wellbeing of animals by avoiding or minimising known or potential causes of harm, including pain and distress, to the animals. This includes taking prompt action, including alleviating pain and distress and promptly notifying the AEC, in response to unexpected adverse events and emergencies.

An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were not expected
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Alleviation of pain and distress of a severity that was not anticipated in an approved project must take precedence over an individual animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, animals must be humanely euthanised without delay.

The AEC must take appropriate action in response to unexpected adverse events to ensure that animal wellbeing is not compromised, the issue is addressed promptly and activities that have potential to adversely affect the animal wellbeing cease immediately. Actions may

include consulting with relevant people and, where necessary, suspending or withdrawing approval for the project or activity.

When animal wellbeing is no longer consistent with the project approved by the AEC, immediate action is required by the person who first identifies the issue. The investigator (or delegate), animal facility manager and veterinarian must all be notified immediately and animal welfare assessed to determine the most appropriate form of action to address the welfare concerns or alleviate suffering (e.g. treatment, euthanasia, autopsy, intensive monitoring).

If an emergency welfare intervention is considered necessary for an animal allocated to a project (e.g. treatment or humane euthanasia of an animal), animal carers must take reasonable steps to first contact the responsible investigator. However, the welfare of the animal must be the priority at all times and may necessitate immediate intervention. Animal carers must promptly advise the responsible investigator of actions taken and reasons for emergency interventions.

When an animal dies unexpectedly, or is humanely euthanised due to unforseen complications, a necropsy should be performed by a competent person.

Within 24 hours the investigator must notify the AEC Secretary (by either telephone or email) that an adverse event has occurred and provide an overview of the event and actions taken. An Adverse Event Report form must be completed which summarises the adverse event for the AEC and includes details relating to animal information, outline of the event, impact of event and steps taken to reduce future re-occurrence. The report must be submitted within seven days of the adverse event occurring and emailed to the AEC Secretary, Facility Veterinarian and Facility Manager. Once received by the AEC Secretary the report will be forwarded to AEC Chair and Category A AEC member for review prior to review by the full AEC at the next scheduled meeting.

Records of the monitoring and assessment of animal wellbeing must be sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies. The records must be accessible to all people involved in the care of the animal and available for audit by institution, AEC and authorised external reviewers.

Submission

All adverse event reports must be submitted using the current version of the St Vincent's Hospital (Melbourne) AEC Adverse Event report form; no other formats will be accepted. Reports can be submitted via hard copy to the Research Governance Unit or electronic copy emailed to research.ethics@svhm.org.au (copies are not required.) Copies of any associated documentation such as necropsy reports must also be submitted.

Once the report is received by the AEC Secretary an acknowledgement email will be sent to the Principal Investigator and added to the agenda for the next scheduled AEC meeting.

An Adverse Events Register will be maintained by the AEC Secretary that includes details of all adverse events reported to the AEC.

Associated Procedures/Instructions
Nil

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
Director of Research

Author: Research Governance Unit	
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