

# Animal Welfare Non Compliant Events Procedure

## Section 1 - Purpose / Objectives

(1) The purpose of this procedure is to ensure appropriate investigation and management of any non-compliant events in relation to the use of animals or animal tissue, in accordance with sections 5.9 and 5.10 of [The Australian Code for the care and use of animals for scientific purposes 8th Edition 2013 \(the Code\)](#).

## Section 2 - Scope / Application

(2) This procedure applies to:

- a. Victoria University staff or students (wherever located) who undertake research, teaching or artistic work using animals.
- b. Victoria University staff or students (wherever located) who undertake research, teaching or artistic work using animal tissue, whether extracted from a living or dead animal.

## Section 3 - Definitions

(3) Nil

## Section 4 - Policy Statement

(4) Nil

## Section 5 - Procedures

### Part A - Roles and Responsibilities

| Roles   | Responsibilities  |
|---|---|
| Animal Welfare Officer(AWO)                                 | May identify or receive notification of non-compliant event<br>May determine severity of non-compliant event  |
| Scientific Procedures Premises License Holder (SPPL Holder) | Is informed of outcome of all AEC investigations of non-compliant event<br>May be part of the investigation team for serious non-compliant event investigation  |
| Animal Ethics Committee (AEC)                               | Considers all non-compliant events brought to its attention<br>Authorises immediate cessation of activities pending investigation if the allegation is considered to be of a serious nature<br>Arranges for investigation of non-compliant event<br>Orders the appropriate remedial action<br>Refers the matter to a research misconduct process if appropriate |
| AEC Chair   | Receives notification of non-compliant event<br>Provides initial review of non-compliant event to determine severity  |

| Roles              | Responsibilities   |
|--------------------|--|
| Chief Investigator | Person with overall responsibility for an AEC approved project Ensures any required actions from the AEC regarding management of the project or related projects are undertaken and if necessary reported back to the AEC. |
| AEC ethics officer | Provides administrative support to the AEC   |
| College Dean       | Co-operates with the AEC in the investigation of a non-compliant event Ensures any College Level required actions from the AEC are undertaken and where necessary reported back to the AEC                                 |

## Part B - General

(5) All non-compliant or suspected non-compliant events must be reported in writing to the AEC Chair this may be via the AWO or the AEC ethics officer. This is the responsibility of anyone working with animals at Victoria University.

(6) Reporting of a non-compliant event may occur as a result of following the animal use complaint management procedure or animal use adverse event procedure or may be made independently of these processes.

(7) An investigator, upon realising that a non-compliant event has occurred, must immediately notify the AEC Chair via the AEC ethics officer in writing. Reporting of non-compliance is to be encouraged and is consistent with a functional internal audit process.

(8) In some circumstances it will not be possible to determine the nature or extent of the non-compliance until an investigation has occurred. Such investigation will be undertaken in a manner to ensure minimal impact to animal welfare and timely reporting to the AEC.

(9) In investigation of a suspected non-compliant event it is essential that the principles of fairness are built into the investigation process.

(10) The AWO will be informed if there are or may be impacts to animal wellbeing and any decisions made by the AWO regarding the fate of individual animals are final. This may include euthanasia of animals.

(11) If a non-compliant event has resulted in adverse effects to animal wellbeing the adverse event procedure must be followed and an adverse event report submitted to the AEC.

## Part C - Investigation Process

(12) The process of investigation of a non-compliant or suspected non-compliant event involves the following steps.

### Categorisation of the event

(13) Upon notification the AEC chair (or delegate) will decide the severity of the non-compliance or potential non-compliance (this may be in consultation with the AWO and members of the AEC) and make a decision to assign one of three categories.

#### A. Minor non compliance

(14) Examples of minor non-compliant events include:

- a. An administrative error.
- b. Minor deviation from the approved protocol that is extremely unlikely to impact on animal welfare.
- c. Failure to maintain adequate records with no potential impact to animal welfare.
- d. Failure to supply required notification to the AEC with no potential impact to animal welfare.

## **B. Moderate non compliance**

(15) Examples of moderate non-compliant events include:

- a. Deviation from the approved protocol with no or minor impact to animal welfare.
- b. Failure to report on project progress as required by the AEEC.
- c. Failure to maintain adequate records with potential to impact on animal welfare.
- d. Animal facility environmental changes with no or minor impact to animal wellbeing.
- e. Failure to supply required notification to the AEC with potential impact to animal welfare.

## **C. Serious non compliance**

(16) Examples of serious non-compliant events include:

- a. Deliberate or negligent deviations from approved protocol where there has or there is the potential for significant impact to animal welfare.
- b. Failure to report an adverse event impacting on animal welfare to the AEC
- c. Animal use outside of an approved protocol.
- d. Change to animal facility environmental conditions that have significantly impacted on animal welfare or AEC approved projects.

## **Action**

(17) The action taken will be determined by the severity of the non-compliance or suspected non-compliance.

(18) In all cases the chief investigator or responsible person will be contacted by the AEC chair to provide a report to the AEC outlining the circumstances of the potential non-compliant event.

(19) While the person with primary responsibility for the welfare of animals allocated to a project is the chief investigator, consideration will be given to requiring information from all persons involved in the event.

(20) All investigators involved in the event must provide required and relevant information in an accurate and timely manner. Prompt response to all enquiries from the AEC and attendance at any meetings is expected.

(21) If the investigator is the person reporting the non-compliant event such a report should accompany the notification of the event.

(22) If the non-compliant event relates to animal facility management then the Animal Facility Manager will be contacted to provide a report regarding the non-compliant event.

## **A. Minor non compliance**

(23) The AEC Chair or AWO will report to the AEC the non-compliance or potential non-compliance and the AEC will review the relevant information at the next AEC meeting.

(24) In order to facilitate timely resolution of the matter the Chief investigator or responsible person and other relevant persons must be notified of the date of the AEC meeting at which the matter is to be discussed. All efforts should be made to be available should the AEC wish to meet to discuss the matter.

(25) In the case of a non-compliant event relating to animal facility management relevant parties may be required to attend the AEC meeting.

(26) The AEC will:

- a. Assess the information provided to determine if a non-compliant event has occurred.
- b. Determine any actions to be taken by the chief investigator or other persons.
- c. The AEC may choose to require additional information, review of records, and submission of a request for minor amendment form or other documentation to satisfy the committee that such an event will not occur in the future.
- d. Give consideration to the need to review other approved projects with which the chief investigator is also involved.
- e. Ensure the focus of investigation and review is on improvements in processes or protocols that will enhance animal welfare.
- f. On completion of the review, if it is determined that a non-compliant event has occurred, inform the license holder of the outcome of the assessment of the event, actions required and improvements that have been made.
- g. In order to determine that ongoing improvement has taken effect the AEC may set an appropriate time point to review the project and all related projects.

(27) The AEC secretary will ensure that all records relating to the event are filed. Records will be managed in accordance with the University's [Records Management Policy](#) and procedures , and retained in accordance with the [Retention & Disposal Authority](#) for University records.

## **B. Moderate non compliance**

(28) All steps in the minor non-compliance process will be followed.

(29) In addition the AEC Chair may determine that the event is to be considered by an out of session executive of the AEC.

(30) The executive may elect to suspend all activity associated with the project except ongoing maintenance of animals until the next full AEC meeting where the event can be discussed.

(31) In the case of an event relating to animal facility management the executive may elect to involve the license holder to ensure all animal facility stakeholders act promptly to resolve the issue.

(32) The license holder will be informed of the event and kept up to date with progress of any investigations or decisions.

(33) The AEC Chair in determining that an event of moderate non-compliance may have occurred will establish an investigation team which will include at a minimum the AEC Chair and the AWO to review the project under investigation and all related projects.

(34) The investigation team will assess the information provided to determine if in fact a non-compliant event has occurred. This may involve meeting with all relevant personnel involved with the project.

(35) The investigation team will:

- a. review all related projects.
- b. make all efforts to complete the review in order to present the finding at the next AEC meeting.
- c. make recommendations to the AEC regarding actions required to address the non- compliance.

(36) The chief investigator or responsible person will be required to attend the AEC meeting at which the matter is reported to discuss the findings and any required actions with the AEC.

## C. Serious non compliance

(37) All steps in the minor non-compliance process will be followed.

(38) The AEC Chair will immediately notify the License holder, AEC members and the chief investigator or responsible person and may instruct the chief investigator or responsible person that all work on the project other than ongoing maintenance of the animals be stopped pending an investigation.

(39) The AEC chair and or an executive of the AEC may allow in certain circumstances for work on remaining animals in a project to continue if there is no ongoing potential impact to animal welfare due to the non-compliant event pending the outcome of the investigation.

(40) The chief investigator will be required to submit a report to the AEC outlining the project and events. Such a report must be received within five working days of the notification of a requirement for a report.

(41) The AEC will establish an investigation team consisting of an executive of the AEC including the AWO; the license holder may elect or be asked by the AEC to be part of this team.

(42) This team will review the circumstances of the potential non-compliant event and report to the AEC.

(43) In exceptional circumstances and in discussion with the License Holder the Chair may determine that the investigation team not consists of an executive of the AEC, the investigation team will always include the AEC Chair.

(44) The investigation team will assess the information provided to determine if in fact a non-compliant event has occurred and may elect to meet with all relevant personnel involved with the project.

(45) The investigation team will also:

- a. review all related projects.
- b. meet with the chief investigator.
- c. make all efforts to complete the review in order to present the finding at the next AEC meeting.
- d. make recommendations to the AEC regarding actions required to address the non- compliance.
- e. contact the Bureau of Animal Welfare (BAW) to seek assistance in determining appropriate actions to be taken if the investigation team establishes that a serious event of non-compliance has occurred.

(46) The chief investigator or responsible person will be required to attend the AEC meeting at which the investigation team report is reviewed to discuss the findings and required actions with the AEC.

(47) If determined necessary by the AEC or the BAW, outcomes of required actions will be reported to the BAW.

(48) The focus of investigation and review should be on improvements in processes or protocols that will enhance animal welfare, and reduce the risk of such an event occurring in the future.

(49) On completion of the review, if it is determined that a serious non-compliant event has occurred, the AEC investigation team will liaise with the license holder to review the assessment of the event and actions required. See below for sanctions of such an event.

(50) If appropriate, in order to determine that ongoing improvement has taken effect the AEC will set a time point to review the project and all related projects.

(51) The AEC secretary will ensure that all records relating to the event are filed. Records will be managed in accordance with the University's [Records Management Policy](#) and procedures , and retained in accordance with the [Retention & Disposal Authority](#) for University records.

## **Sanctions**

(52) Sanctions are applied according to the categorisation of the event.

### **A. Minor non compliance**

(53) All required actions will be identified by the AEC and must be undertaken.

(54) The license holder notified of the non-compliant event and required actions.

### **B. Moderate non compliance**

(55) Work on the project and other related projects may be suspended pending AEC investigation.

(56) All required actions identified by the AEC and must be undertaken and reported back to the AEC.

(57) Prior to closure of the matter endorsement of the actions from the license holder will be required.

### **C. Serious non compliance**

(58) Work on project and other related projects will be suspended unless there is no potential impact to the wellbeing of the animals remaining in the project. This decision will be made by the AEC Chair and or an executive of the AEC.

(59) BAW will be informed and this may result in the BAW taking legal action such as fines or prosecution.

(60) The License Holder will be informed throughout the investigative process, and once the investigation is complete, the License Holder will give consideration to referring the matter for disciplinary action under the relevant misconduct provisions.

## **Section 6 - Guidelines**

(61) Nil

## Status and Details

|                            |   |
|----------------------------|---|
| <b>Status</b>              | Historic  |
| <b>Effective Date</b>      | 2nd September 2014  |
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