

Animal Welfare Non-Compliant Events Procedure

Section 1 - Summary

(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 current [Australian code for the care and use of animals for scientific purposes](#) (referred to as "the Code").

Section 2 - TEQSA/ASQA/ESOS Alignment

(2) HESF: 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity.

Section 3 - Scope

(3) This Procedure applies to:

- a. Victoria University staff or students (wherever located) who undertake research, teaching or artistic work using animals. This would include any visitors (when onsite at VU or off-site working on VU AEC approved projects).
- b. VU staff or students (wherever located) who undertake research, teaching or artistic work using animal tissue, whether extracted from a living or dead animal. This would include any visitors (when onsite at VU or off-site working on VU AEC approved projects).

Section 4 - Definitions

(4) Nil.

Section 5 - Policy/Regulation

(5) [Animal Welfare Policy](#)

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

| Roles | Responsibilities |
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| Animal Welfare Officer (AWO) | Will identify or receive notification of a non-compliant event. Will determine the severity of a non-compliant event. |
| Scientific Procedures Premises Licence Holder (SPPL Holder) | Is informed of the outcome of all AEC investigations of non-compliant events. |

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| Animal Ethics Committee (AEC) | Considers all non-compliant events brought to its attention. Authorises immediate cessation of activities pending investigation if the allegation is considered to be of a serious nature. Arranges for investigation of the non-compliant event. Orders the appropriate remedial action. Refers the matter to a research misconduct process if appropriate. |
| AEC Executive Officer | The AEC Executive Officer provides support services to the Committee. The Executive Officer is the first point of contact for Investigators wishing to access the AEC. |
| AEC Chair | Receives notification of a non-compliant event. Provides an initial review of the non-compliant event to determine severity. |
| Chief Investigator | The person with overall responsibility for an AEC approved project. Ensures any required actions from the AEC regarding the management of the project or related projects are undertaken and if necessary reported back to the AEC. |
| Investigator | Any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys. |
| AEC Executive Officer | Provides administrative support to the AEC. |
| Research Centre or Institute Directors of Centres or Institutes | Cooperates with the AEC in the investigation of a non-compliant event. Ensures any Centre, Institute, College-Level required actions from the AEC are undertaken and where necessary reported back to the AEC. |
| Executive Dean | Reviews a decision of the AEC in a complaint matter if a question is raised about the AEC process. |

Part B - General

(6) A non-compliant event is any event that is in accordance with the principles outlined in “The Code”. This includes but is not limited to conducting research or procedures with animals or by persons that are not approved by the Animal Ethics Committee. 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 Executive Officer. This is the responsibility of anyone working with animals at Victoria University.

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

(8) Reporting of a non-compliant event may occur as a result of following the [Animal Welfare Complaints Procedure](#) or [AEC - Procedure for Handling Adverse Events](#) or may be made independently of these processes.

(9) 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 on animal welfare and timely reporting to the AEC.

(10) The principles of procedural fairness will be followed in the investigation of a suspected non-compliant event. Key principles include the processing of complaints without delay, the right of the person accused of non-compliance to reply, and the right to fair and impartial decision making.

(11) 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.

(12) If a non-compliant event has resulted in adverse effects to animal wellbeing the [AEC - Procedure for Handling Adverse Events](#) must be followed and an adverse event report submitted to the AEC.

Part C - Investigations Process

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

Categorisation of the Event

(14) 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

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

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

(b) Moderate non-compliance

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

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

(c) Serious non-compliance

(17) 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 moderately or severely impacting on animal welfare to the AEC.
- c. Animal use outside of an AEC approved protocol.
- d. Change to animal facility environmental conditions that have significantly impacted on animal welfare or AEC approved projects.

Action

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

(19) 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.

(20) 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.

(21) 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 as requested is required.

(22) If the investigator is the person reporting the non-compliant event such a report should accompany the notification of the event. This will occur within a period of 14 days.

(23) 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.

(24) Depending on the outcome of the AEC investigation of non-compliance, the matter may constitute a breach of Victoria University's [Research Integrity Policy](#). In this event, the matter may be referred to Victoria University's Research Integrity Officer. Further information on this Procedure can be found at [Research Integrity-Guide to the Management of Potential Breaches of the Australian Code Procedure](#).

(a) Minor non-compliance

(25) 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 scheduled AEC meeting. 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. It is required that Chief Investigator be available at the time of the AEC meeting should the AEC wish to discuss the matter further. Availability in person, teleconference or via telephone should be arranged with the AEC Executive Officer prior to the AEC meeting time.

(26) In the case of a non-compliant event relating to animal facility management, relevant parties may be required to attend the AEC meeting. Availability in person, teleconference or via telephone should be arranged with the AEC Executive Officer prior to the AEC meeting time.

(27) 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.

(28) The AEC Executive Officer 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

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

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

AEC.

(31) 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.

(32) 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.

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

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

(35) 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.

(36) 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.

(37) 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

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

(39) 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.

(40) 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.

(41) 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.

(42) The AEC will establish an investigation team consisting of members of the AEC including the AWO; the license holder may elect or be asked by the AEC to be part of this team. In situations where the Licence Holder may perceive that being part of the investigation team would represent a conflict of interest, they may elect a nominee to be part of the investigation team.

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

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

(45) 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.

(46) 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 Agriculture Victoria to seek assistance in determining appropriate actions to be taken if the investigation team establishes that a serious event of non-compliance has occurred.

(47) 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.

(48) If determined necessary by the AEC or Agriculture Victoria, outcomes of required actions will be reported to Agriculture Victoria.

(49) 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.

(50) 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 the actions required. See below for sanctions of such an event.

(51) 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.

(52) The AEC Executive Officer 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

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

(a) Minor non-compliance

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

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

(b) Moderate non-compliance

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

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

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

(c) Serious non-compliance

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

(60) Agriculture Victoria will be informed and this may result in Agriculture Victoria taking legal action such as fines or prosecution.

(61) 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. This may include further investigation under the Australian Code for the Conduct of Responsible Research and the Victoria University [Research Integrity Policy](#).

Part D - Reporting Obligations

(62) A summary of non-compliance(s) with the Code as determined by the Victoria University AEC will be provided to the Animal Welfare Victoria as part of a mandatory annual animal usage report. In addition, non-compliance will be reported to the License Holder and the Research and Research Training Committee in a quarterly report.

(63) Instances, where there is a presumed breach of the Victoria University [Research Integrity Policy](#), will be reported as outlined in Part J of the [Research Integrity – Guide to the management of potential breaches of the Australian Code Procedure](#).

Status and Details

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