AUSTIN HEALTH AEC (2020) PROCEDURE FOR NON-COMPLIANT EVENTS

1. PURPOSE

The purpose of this procedure is to ensure non-compliant events are investigated and managed appropriately and in accordance with The Australian Code for the care and use of animal for scientific purposes 8th Edition 2013.

The relevant sections of the Code are:

2.1.7 Institutions must identify clear lines of responsibility, communication and accountability by:

(ii) ensuring that procedures are developed for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes (see Section 5).

2.2.20 Institutions must establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use. These procedures should include declaration of interests and management of conflicts of interest, confidentiality, appointment of and delegation of functions to an AEC Executive, administrative processes, meeting procedures, communication, complaints and non-compliance, records and documentation.

2.2.29 Institutions must have procedures for dealing with complaints and non-compliance with the Code, complaints related to the AEC process, and irreconcilable differences between the AEC and an investigator (see Section 5).

2.3.25 when projects or activities that are in breach of the Code are detected, the AEC must ensure that:

(i) actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately (see Clauses5.2 [i] and 5.4 [i]). Actions may include suspending or withdrawing approval for the project or activity.

(ii) actions are taken to address the issues in consultation with the person(s) involved.

(iii) when considered necessary, such matters are referred to the institution for action.

(iv) non-compliance receives appropriate follow-up.

5.1 Institutions must have procedures for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes, including:

(iv) non-compliance with the Code by any party or person involved in the care and use of animals including investigators, animal carers, the AEC, governance officials, and external parties subject to agreements described in Clauses 2.6.3 and 2.6.6.

Non-compliance may also involve breaches of relevant state or territory legislation, and institutions should have procedures for advising regulatory authorities (see Clause 5.12).

5.2 Institutional procedures must:

(i) give priority consideration to the wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately.

(ii) clearly define the mechanisms for receiving, investigating and addressing complaints.

(iii) clearly define the mechanisms for addressing non-compliance with the Code.

(iv) clearly define the responsibilities of all parties.

(v) ensure fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers.

(vi) identify and ensure appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies.

(vii) be made available to all relevant people.

5.9 Institutions must have procedures for addressing non-compliance with the Code, so that behaviours that create and support compliance are encouraged, and behaviours that compromise compliance are not tolerated.

5.10 The institution must maintain records of breaches of the Code.

2. GENERAL

- This procedure applies to all staff, researchers and students involved in the care and use of animals for scientific purposes within Austin Health and all users of the BioResources Facility (BRF).
- It is the responsibility of all people within the BRF, to report any non-compliant event or suspected non-compliant event to the AEC. The non-compliant events may be initially reported to the AEC via AWO or BRF manager, who will then ensure the AEC is informed. This report must be in writing and a template for this report can be found on the Austin Health website.
- The reporting of a non-compliant event should be immediate as this ensures that any compromise to animal welfare is eliminated or significantly reduced. Self-reporting of non-compliant events is encouraged and assists in improvement of protocols and AEC processes.
- A non-compliant event may arise out of an investigation into an adverse event or from a formal complaint or an independent event. If an adverse event is involved in the non-compliance then the adverse event procedure must also be followed.
- The AEC will investigate the non-compliant event and any decision determined by

the AEC must be acted upon. The BRF manager and/or AWO may determine the fate of the animals prior the full AEC investigation and all decisions regarding animal welfare must be complied with, including humane euthanasia.

3. AEC NON-COMPLIANT EVENT INVESTIGATION PROCEDURE

A. Classification

When a non-compliant event has been reported to the AEC, the AEC chair will be notified and they will determine the classification of the event. The course of action will be dictated by this classification and may be done in consultation with the AWO, BRF manager and members of the AEC.

The classifications of the non-compliant event are determined primarily on the impact or potential impact to animal welfare and intent e.g. if there has been repetitive, wilful or intentional disregard for AEC procedures.

The classifications are as follows;

1. Minor Non-compliance

This includes events that have no impact or potential impact to animal welfare. Examples of such events include:

a) Record keeping error or omission that has no impact on animal welfare.
b) Deviation from approved protocol that has no or very limited impact on animal welfare.
c) Delay in notifying the AEC of the event with no impact on animal welfare
d) Facility environmental alteration with no or little impact on animal welfare.

2. Moderate Non-compliance

This includes events that have some impact or potential impact to animal welfare. Examples of such events include:

a) Record keeping error or omission such as poor monitoring records that have some impact or potential impact on animal welfare.
b) Failure or significant delay in reporting to the AEC as requested regarding project progress or annual/final reports or significant delay in investigator responses to AEC request for information.
c) Repeated instances of minor non-compliance by an investigator or within a project.

3. Serious Non-compliance

This includes events that have significant impact or the potential for significant impact on animal welfare, or repetitive non-compliant behaviour, with or without previous sanctions from AEC for non-compliance.
Examples of such events include:

a) Deliberate or repeated deviations from an approved protocol where there is potential for significant impact to animal welfare.

b) The use of animals outside of an approved protocol. This includes the following but is not limited to:
   i. Using numbers of an approved strain in excess of those approved for that strain;
   ii. Using numbers of an approved strain in excess to those approved;
   iii. Use of animals after the period of approval has expired;
   iv. Change of animal strain or procedure including changes in drugs, dosages or route without approval from the AEC;
   v. Use of animals without AEC approval.

c) Deliberate or repeated ignorance of AEC requests regarding project reporting.

d) Failure to report an adverse event or known non-compliance to the AEC.

e) Facility environmental alteration that has significant impact on animal welfare.

B. Action

The actions undertaken by the AEC will be dependent on the classification of the non-compliant event. In all cases the following will apply:

a) The Principal Investigator (PI) will be informed by the AEC chair and be required to provide a written report to the AEC regarding the event. This report should include the events that contributed to the non-compliance, the time frame and outcome of the non-compliance and how the PI plans to prevent reoccurrence of such an event. This report can be tabled at the same time as the initial notification of the event to the AEC. A template for this report can be found on the Austin Health website.

b) All investigators involved in the non-compliance may be required by the AEC to provide information pertaining to the event.

c) The AEC chair and/or executive may determine that work on the protocol may be continued if it is deemed beneficial for animal welfare to continue the work.

d) Reports may also be required from the BRF staff and AWO and/or other investigators and if requested must be provided.

e) These reports and responses must be provided in a timely manner and if not provided the matter will be escalated to a serious non-compliant event,

regardless of the initial classification. Co-operation with all AEC requirements is mandatory, including attendance at meetings if requested.

f) The manager of the BRF will be required to provide a report to the AEC if the non-compliance relates to a facility environmental alteration.

1. Minor non-compliance

a) The AEC chair and/or AWO and/or BRF manager and/or Veterinary Consultant will report to the AEC at the next meeting regarding the events of the non-compliance and how the issues have been addressed.

b) The PI and investigator involved will be informed of the date at which the event will be reviewed and must be available to attend as required by the AEC.

c) The AEC will review the reports of the non-compliance and determine what actions are required by the PI and other investigators involved. This review should focus on improvement of processes and procedures to ensure animal welfare is protected and, if possible, enhanced.

d) The AEC may request all current approved protocols the PI and other investigators are involved with be reviewed and audited.

e) If the AEC determines that a non-compliant event has occurred then, if appropriate, the head of department and licence holder should be informed of the review and outcome.

f) A timely review by the PI of the improved processes and procedures may be requested by the AEC and this must be provided within the time frame allocated.

g) All data relating to the noncompliant event will be recorded and records kept by the AEC secretary as per the Office For Research standard data management policy.

2. Moderate Non-compliance

a) All of the actions involved in a minor non-compliance investigation will be followed.

b) The AEC chair may determine that an AEC out-of-session~~s~~ meeting or executive meeting is required to investigate whether the event is deemed a moderate non-compliance.

c) Once a moderate non-compliant event has been determined to have occurred, the following will be instigated:

   i. The AEC chair and/or executive may elect to temporarily halt any interventions within the protocol and only maintain animals whilst investigating. If animal welfare is compromised by this decision, then animals in the protocol may be humanely euthanased whilst the investigation is proceeding. This temporary protocol suspension may be

in place until the next scheduled full AEC meeting.

ii. The AEC chair will establish a team to investigate the event. This team will include at least the AEC chair and AWO and they will review the events leading to the non-compliance, the protocol and the non-compliance report submitted by the PI. This review may encompass all current approved protocols the PI and investigators are involved in.

iii. Once all information pertaining to the event has been investigated by the team then the team will meet with all those involved with the non-compliant event.

iv. The licence holder and, if appropriate, the head of department, will be informed of the non-compliant event~~,~~ and will be updated as the investigation process is undertaken and notified of the eventual outcome of the investigation.

v. Once the investigation is completed, the team will report to the AEC at the next scheduled meeting and make recommendations to the AEC regarding further actions to be taken.

vi. The PI will be required to attend and address the AEC meeting at which the event is being discussed.

vii. If the non-compliance event relates to the functioning of the BRF then the manager of the BRF must provide a report to the AEC at the next meeting.

3. Serious Non-compliance

a) All of the actions for the minor non-compliance will be followed.

b) The AEC chair will immediately notify the licence holder, the AEC, the PI and head of department/supervisor that a serious non-compliant event is being investigated.

c) The AEC chair and/or executive may instruct that all work on the protocol be halted whilst the investigation is pending, and if welfare is compromised then all animals on the protocol may be euthanased.

d) The AEC chair and/or executive may determine, in exceptional circumstances, that work on the protocol may be continued, if it is deemed beneficial for animal welfare to continue the work.

e) The PI must supply a written report to the AEC regarding the non-compliance within 2 working days.

f) Once a serious non-compliant event has been identified an investigation team will be established by the AEC chair and comprise of an AEC executive and will always include the chair.

g) The investigation team will determine the extent of the non-compliant event and may interview all persons involved with the event, including staff of the BRF.

h) The investigation team must be granted access to all records and information

pertaining to the non-compliant event, including any BRF monitoring records, laboratory books and/or database information.

i) The team will meet with the PI and any other investigators involved.
j) The investigation team will inform of progress and make recommendations to the AEC and the licence holder. They may also inform the regulator, Animal Welfare Victoria, to garner advice and/or to report progress of the non-compliance.
k) The investigation team will maintain records of all their determinations and these are to be maintained by the AEC secretary.
l) The PI must attend the AEC meeting at which their non-compliant event is discussed to provide a report and discuss actions required by the AEC.
m) The results of the review and investigation will be reported to the PI, the licence holder and may, if necessary, be reported to the regulator.
n) The AEC will then monitor and review the progress of the PI and investigators involved as is deemed necessary.
o) All records pertaining to the non-compliant event will be recorded and maintained by the AEC secretary.

C. Sanctions

These are determined by the classification of the non-compliant event:

1. Minor Non-compliance

a) All actions determined by the AEC must be followed.
b) The licence holder will be informed at an appropriate time.
c) Training and or education on the use of animals in research may be required.

2. Moderate Non-compliance

a) All actions determined by the AEC must be followed.
b) Work on the protocol may be suspended until the investigation is complete.
c) The licence holder will be informed.
d) The investigator involved may be required to complete further training and may not be granted access to the BRF until all AEC conditions have been satisfied.

3. Serious Non-compliance

a) All actions determined by the AEC must be followed.
b) Work on all protocols involving the investigator will cease unless the AEC determine that there are animal welfare implications for doing so. Animals may be humanely euthanized if required.

c) The licence holder will be informed.
d) The regulator will be informed and if they determine, legal proceedings may be instigated by the regulator.
e) The AEC may refer the matter to the appropriate body for research misconduct investigations to be implemented.
f) The investigator will not be permitted into the BRF until all AEC requirements have been fulfilled and may never regain this privilege.