STANDARD OPERATING PROCEDURE FOR NON COMPLIANCE OF ANIMAL ETHICS

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POLICY
The Animal Ethics Committee (AEC) is required to investigate alleged incidents or complaints relating to animal welfare to determine whether a non-compliance has occurred, and to act on the findings of the investigation based on the degree of non-compliance identified in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004) (the Code).

RESPONSIBILITIES
1.1 The University, the AEC, investigators and teachers have responsibility for compliance with the Code and the WA State Animal Welfare Act (2002) (the Act).
1.2 Investigators and teachers have personal responsibility for all matters related to the welfare of the animals they use. This responsibility begins when the animal is allocated to a project and ends with its fate at the completion of the project.
1.3 In order to ensure the wellbeing of animals used in their projects, investigators and teachers must ensure that the level of supervision of personnel involved in the care and management of the animals in their projects takes into account the levels of competence of each person and the responsibilities they are given.
1.4 Investigators are responsible for documenting any adverse event associated with their approved projects as soon as practicable following the event using the adverse event/unexpected death report template (http://www.research.uwa.edu.au/__data/assets/rtf_file/0009/514449/Notification-of-animal-death.rtf) and providing this report to the Animal Ethics Office (AEO) for presentation at the next scheduled AEC meeting for discussion.
1.5 In situations where a non-compliance/breach is reported, the AEC is responsible for conducting an investigation and determining an appropriate response which may include formally withdrawing approval for a project or authorising the treatment or humane killing of any animal.
1.6 The Deputy Vice-Chancellor (Research), as the scientific license holder for the university, is responsible for responding promptly and effectively to recommendations of the AEC to ensure that all use of animals for scientific purposes within the University remains in accord with the Code and the Act.

PROCEDURE
Adverse Events/Unexpected Deaths
2.1 Investigators, teachers and/or Animal Care Services (ACS) staff must report any adverse event/unexpected death involving an animal to the Technician-in-Charge (TIC) or the Manager Animal Care Services (MACS) as soon as practical after the event. The Animal Welfare Officer (AWO) must then be informed immediately who will communicate to the Chair of the AEC in writing. In some instances the Animal Welfare Veterinary Advisors (AWVA), ACS Veterinary Officers (VO) or AEO may be advised of an adverse event/unexpected death and, once reported, it is the responsibility of the person notified to inform the AWO and the Investigators as soon as practical.
2.2 Animals dying without a known cause are required by the NHMRC to be submitted for pathology testing. In the case of an adverse/unexpected death the animal facility TIC or the MACS will consult with the Investigator(s) and will arrange for an initial necropsy to be conducted, where appropriate, and organise pathology testing. The extent of testing (eg. gross post mortem + histopathology) is to be determined on a case-by-case basis. The report(s) is to be made available to the Investigator(s) who is to document the adverse event using the unexpected death report template (see 1.4 above) and at the same time the MACS is to report the unexpected death as part of his/her monthly report to the next AEC meeting where subsequent discussion and actions are minuted.
2.3 Adverse event/unexpected deaths and the actions taken are to be reported on the NHMRC annual Statement of Compliance, to the State Regulator as part of the annual animal usage report and licensing documentation, and to the Deputy Vice-Chancellor (Research) as part of the annual AEC report to UWA.
2.4 Repeated incidences of adverse events and/or unexpected deaths are to be reported and investigated as a potential non-compliance (see below).
Non-Compliance

3.1 Reports of incidents and complaints alleging non-compliance may come from any internal or external source and may be reported to the AWO, the Chair of the AEC, or the AEO. If the complainant considers it inappropriate to report their concerns to any of these persons, the Deputy Vice-Chancellor Research (DVC(R)) is to be contacted. Once reported, it is the responsibility of the person notified to immediately inform the AEC Chair, AWO and DVC(R).

3.2 The AEC Chair, based on advice from the AWO, is responsible for determining whether the:
   - Alleged incident or complaint should be investigated for non-compliance, as detailed in Figure 1.
   - Activity needs to be ceased immediately, and whether immediate action is required to alleviate any animal suffering or distress.
   - If immediate action is taken the Chair of the AEC is to advise the Investigator(s) and the MACS in writing.

3.3 The AEC will investigate and determine whether non-compliance has occurred, the degree of the non-compliance, and the action to be taken based on the degree of the incidence. This decision is to be made as soon as practical after notification.

3.4 The AEC investigation will be conducted by a review team that must include one each of Category A to D members, and the Chair or Deputy Chair of the AEC. The investigation should include interviews with the Investigators and other parties if deemed necessary, and will provide a written report to the full AEC as soon as practicable. Within 10 working days of the completion of the investigation, the AEC will convene an extraordinary meeting to consider the findings and decide a course of action.

3.5 If the AEC determines a non-compliance has not occurred:
   - The person making the allegation is informed
   - The investigator is informed

3.6 If the AEC determines that a non-compliance has occurred, the degree of non-compliance is assessed as per Table 1:

   Minor Non-Compliance
   - The investigator, Head of School and DVC(R) are informed
   - The allegation, assessment and recommended actions are reported in the AEC minutes
   If there is a repeat of the incident, it is to be dealt with as a major non-compliance.

   Major Non-Compliance
   - The investigator, Head of School and DVC(R) are informed
   - The activity must cease immediately
   - Appropriate action is to be taken to alleviate any animal suffering or distress (if not already implemented).
   - The allegation, assessment and recommended actions are reported in the AEC minutes.

3.7 Recommended actions of the AEC will depend upon the degree of the non-compliance and may include, but are not limited to:
   - Cautioning the investigator
   - Suspending or withdrawing approval of the project
   - Recommending disciplinary action to the DVC(R). The AEC does not have the legal authority or responsibility to discipline personnel of the University
   - In the case where non-compliance is detected after the completion of the project, the AEC may recommend some remedial action be taken by the DVC(R).

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1 The AWO can make the decision to alleviate any animal suffering or distress immediately upon notification if deemed necessary for the welfare of the animal.
**Reporting of Non-Compliance**

4.1 The AEC Chair is to report the incident and the outcomes of the AEC decision to the DVC(R), and, if the incident involves non UWA staff, to the employing Institution.

4.2 The AEC Chair is to inform the Investigator who has the right to appeal (see Section 5).

4.3 The AEC should report any adverse events, unexpected deaths or incidents of non-compliance to the NHMRC, the State Regulator and the DVC(R) as part of the NHMRC Annual Statement of Compliance, the State Annual Animal Usage Report and Licensing documentation, and the Annual AEC Report to the University, respectively.

4.4 The Deputy Vice-Chancellor (Research) is to inform the Statutory Authority and the NHMRC or other stakeholder of incidents of major non-compliance, while incidents of minor non-compliance will only be reported if deemed necessary.

**Resolution of Disagreements**

5.1 Irreconcilable differences between the AEC and an investigator or teacher must be referred to the Animal Ethics Executive\(^2\) for review of due process. The ultimate decision of the AEC after such review must not be over-ridden (see 2.2.14 of the Code).

5.2 Disagreements between AEC members and the University must be referred to the Animal Ethics Executive for fair resolution in the first instance, and may then be referred to the UWA complaints handling process at [http://www.complaints.uwa.edu.au/](http://www.complaints.uwa.edu.au/) if further resolution is required.

**Records**

6.1 Records of all adverse events, unexpected deaths and non-compliance investigations will be maintained by the AEC Secretary with a copy stored on the TRIM project file.

**REFERENCES**


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\(^2\) The Animal Ethics Executive includes the DVC(R), the Chair of the AEC and one other person nominated from Category C or D members.
Table 1 – Guide to the degree of non-compliance of animal ethics

<table>
<thead>
<tr>
<th>Major</th>
<th>Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Unauthorised animal use:</td>
</tr>
<tr>
<td>b.</td>
<td>Unauthorised animal use:</td>
</tr>
<tr>
<td>c.</td>
<td>Refusal or failure to submit annual or progress report</td>
</tr>
<tr>
<td>d.</td>
<td>Unauthorised animal use:</td>
</tr>
<tr>
<td>e.</td>
<td>Failure to report adverse outcomes to AEC</td>
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<tr>
<td>f.</td>
<td>Unauthorised animal use:</td>
</tr>
<tr>
<td>g.</td>
<td>Failure to submit an annual or final report on time</td>
</tr>
<tr>
<td>h.</td>
<td>Failure to keep satisfactory records of animal use</td>
</tr>
<tr>
<td>i.</td>
<td>Animals held and not used</td>
</tr>
<tr>
<td>j.</td>
<td>Unauthorised investigator: animal procedure performed by an investigator not included on project application</td>
</tr>
<tr>
<td>k.</td>
<td>Incomplete paperwork e.g. no signatures</td>
</tr>
<tr>
<td>l.</td>
<td>Unsatisfactory annual or final report</td>
</tr>
</tbody>
</table>

Please note that:

(i) This document is for guidance only and each breach should be determined on a case-by-case basis keeping in mind the number of incidents, length of response time and whether the non-compliance was deliberate, a mistake or supplier error etc.

(ii) Communication between the AEC and animal facility staff is important to help ensure compliance when reporting or when special conditions have been imposed.
Figure 1 – Schematic representation of non-compliance procedures

1. Complaint alleging non-compliance of animal ethics
   This may come from any source internal or external to the University

2. Chair of AEC, AWO and DVC(R) notified
   Chair of AEC to determine if alleged incident or complaint should be investigated for non-compliance
   Chair of AEC and/or AWO to decide if activity ceased immediately to alleviate animal suffering and distress

3. AEC to consider alleged incident or complaint to determine if non-compliance has occurred

4. **Yes**
   - Degree of non-compliance is assessed

5. **Major**
   - Investigator, Head of School and DVC(R) informed
   - Activity must cease immediately
   - Appropriate action taken to alleviate animal suffering and distress (if not already implemented)

6. Repeat of incident

7. **Minor**
   - Investigator, Head of School and DVC(R) informed
   - Allegation, assessment and recommended actions reported in AEC minutes

8. **No**
   - Person making allegation is informed
   - Investigator is informed

Depending on the degree of non-compliance the AEC may:
- Caution the investigator
- Suspend or withdraw approval of the project
- Recommend disciplinary action to the DVC(R). The AEC does not have the legal authority or responsibility to discipline personnel of the University
- In the case where non-compliance is detected after the completion of the project, the AEC may recommend some remedial action to be taken by the DVC(R)

9. AEC to report incidents on non-compliance as part of NHMRC Annual Statement of Compliance, the State Annual Animal Usage Report and Licensing documentation, and the Annual AEC report to the University
The DVC(R) is to inform the Statutory Authority and the NHMRC of incidents of major non-compliance, if deemed necessary.