AMREP Animal Ethics Governance and Policy Committee

Procedures for responding to non-compliance with the Australian code, legislation or animal ethics committee decisions

Purpose

These procedures provide a framework for the Alfred Medical Research and Education Precinct (AMREP) Animal Ethics Committee to investigate alleged non-compliance and to act on the findings of the investigation based on the degree of non-compliance identified in accordance with the *Australian code for the care and use of animals for scientific purposes 8th Edition 2013*.

Requirements of the Code

Section 2.1.1 The governing body of an institution is responsible for ensuring that the care and use of animals for scientific purposes conducted on behalf of the institution complies with the Code.

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

i. ensuring that procedures are developed for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes.

Section 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.

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

i. complaints concerning the care and use of animals by the institution, including conscientious objection in the case of teaching activities
ii. complaints concerning the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution
iii. SPPL – Scientific Procedure Premise Licence
iv. SABL – Specified Animal Breeding Licence
v. SPFL – Scientific Procedure Fieldwork Licence.

Definitions

AMREP means Alfred Medical Research and Education Precinct, and includes:

- Baker IDI Heart and Diabetes Institute
- The Alfred Hospital
- Monash University Central Clinical School
- Burnet Institute
- AMREP AS Pty Ltd.
- Tenants or other entities nominating the AMREP Animal Ethics Committee A or B on their SPPL, SABL, or SPFL.

AEC means AMREP Animal Ethics Committee A or B.

AEC Chair means the Chairperson of Animal Ethics Committee A and/or B

AWO means Animal Welfare Officer.

AMREP AS means AMREP Animal Services, which runs the Precinct Animal Centre.

GAP Chair means the Chairperson of the AMREP Animal Ethics Governance and Policy Committee.

Government Regulator means Department of Economic Development, Jobs, Transport and Resources (DEDJTR).

Licence Nominee means the scientific licence nominee of one of the AMREP partner institutions.

Research Conduct Officer means the person nominated by the institution to investigate and record allegations of research misconduct

Procedures

1. Non-Compliance

1.1 **Non-compliance is:**

- A breach of one or more of:
  - the *Australian Code for the Responsible Conduct of Research (2007)*
  - the *Prevention of Cruelty to Animals Act*
  - the *Australian Code for the Care and Use of Animals for Scientific Purposes*
  - the *Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits*
  - the *Code of Conduct for scientific procedures using animals under AMREP licences*
  - AMREP AEC or AMREP Animal Ethics GAP Committee procedures and guidelines.
- breaking of an agreement or commitment made by scientific investigators with the AEC.

1.2 Reports of incidents and complaints alleging non-compliance may come from any internal or external source and may be reported to the AWO, AMREP AS management, the AEC Chair or directly to the Animal Ethics Office. AEC members may identify potential instances of non-compliance during inspections of the PAC or laboratories where animal work is undertaken.

1.3 Repeated instances of adverse events are to be reported and investigated as a potential non-compliance.

1.4 The AWO or nominee in their absence is responsible for determining whether immediate action is required to alleviate any suffering or distress in an animal.

1.5 The AEC Chair, based on advice from the AWO and/or in consultation with the AEC executive, is responsible for determining whether the:

- activity must cease immediately
- if the alleged incident or complaint should be investigated for non-compliance

If immediate action is required, the AEC Chair is to advise the investigator(s), the AEC Secretary and the General Manager, AMREP AS, in writing.

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

1.7 The AEC investigation will be conducted by a review team that must include one of each of Category A to D members, and the AEC Chair or Deputy Chair. The investigation should include interviews with the investigators and other parties as deemed necessary. The review team will provide a written report to the full AEC as soon as practicable.

1.8 If the AEC determines that non-compliance has not occurred:

- the person making the allegation is to be informed
- the investigator is to be informed.

1.9 If the AEC determines that non-compliance has occurred, the degree of non-compliance will be assessed with reference to Table 1.

2. Assessment of Degree of Non-compliance

2.1 Minor non-compliance (Score of 1, Table 1)

- The Investigator is informed
- The Licence nominee may be 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.

2.2 Major non-compliance (Score of 2-3, Table 1)

- The investigator and the Licence Nominee 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 to be reported in the AEC minutes
- Where appropriate, the allegation, assessment and recommended actions may be reported to the Government Regulator
- The allegation, assessment and recommended actions may be reported to the institutions Research Conduct Officer if the AEC believes serious research misconduct may have occurred

3. Recommended Actions

3.1 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 withdrawal of approval of the project:
  - The AEC should specify a deadline for the investigator to provide a summary outlining the following:
    - status of all animals and cohorts allocated to the project to date, as well as any animals due (already assigned) to commence in the project
    - procedures and project aims the animals will be subjected to and endpoint dates.
  - The AEC should refer to this summary in order to determine on a case by case basis if:
    - The whole project is suspended either temporarily or indefinitely or
    - The project is only partially suspended with some parts of the project allowed to continue and specifically which component of the aims can be conducted if the aim has multiple protocols.
  - If the AEC decides to suspend the whole project the AEC must:
    - Notify all investigators listed on the project of the project status.
    - Specify the date when all animals in the project must be removed from shelf.
    - Be provided with a record of animals killed or removed.
    - Specify the date when the Animal Ethics Office should close the project in the animal ethics database.
  - Where the AEC decides to only suspend parts of the project the AEC must:
    - Clearly document which parts of the project can continue and which parts are suspended and ensure all correspondence is consistently labelled and

itemised accordingly. All correspondence should specify deadlines and timeframes applicable to all continuing and suspended activities.

- Specify the date when animals that are ceasing activity in the project must all be removed from shelf.
- Be provided with a record of animals killed or removed from the project
- Ensure the Chief Investigator acknowledges the status of their project in writing and understands that no further consideration will be given to any other animals or experiments identified by the investigator after this point.
- Notify all personnel listed on the project of the project status.

- All members of the review team must be consulted, either face to face or out of session, before making any further changes to the project status.

- When non-compliance is detected after the completion of the project, the AEC may recommend some remedial action be taken by the applicable licence nominee.

3.2 The AEC does not have the legal authority or responsibility to discipline personnel but may recommend disciplinary action to the applicable Licence Nominee.

3.3. In order to finalise its investigation, the review team should receive notification from the applicable Licence Nominee within a specified timeframe regarding the disciplinary action and improvements they will implement in order to manage future risk of non-compliance. Where applicable, the review team may request further confirmation from the licence nominee and/or investigator that these steps have been followed through.

4. Reporting of Non-Compliance

4.1 The AEC Chair is to report the incident and the outcomes of the AEC decision to the relevant Licence Nominee.

4.2 The AEC Chair is to inform the Investigator who has the right to appeal (refer to *Grievance procedures*).

4.3 Any incidents of major non-compliance are to be reported by the Animal Ethics Office to the NHMRC (if NHMRC-funded) as part of the NHMRC Annual Statement of Compliance, the Government Regulator (where appropriate), in the annual report to the AEC and the AEC Annual Report to the Licence Nominees. Incidents of minor non-compliance will only be reported if deemed necessary by the review team.

5. Records

5.1. Records of all correspondence related to the non-compliance investigation, including email correspondence, will be maintained and logged.

5.2. All instances of non-compliance will be recorded in a central register within the Animal Ethics Office.

Table 1: Guide to the degree of non-compliance

Incidents of non-compliance are determined by level of severity and type. The levels of severity are from 1 to 3, where 1 is the least severe and 3 is regarded as major non-compliance. Incident types can be identified as administrative, or as causing actual or potential adverse impact on animal welfare.

Please note: this table is intended to be a guide only. The level of severity will vary depending on the individual circumstances of the incident. The AEC will investigate and determine whether non-compliance has occurred, the degree of the non-compliance, and the action to be taken on a case by case basis.

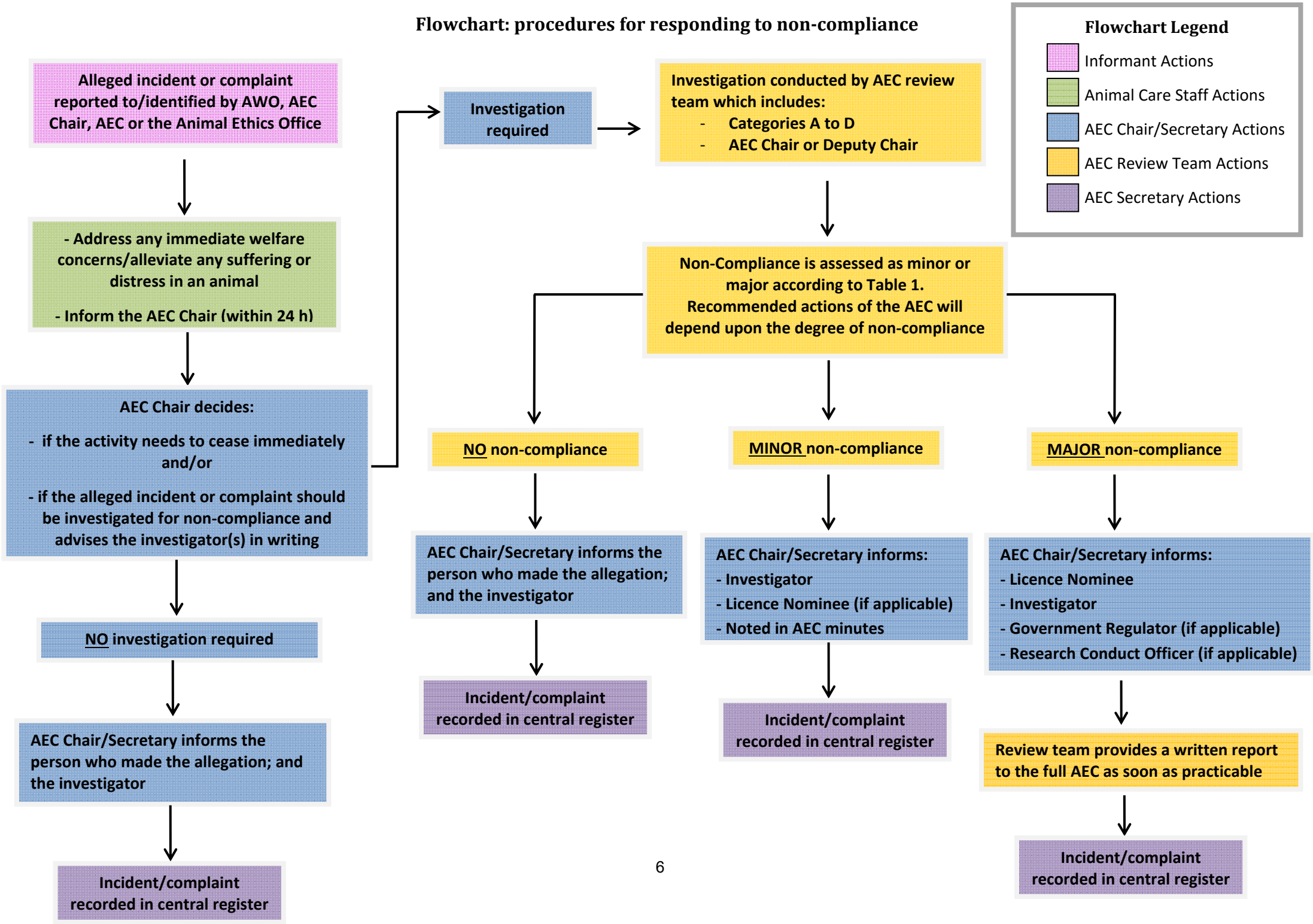
Level of severity	Incident	Type of incident

3	• Unauthorised animal use:
	  • Animal use for a project or use of an animal procedure without submission of an application to the AEC
	  • Animal use for a project commences prior to written approval
	  • Animal procedure performed that is specifically prohibited by the AEC or legislation
	  • Animal procedure performed incompetently so as to have a negative impact on animal welfare or animals in pain and distress are not treated appropriately i.e. by the introduction of supportive care or euthanasia
	  • Animal use continued after approval has been withdrawn or suspended
	  • Animal use continued on a project after the period of AEC approval has expired
	  • Overuse of animals is detected by the AEC or another party, or reported by the investigators
	  • Change of procedures without AEC approval
	  • Animal procedures performed by an unauthorised investigator
	  • Change of animal species without AEC approval
	  • Change of animal strain with a higher welfare impact without AEC approval
	• Failure to report adverse events to the AEC
		Animal Impact
		
		Animal Impact

2	• Unauthorised animal use:
	  • Failure to perform a procedure (e.g. regular monitoring, euthanasia, analgesia use) resulting in likely animal suffering
	  • Change of animal strain with no change in welfare impact without AEC approval
	• Failure to keep satisfactory records of animal use
	• Animals held but not used in the course of research
	• Failure to submit an annual or final report by the due date
		Animal Impact
		
		Administrative/Animal Impact
		
		Administrative

1	• Failure to submit a complete annual or final report to the satisfaction of the AEC	Administrative

Flowchart: procedures for responding to non-compliance



Supporting documents:

Australian code for the responsible conduct of research 2007
http://www.nhmrc.gov.au/guidelines/publications/r39

Australian code for the care and use of animals for scientific purposes 8th edition 2013
http://www.nhmrc.gov.au/guidelines/publications/ea28

Code of conduct for scientific procedures using animals under AMREP licences – August 2015
http://amrepaec.bakeridi.edu.au/LinkClick.aspx?fileticket=DkrJ9Jo50i4%3d&tabid=647

AMREP AEC terms of reference and operating procedures – November 2015
http://amrepaec.bakeridi.edu.au/LinkClick.aspx?fileticket=Lg9XOQY330U%3d&tabid=636

Record of version

Version No.	Author	Date	Version Reason	Due for Review
1	AMREP Animal Ethics GAP Committee	June 2013	New	June 2015
2	AMREP Animal Ethics GAP Committee	September 2013	Revisions	September 2015
3	AMREP Animal Ethics GAP Committee	October 2013	Revisions	October 2015
4	AMREP Animal Ethics GAP Committee	November 2015	Revisions	November 2018
5	AMREP Animal Ethics GAP Committee	September 2016	Revisions	September 2019