

## COMPLIANCE POLICY for the Animal Ethics Committee

### Document Purpose

The purpose of this document is to outline how the Department of Primary Industries, Parks, Water and Environment (DPIPWE) Animal Ethics Committee (AEC) meets its responsibilities for ensuring compliance as defined in the *Australian code for the care and use of animals for scientific purposes, 8<sup>th</sup> edition, 2013* (the Code). Compliance with the Code is a requirement under the *Tasmanian Animal Welfare Act 1993* (the Act).

### DPIPWE Compliance Guidelines

In accordance with the Code, the institution and the AEC must prepare written procedures to deal with non-compliance and any grievance related to the AEC process, which must clearly define the reporting mechanisms and the responsibilities of all parties to ensure fair and effective processes (2.2.29; 5.1).

All concerns or grievances raised will be treated in the strictest confidence and in accordance with the principles of natural justice. Reporting of concerns or complaints will in no way jeopardise the employment or future research opportunities of the complainant.

Under section 1.31 of the Code, institutions, AECs and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities and act in accordance with the Code. It is the DPIPWE AEC's responsibility to take an appropriate course of action for any case of non-compliance with the Code (2.1.6) with respect to projects approved by the AEC.

### Responsibilities of Investigators (Section 2.4 of the Code)

Investigators have personal responsibility for all matters related to the welfare of animals that are used in the course of approved research and must act in accordance with all requirements of the Code (2.4.1) and the AEC. This responsibility extends throughout the period of approved use and until provisions are made for the animal at the conclusion of their use.

Prior to commencing a project or undertaking an amendment to an approved project that involves the use of animals investigators must apply for and obtain written approval from an AEC by way of a written AEC application (2.4.4). Following AEC approval, investigators must:

- apply the principles of the Code in all aspects of care and animal use;
- follow relevant policies and procedures established by the institution and the AEC;
- adhere to all requirements and conditions of approval set for the project;

- cease a project immediately if AEC approval is suspended or withdrawn;
- ensure appropriate education and training is undertaken to achieve the competency required to undertake a project; and
- ensure that procedures are performed competently and that records of animal care and use are adequately maintained (2.4.4).

As a condition of AEC approval, investigators are also required to make regular reports to the AEC, including annual and final reports, as well as prompt notification of any adverse or unexpected events that impact on animal wellbeing (2.4.18).

## Responsibilities of the AEC and the Institution (Sections 2.1, 2.3 & 5.1 of the Code)

The primary responsibility of the AEC is to ensure, on behalf of the institution, that all care and use of animals is conducted in accordance with the Code (2.3.1). The AEC must provide a competent, fair, consistent and timely review of the applications and reports it receives in relation to projects involving the care and use of animals for research and must only approve research using animals that is ethically justified, provides for the welfare of animals, and complies with the principles of the Code (2.3.3; 2.3.5). It is the AEC's responsibility to monitor AEC-approved projects, to only allow continuation of projects that conform to the Code and to take appropriate actions in response to suspected non-compliance with the Code (2.3.2).

The institution is responsible for responding promptly and effectively to recommendations from the AEC, to promote compliance and to ensure that, through the operation of an AEC, all care and use of animals for scientific purposes conducted on behalf of the institution is in compliance with the Code (2.1.2). This includes addressing concerns raised by the AEC regarding non-compliance with the Code and may include disciplinary action upon advice of the AEC.

## Responsibilities of External Institutions (Section 2.6 of the Code)

When an institution uses an AEC that has been established by another institution, such use must be based on a formal agreement that has been developed in consultation with the AEC (2.6.2). Under this agreement, external institutions which utilise the DPIPWE AEC are expected to comply with the AEC policies, particularly in accordance with sections 2.1, 2.2 and 2.6 of the Code.

## Non-compliance (Section 2.3.25 of the Code)

Non-compliance with the Code may include but is not restricted to:

- Failure to comply with AEC decisions, processes or conditions of approval
- Failure to comply with the principles or requirements of the Code
- Failure to comply with relevant codes and legislation (e.g. the *Australian code for the responsible conduct of research 2007*; the *Tasmanian Animal Welfare Act 1993*)
- Concerns regarding the decisions, behaviour, beliefs (including conflicts of interest) or procedures of the AEC

Specific incidents of non-compliance may include (but are not limited to):

- Conducting research without appropriate approvals (written AEC approval, scientific permits)
- Unauthorised animal use
- Unauthorised procedure use
- Failure to notify of changes to a project such as to procedures, animal use or staffing.
- Failure to notify of an unexpected adverse event
- Failure to submit a satisfactory report by the due date without prior notification
- Failure to comply with requests from the AEC (e.g. for paperwork, information on a project)
- Failure to cease procedures or activities that may adversely affect animal wellbeing
- Failure to perform a procedure (e.g. monitoring, euthanasia, analgesia) to identify, reduce or prevent unnecessary animal suffering
- Failure to adequately and appropriately disseminate research data

## Detecting, Assessing and Responding to suspected non-compliance

Section 5.1 of the Code stipulates that “institutions must have procedures for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes.”

This document is for guidance only and each case of suspected non-compliance with the Code is assessed on a case by case basis with the AEC using guiding principles in order to deliver an appropriate response. In line with DPIPWE’s compliance policy, the AEC’s process for responding to suspected non-compliance is a 3-stage process, “Detection”, “Assessment” and “Response”.

### Detection

Detection of suspected non-compliance by the AEC may occur by a variety of means:

- Third party notification
- Through routine AEC administrative processes such as annual or final reports or adverse incident reports
- Notification by an investigator
- During a routine AEC inspection or monitoring activity

All reports / cases of suspected non-compliance will be taken seriously and will be recorded in an appropriate manner. Once non-compliance has been detected, the AEC will then move on to the assessment phase of the process.

### Assessment

Once a suspected non-compliance is detected, the AEC will assess the breach taking into account a number of criteria in order to determine an appropriate response. These criteria are a guide only:

- the seriousness of the non-compliance in the context of the legislation;
- the legitimacy of the complaint;
- the length of time since the complaint;
- failure to comply with conditions of approval or any formal request;
- previous history / compliance issues;
- the level of public concern / interest;
- culpability of the person;
- steps / initiative taken by the ‘offender’ to mitigate or acknowledge non-compliance;

- failure to notify an unexpected adverse event; and
- impact on or risk to animal welfare.

## Response

The AEC will make a decision based on the nature of the offence and the circumstances involved. Possible compliance actions taken by the AEC in response to non-compliance can be split into three broad categories:

- communication and encouragement of compliance;
- enforcement action through the issuing of warnings, notices or similar within the powers of the AEC; and
- referral to the Regulator, Animal Research for further investigation.

These actions may include, but are not limited to:

- monitoring and inspection of a facility or project;
- issuing of a formal caution, notice or direction;
- imposing additional conditions on a project;
- suspending or withdrawing approval for a project;
- suspension of an investigator from a project;
- requiring an investigator to undertake further relevant training / education;
- requiring the modification of a project;
- recommending disciplinary action to the investigator's manager;
- referring the matter to the Animal Biosecurity and Welfare Branch for investigation of alleged breaches of the Act. This may result in infringement (a fine) or prosecution; and
- advising relevant State Government authorities of alleged breaches of other legislation.

## Process of Action (Section 5.9 of the Code)

Depending on the level of urgency and the impact on animal welfare, the following AEC process will be undertaken:

1. **High risk breach:** The Chair and executive officer discuss the situation which requires an immediate response and make a decision. The AEC is then advised of the course of action;
2. **Moderate risk breach:** Executive officer provides details of the breach to the AEC Executive and a decision is made on an appropriate course of action with a minimal delay. The AEC is then advised of the course of action; and
3. **Low risk breach:** Executive officer provides details of the breach to the entire AEC for input and a decision is made by all members, their full involvement afforded by the less urgent nature of the breach.

The Chief Investigator and relevant managers (as appropriate) will be advised of the AEC's decision as soon as possible.