

Summary Document | Independent External Review of Animal Care and Use

The University of Melbourne

13 December 2024



Nous Group acknowledges Aboriginal and Torres Strait Islander peoples as the First Australians and the Traditional Custodians of country throughout Australia. We pay our respect to Elders past, present and emerging, who maintain their culture, country and spiritual connection to the land, sea and community.

This artwork was developed by Marcus Lee Design to reflect Nous Group's Reconciliation Action Plan and our aspirations for respectful and productive engagement with Aboriginal and Torres Strait Islander peoples and communities.

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Acronyms and glossary

Term	Description
ACUA	Animal Care and Use Advisory
AEC	Animal ethics committee
AWEC	The Animal Welfare and Ethics Committee
AWET	Animal Welfare and Ethics Training
Nous	Nous Group
OREI	Office of Research Ethics and Integrity
SOP	Standard operating procedure
SPPL	Scientific Procedures Premises Licences
The Code	Australian code for the care and use of animals for scientific purposes ¹
UoM / the University	University of Melbourne

¹ National Health and Medical Research Council – Australian Research Council. Australian code for the care and use of animals for scientific purposes: 8th Edition 2013 (updated 2021). Australian Government. 2021.

Executive Summary

Purpose for the Review

This document is an independent external review (the Review) conducted by Nous Group (Nous) for the care and use of animals in research at the University of Melbourne (UoM or the University) as required under Section 6 of the *Australian code for the care and use of animals for scientific purposes* (the Code).

The Code aims to promote the ethical, humane and responsible care and use of animals for scientific purposes through providing an ethical framework and governing principles to guide decisions and actions of all those involved in the care and use of animals for scientific purposes.² It details the responsibilities of investigators, animal carers, institutions and animal ethics committees (AEC)s involved in the care and use of animals and describes processes for accountability.

The Code encompasses all aspects of the care and use of animals when the aim is to acquire, develop or demonstrate knowledge or techniques in any area of science – for example, medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching.³ It includes the use of animals in research, teaching associated with an education outcome in science, field trials, product testing, diagnosis, the production of biological products and environmental studies.⁴

Section 6 of the Code requires an institution to commission an independent external review of its operation at least every four years to assess its compliance with the Code and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code.

The Code mandates that the independent external review should include the following areas:

- The conduct of all people involved in the care and use of animals for scientific purposes on behalf of the institution, including the AEC, institutional officers and administrators, investigators and animal carers.
- The adequacy of the institutional program to ensure that the care and use of animals for scientific purposes is conducted in compliance with the Code; is subject to ethical review, approval and monitoring by an AEC; and is conducted in accordance with the AEC approval.
- The adequacy of institutional support, resources and educational programs for the AEC and its members and for people involved in any aspect of the care and use of animals for scientific purposes to ensure that they can meet their responsibilities under the Code.
- Whether the AEC is operating effectively in accordance with the Code.
- The effectiveness of institutional strategies to promote and monitor the implementation of the governing principles.
- Whether there is effective monitoring of the wellbeing of animals.
- Whether facilities used to house animals are managed to support and safeguard animal wellbeing.
- If applicable, an assessment of the report from the previous external review and actions taken in response to recommendations in that report.

² Australian code for the care and use of animals for scientific purposes 8th Edition (updated 2021) - Introduction

³ Australian code for the care and use of animals for scientific purposes 8th Edition (updated 2021) – Scope of the Code.

⁴ Ibid.

Scope of the Review and compliance assessment

This Review targets a sample of the full scope of animal care and use activities across the University, which at the time of writing encompasses 18 animal facilities, with over 30 species and a total of approximately 370,000 animals. The sampling approach involved selecting a subset of AECs and animal facilities that were representative of the current state. To do so, the Review developed selection criteria for this process in conjunction with the University that considered the diversity of care and use activities, the scale of activity, and the feasibility of the review process.

Guided by these criteria, the AECs and facilities outlined in Table 1 below were included in the Review.

Table 1 | AECs and facilities included in the Review

AEC	Facility
LEA2	PIPER
	Biosciences 4 Basement Facility
SLA1	Peter Doherty Institute
	AgriBio Animal Facility

Based on the engagements with the sampled AECs and facilities, the Review observed that the University is broadly compliant with the Code. There have been significant improvements made in recent years, with University staff generally aware of their responsibilities and supported by a strong governance framework. However, there are specific areas that require focus to continue to strengthen University compliance.

Findings against sections of the Code

The Review was structured in accordance with the seven sections of the Code. Findings from quantitative and qualitative data analyses were collated against these sections to assess compliance and provide recommendations to enhance the University's current structures and processes. A summary of the findings against each section of the Code has been provided below.

Section 1 | Governing Principles

The independent external Review was conducted in accordance with the governing principles of the Code.

Section 2 | Responsibilities

The University cares for and uses a large number and variety of animals across its research and educational facilities. This work extends across campuses and, at times, occurs on the premises of other institutions. As such, requirements of the University and its staff to maintain compliance with the Code is challenged by the volume and breadth of this work.

To address this, the University incorporates an extensive governance structure. The Office of Research Ethics and Integrity (OREI) assumes a significant role in acquitting the University's institutional responsibilities under the code, with the five separate AECs overseeing individual research and educational activities involving the care and use of animals. Recent changes from OREI to increase institutional expertise and strengthen support, such as the re-design of Animal Welfare and Ethics Training (AWET) and the introduction of Animal Care and Use Advisors (ACUAs), has helped to enhance understanding and compliance with the Code.

At present, animal facilities across the University are guided by independently developed standard operating procedures (SOPs) which are reportedly not reviewed and approved by the AECs. As such, these SOPs are not given effect and cannot be directly referenced in project ethics applications, with new procedures requiring detailed descriptions prior to approval. This presents an opportunity for the University to achieve more consistency with the Code.

Additional opportunities to enhance compliance are found within the structure and function of the AECs. At present, the University operates five AECs to help effectively manage the scale and complexity of work conducted by investigators. The Review observed that AECs are also currently siloed, with limited opportunities for sharing learnings. There are reported concerns with the current composition of AEC Chairs with issues around conflicts of interest, capability and capacity. Communication from these committees to investigators and animal care staff can be delayed and unclear, particularly with reference to resolution of incident reports. This leads to inconsistency and limits institution-wide visibility.

There also remains a lack of clarity around important roles that contribute to ethical practice, including Scientific Procedures Premises Licences (SPPL) Licence Nominees and the Animal Welfare and Ethics Committee (AWEC), whose role as an ethical oversight body is not necessarily reflected in meeting agenda or membership, which can be operationally focussed. The lack of governance clarity extends to procedures that occur on non-University premises, which function under the oversight of external AECs.

Although animal care staff are aware of their responsibilities under the Code, the Review found that these staff could be better supported by the University considering current arrangements outside the Bioresources Platform. This includes training and veterinary support for non-model organisms. Additionally, the Review observed uncertainties among staff regarding the responsibility of incident reporting despite the existence of the *Animal Care and Use Incident Management Procedures Guidelines (2023)*. The Review heard reports from staff indicating that only investigators could submit incident, contrary to University guidelines and Code stipulations indicating this responsibility extends to facility managers.

Section 3 | Animal wellbeing

The Review found that staff have a strong understanding of the potential causes of adverse impacts on animal wellbeing and take steps to avoid these impacts. This is supported by approved research applications, which include safeguards and humane endpoints for animal use. OREI has introduced measures to monitor strategies that support and safeguard animal wellbeing, including the use of ACUAs, physical signage that illustrates appropriate decision-making in cases of adverse incidents and ease of access to SOPs within facilities.

The use of multiple digital systems within facilities assists to distil the complexity of information involved in animal care and use. However, these remain segregated and can lead to the need for clarification from investigators. The Review observed that such data fragmentation can increase the risk of delayed, incomplete and inaccurate records. The Review noted that established procedures and protocols exist to support and safeguard animal wellbeing, and for monitoring animal environments. This includes the use of cards on animal cages to denote key research information. Veterinary care and advice are made available for staff, although this was noted to be a stretched resource that covers a significant number of animals across several facilities. The Review observed opportunities for greater clarity surrounding which staff are responsible for animals at different stages of the research cycle. This was particularly noted when animals transfer between breeding to experimental phases.

Staff working with small laboratory animals maintain their competency in specific procedures through the *TrainMe* system, which is regularly reviewed to identify which staff are due for mandatory refresher courses. There remains opportunity to enhance this training system by including education around non-model organisms. The University cares for and uses several non-model organisms, which do not have well established protocols for staff to follow and consequently can rely on self-research for best practice.

Section 4 | The care and use of animals for the achievement of educational outcomes in science

The Review observed that compliance with the Code for teaching at the University is supported by AEC consideration on curriculum design and an ethics application process for investigators. The current curriculum minimises animal use and burden, whilst simultaneously fulfilling accreditation requirements for veterinary qualification courses. Animal care and use is monitored, as required in ethics applications, using logbooks, excel spreadsheets and monthly reports submitted to AECs. Teaching staff reflected on the strength of current SOPs to support animal care and use within the University's education activities, with the Review unclear whether SOPs are approved by AECs given that only staff were examined and not the associated facility and AECs.

Although ethical, social and legal responsibilities towards animals is embedded in the curriculum, the Code is not specifically referenced or taught to students, as is required by the Code itself. The Review further reflected that teaching staff are impacted by the delayed decision-making from AECs.

Section 5 | Complaints and non-compliance

The Review noted infrequent reports of non-compliance between January 2023 and August 2024, with 13 of 195 incident reports identified as non-compliance cases for approved projects. There remains ongoing confusion regarding around the process for incident reporting, variability in the management of non-compliance and a lack of awareness of guidelines. The Review found examples of staff who maintained that only principal investigators could file reports contrary to the Code's stipulation. Further opportunities stem from resolution of incident reports, with current, unclear direction from AECs regarding responsibility for implementing changes and delays in communication.

The Review noted that the introduction of the *Animal Care and Use Incident Management Procedures Guidelines (2023)* to guide the administrative process of managing incidents, including the AEC's review and resolution of incident reports in alignment with the Code, However, the Review noted that not all AECs have adopted and adhere to the guideline, and there is a reported lack of awareness of the guideline and procedures.

The Review observed that the University lacks formal mechanisms to ensure external AECs manage compliance according to the code for activities facilitated by University SPPL Licences. Additionally, investigators are reportedly unaware of the existing mechanism to notify University AECs when involved in collaborative studies at other institutions, or if named in applications to external AECs.

Section 6 | Independent external review of the operation of institutions

The Review established an independent Review panel which declared their interests before appointment and adhered to the confidentiality requirements of the Review. The Review engaged in a sampled approach by reviewing a subset of AECs and animal facilities independently selected by the Review Panel (the Panel).

The Panel observed that the University had not previously conducted an independent external review within the last four years, as required by the Code, but had received similar engagements through audit reports, external evaluations and an internal audit.

Section 7 | Cosmetic testing

The Review did not find any evidence that animals were used for the purpose of cosmetic testing in the sampled facilities. There are no current policies and procedures in place to ensure that animals are not used for the testing of finished cosmetic products or chemical ingredients. The Review noted that the University is currently drafting a new policy to capture this Code requirement.

Recommendations for the University to improve adherence to the Code

Although the Review did not find significant areas of non-compliance, it did identify several areas across the University that could be enhanced to improve ethical animal care and use. These range from altering current governance arrangements to supporting animal care staff on the ground. These recommendations have been developed by the Review panel based on engagement with sampled staff and facilities. Greater detail of the recommendations in Table 2 below can be found in the “Recommendations” chapter of the report.

Table 2 | Recommendations to improve animal care and use in accordance with the Code

Recommendation	
Governance recommendations	
1.	The Review recommends that the University should implement a single, professional Chair across all five AECs with a senior secretariat from OREI.
2.	The Review recommends that the University reviews AVEC’s ToR to clarify and re-establish its roles and responsibilities formally and communicate it clearly to all relevant UoM staff.
3.	The Review recommends that the University reviews how it incorporates Licence Nominees in its animal welfare management approach and clarify their roles and accountabilities.
4.	The Review recommends that the University establish formal, consistent procedures regarding the governance, decision-making and reporting arrangements involving research activities licensed under the University’s SPPLs at off-campus premises and under the oversight of external AECs.
5.	The Review recommends the University clarify institutional roles and responsibilities through the new animal care and use policy in development.
Process recommendations	
6.	The Review recommends that the University clarify the role of ACUAs, through improved communication.
7.	The Review recommends that the University addresses its current processes in developing SOPs to align with the requirements of the Code.
8.	The Review recommends the University consider introducing decision-making guidance for AECs, which should consider project risks, particularly with projects involving non-model organisms.
9.	The Review recommends that the University should introduce greater clarity and structure to the process of managing the transfer of animals from breeding to experimental stages.
10.	The Review recommends the University consider provisioning additional specialised training for non-model organisms.
11.	The Review recommends the University consider implementing a consistent and structured approach of assessing and recording staff competency across all facilities.
12.	The Review recommends the University establish a guideline for rehoming animals at the conclusion of their use.
Reporting recommendations	

Recommendation

13. The Review recommends that AECs should clarify who can submit incident reports, through improved training and communication.

14. The Review recommends that the University establishes more defined reporting processes (e.g. for annual project progress reports) for investigators and provide greater guidance on the expectations on content and detail requirements.

Monitoring recommendations

15. The Review recommends that the University expand its use of PAMs and target high-risk projects to improve the University's project-level monitoring.

16. The Review recommends that the University introduces formal processes to enhance information sharing across AECs.

17. The Review recommends the University should explore options to improve access to suitably qualified veterinary services.

Systems recommendations

18. The Review recommends the University explore options to improve the collection, reporting and analysis of animal use data across campus.