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1. Framework under the Animal Research Act 1985

1.1 The Animal Research Act 1985

The NSW Animal Research Act 1985 was the first piece of self-contained animal research legislation introduced in Australia. In introducing the legislation in 1985, the Hon. Kevin Stewart, Minister for Local Government, said that it was based on ‘the twin tenets of ... enforced self-regulation and public participation in the decision-making process’. It received bipartisan support in the Parliament when it was introduced in 1985 and continues to do so.

The primary aim of the legislation is to protect the welfare of animals used in research and teaching by ensuring that their use is justified, humane and considerate of their needs. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

The Act establishes a system of accreditation, licensing and authorisation of organisations and individual researchers. The Act also establishes the Animal Research Review Panel (the Panel) to provide a mechanism for representatives of government, scientific and animal welfare groups to participate jointly in monitoring the effectiveness of the legislation.

The Act creates offences for conducting animal research without appropriate authorisation, with substantial custodial and financial penalties.

1.2 The Australian code for the care and use of animals for scientific purposes

The [Australian code for the care and use of animals for scientific purposes](#) (the Code) is a nationally accepted document and is included under the Animal Research Regulation 2010. The Code is reviewed regularly by the Code Advisory Group, under the auspices of the National Health and Medical Research Council (NHMRC). The Code Advisory Group includes representatives from NHMRC, the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council, Universities Australia, the state government ministries with responsibility for animal welfare, commonwealth government departments for the sectors of environment, education and primary industries, the RSPCA Australia and Animals Australia.

1.3 The Animal Research Review Panel

The Animal Research Review Panel has responsibility for overseeing the effectiveness and efficiency of the animal research legislation, investigating complaints, and assisting in evaluating compliance of individuals and establishments with the legislation.

The constitution, membership and mode of operation of the Panel are set out in the *Animal Research Act 1985*. The Panel has twelve members with equal representation from industry, government and animal welfare groups. This provides for a range of expertise in regulating the conduct of animal research in New South Wales.

Apart from developing overall policy on animal research issues, the Panel is closely involved in the administration of the legislation. This is achieved through evaluating applications for accreditation and licences of research establishments, conducting site visits to assess compliance, and investigating complaints. The Panel also has a role in considering amendments to the Animal Research Regulation. NSW Department of Primary Industries staff provide executive support for the Panel.

1.3.1 Mission statement

- To protect and enhance the welfare of animals used in scientific research, testing and teaching in New South Wales.
- To promote an understanding within the New South Wales community of the ethical and technical issues involved in the use of animals for scientific purposes.

The strength of the Panel lies in the diversity of expertise, opinions and ethical perspectives of its members. The development of cohesive and progressive policies has occurred as a result of this diversity. All members are employed in other fields and participate on a largely voluntary basis. Non-government members are paid fees for attending formal meetings and participating in site inspections. Members are not paid for time spent preparing for meetings and inspections, for considering applications for accreditation or licenses, or for drafting discussion papers.

1.3.2 Functions of the Animal Research Review Panel

Section 9 of the Animal Research Act defines the functions of the Panel as:

- The investigation of matters relating to the conduct of animal research and the supply of animals for use in connection with animal research
- The investigation and evaluation of the efficacy of the Code in regulating the conduct of animal research and the supply of animals for use in connection with animal research
- The investigation of applications and complaints referred to it under the Act
- Such other functions as the Minister may from time to time confer or impose on it.

In November 1998, the then Minister, the Hon. Richard Amery MP, conferred the following additional function on to the Panel, pursuant to section 9 (d) of the Act:

The consideration and comment on proposals referred to the Animal Research Review Panel which relate to the making, amendment or review of the regulations under the *Animal Research Act 1985*.

There have been no other functions formally conferred on the Panel under section 9 (d) of the Act since it commenced.

1.3.3 Membership

The Panel consists of 12 members appointed by the Minister based on nominations received from industry, government and animal welfare groups. The nominating organisations are:

- New South Wales Vice-Chancellors' Committee: three nominees
- Medicines Australia: one nominee
- New South Wales Minister for Health: one nominee
- New South Wales Minister for Education: one nominee
- New South Wales Minister for Primary Industries: one nominee
- New South Wales Minister for the Environment: one nominee
- Animal Societies' Federation (New South Wales): two nominees
- Royal Society for the Prevention of Cruelty to Animals (New South Wales) (RSPCA NSW): two nominees.

All members of the Panel are part-time and are normally appointed for a term of 3 years.

During the 2020–21 period, the membership of the Panel was:

- Professor Jacqueline Phillips (Chair) (nominated by the NSW Vice-Chancellors' Committee; reappointed 28 January 2020)
- Professor Robert Mulley (nominated by the NSW Vice-Chancellors' Committee; reappointed 12 November 2019)
- Associate Professor Keiron Rooney (nominated by the NSW Vice-Chancellors' Committee; appointed 12 November 2019)
- Distinguished Professor Annemarie Hennessy (Deputy Chair) (nominated by the Minister for Health; reappointed 14 October 2019)
- Dr Damian O'Brien (nominated by Medicines Australia; appointed 1 October 2019)
- Ms Sally Bannerman (nominated by the Minister for Education and Training; reappointed 6 March 2020)
- Dr Benjamin Russell (nominated by the Minister for the Environment; appointed 12 November 2019)
- Dr Sophie Riley (nominated by the Animal Societies' Federation; reappointed 14 October 2019)
- Ms Paula Wallace (nominated by the Animal Societies' Federation; reappointed 14 October 2019)

- Mr Anthony Croker (nominated by RSPCA NSW; appointed 24 October 2018)
- Mr Scott Meyers (nominated by RSPCA NSW; appointed 14 October 2019)
- Dr Alice Marshall (nominated by the Minister for Primary Industries; appointed 24 September 2020)*

*Panel membership of the nominee for the Minister for Primary Industries was vacant from 1 July 2020 – 23 September 2020.

Information on members of the Panel in 2020–21 is as follows:

Professor Jacqueline PHILLIPS BVSc Hons (Uni of Syd), PhD (ANU) (Chair)

Professor Phillips was appointed to the Panel in 2010. Professor Phillips is Professor of Neuroscience in the Faculty of Medicine, Health and Human Sciences, Macquarie University and is currently Chair of Macquarie Universities Academic Senate. She is a registered veterinarian who has worked in small animal veterinary practice and has extensive experience with laboratory animals. She has served on Animal Ethics Committees as a Category A member at the Australian National University (ACT) and Murdoch University (WA). Professor Phillips succeeded Professor Dart as Panel Chair in November 2019.

Emeritus Professor Robert MULLEY BA (Macquarie), MScAg (Sydney), PhD (Sydney).

Professor Mulley joined the Panel in 2008. He is a nominee of the NSW Vice Chancellors' Committee. He is Professor of Animal Science at Western Sydney University, and has extensive experience in husbandry and management of farmed livestock, particularly pigs, deer and cattle. More recently he has engaged in research on a range of wildlife species.

Associate Professor Kieron ROONEY B. Sci. Hons (Uni of Syd), PhD (Uni of Syd)

A/Prof. Rooney was appointed to the Panel on 14 October 2019. He is Head of the Discipline of Exercise and Sport Science in the Sydney School of Health Sciences, Faculty of Medicine and Health, University of Sydney. He is a registered Nutritionist and has utilised small animal models to investigate parameters of metabolic biochemistry since 1998. A/Prof. Rooney co-leads the Research in Bias Node of the Charles Perkins Centre, is SYRCLE Ambassador, a member of the NC3Rs working group revising the ARRIVE guidelines (2018-2020) and has been a Category B member of the University of Sydney Animal Ethics Committee since 2015.

Dr Damian O'BRIEN BVSc (Uni of Syd)

Dr O'Brien was appointed to the Panel on 1 October 2019. He is an employee of MSD Animal Health, a registered veterinary surgeon who has had a career in private veterinary practice and in the pharmaceutical industry. He currently manages Technical Market Development for MSDAH across Australia and New Zealand, involving research and development of innovative pharmaceuticals and vaccines for use in farm and companion animals.

Distinguished Professor Annemarie HENNESSY MBBS, FRACP, PhD (Deputy Chair)

Professor Hennessy was previously a member of the Panel from 2008 to 2010. She was re-appointed in January 2014 and again in October 2019. She is the Director of the National Baboon Colony and an active medical teacher and researcher. She is a qualified nephrologist and specialises in general medicine, renal medicine and obstetric medicine. She is the Dean, School of Medicine, at Western Sydney University.

Ms Sally BANNERMAN BSAgr (Syd), Grad Dip Ed

Ms Bannerman is the Animal Welfare Coordinator for the NSW Department of Education, Catholic Schools NSW and the Association of Independent Schools of NSW. She administers the work of the Schools Animal Ethics Committee for the three school sectors and their 3500 schools. She has extensive experience in agricultural education and has worked in face to face delivery, distance education and teacher support for over 30 years. Ms Bannerman was reappointed in October 2019.

Dr Benjamin RUSSELL

Dr Russell was appointed to the Panel on 14 October 2019. He is the Manager of Pests and Weeds for the National Parks and Wildlife Services (NPWS). He has worked on pest and weed management with NPWS for over 16 years and before that spent six years at the University of New South Wales, teaching a wide range of biological and ecological subjects while completing his PhD. Dr Russell represents NSW on the National Environment and Invasives Committee as well as being the Chair of their Terrestrial Vertebrate Pest Working Group. He is also a member of the NSW Biosecurity Advisory Committee and State Pest Animal Committee. He is involved in a range of research projects on the impacts and management of the terrestrial vertebrate pests which threaten our native species and agricultural production, with colleagues in both government departments and academic institutions across Australia.

Dr Sophie RILEY

Dr Riley is a senior lecturer in the Faculty of Law at the University of Technology Sydney. She teaches Animal Law and Policy, Environmental Law, Environmental Ethics and Corporate Law. Dr Riley's research interests focus on the ethics and treatment of invasive species, farm animals and wildlife welfare. She has also published in the area of legal education, particularly regarding the pedagogy of international students. Dr Riley is the editor of an animal law case book, comprising case notes written by students as part of their assessment; and she has also written a book titled "The Commodification of Farm Animals", to be published by Springer in November 2021. In 2020 she was appointed as one of two review editors for Chapter 6 (policy) of a report on invasive alien species that IPBES, (the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services) is preparing for the United Nations. Dr Riley was reappointed to the Panel in October 2019.

Ms Paula WALLACE

Ms Wallace is a communications professional who has operated a consultancy business since 2000. Her writing has been published widely in Australia's business and specialist press with a focus on environmental and sustainability matters. Ms Wallace has a deep interest in the areas of enterprise which involve animals and how related industries can provide leadership from an ethical and practical perspective. She is spearheading the movement for rehoming animals from research and has established the Liberty Foundation to further these aims. Ms Wallace was reappointed to the Panel in October 2019.

Mr Anthony CROKER

Mr Croker holds a Diploma of Government Investigations among other certificates. Mr Croker has been an Inspector for the RSPCA NSW since 2001 and Team Leader of the Southern Region since 2005. He has also been a Category C (animal welfare) Animal Ethics Committee member on multiple committees since the early 2000's. Mr Croker was appointed to the Panel in October 2018.

Mr Scott MEYERS

Mr Meyers was appointed to the Panel on 14 October 2019. He is the Chief Inspector of RSPCA NSW and has been with RSPCA NSW for the past 14 years, previously holding the roles of Deputy Chief Inspector, Inspectorate Team Leader and RSPCA NSW Shelter Manager for the Hunter Region. Mr Meyers holds a Diploma in Management and Government Investigation. Mr Meyers has investigated in excess of 4500 animal cruelty complaints across his career and has been involved in complex prosecutions involving aggravated cruelty, puppy factories and matters of significant public interest.

Dr Alice Marshall BVSc Hons I (Uni of Syd).

Dr Marshall was appointed to the Panel in September 2020 as the nominee of the NSW Minister for Primary Industries. Alice is Team Leader, Animal Welfare Programs and Policy for the NSW Department of Primary Industries. In this role she leads a team of technical experts to deliver targeted, evidence-based animal welfare outcomes and reports to the NSW Chief Animal Welfare Officer. She is a registered veterinarian with experience across mixed veterinary practice, animal pharmaceutical and nutrition roles. She has a background in media and communications and is a trained journalist. Alice is registered to undertake the MANZCVS Animal Welfare Chapter examination at its next sitting date in 2022.

1.4 Animal Ethics Committees

At the establishment level, Animal Ethics Committees (AECs) provide avenues for public participation in the regulation of animal research.

AECs are responsible for approving and monitoring research within establishments, including inspections of animals and facilities. No animal research may be carried out without AEC approval. AECs must consider and evaluate applications to conduct research based on the researchers' responses to a comprehensive set of questions, including their justification for the research, its likely impact on the animals, and procedures for preventing or alleviating pain or distress. On behalf of the establishment, AECs have the power to stop inappropriate research and to discipline researchers by withdrawing their research approvals. They can require that adequate care, including emergency care, is provided for animals. They also provide guidance and support to researchers on matters relevant to animal welfare, through means such as the preparation of guidelines and dissemination of relevant scientific literature. AECs are responsible for advising institutions on the changes to physical facilities that should be made to provide for the needs of the animals used.

The membership and duties of AECs are laid down in the NSW legislation and in the *Australian Code for the Care and Use of Animals for Scientific Purposes* (the Code), which also provides guidance on how AECs should operate.

Committee membership must include members as follows:

Category A: a veterinarian

Category B: an animal researcher

Category C: a person with a demonstrated commitment to animal welfare who is not associated with the establishment, and not currently involved in the care and use of animals for research.

Category D: an independent person who does not fit the requirements of the other categories, is not associated with the establishment and who has never been involved in the use of animals for research.

The Code states that more than one person may be appointed to each category and, if a Committee has more than four members, categories C plus D must represent no less than one-third of the members.

The criteria used by the Panel for assessment of AEC membership are documented in a Panel policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (<http://www.animaethics.org.au/policies-and-guidelines/operation>). In examining applications from establishments for accreditation as animal research establishments, the membership of AECs is assessed to ensure they are of acceptable composition. The Panel also assesses, and makes recommendations to NSW DPI, on the suitability of all new appointments to AECs. All new AEC appointments must be approved by the Department. During site inspections, the Panel assesses the operation of the AECs.

1.5 Accreditation and licensing

The legislation requires that all applications for Accreditation and Animal Supply Licences be referred to the Panel for consideration. The Panel has established procedures to deal with the considerable workload this entails and has regularly reviewed and updated these procedures to take account of changes in needs and resources.

In the 2018 -19 year, procedures were amended with a move of accreditation and licensing functions from the NSW DPI Animal Welfare Unit to the Compliance Unit.

There are two components in the assessment of applicants by the Panel:

- consideration of a written application to determine whether the applicant is complying with the fundamental requirements of the legislation
- evaluation of the applicant at a site inspection, when a much broader approach is taken.

The recommendations of the Panel are referred to the delegate of the Secretary of the Department of Planning, Industry and Environment (transitioned to the Department of Regional NSW from 2 April 2020), who has statutory authority for the issue of accreditation and licences and for imposing conditions of accreditation or licence.

Accreditation and licences are usually issued subject to standard conditions. Other conditions may also be stipulated, as relevant to the operation of each establishment. The standard conditions that are applied were revised with the move of the accreditation and licensing functions to the NSW DPI Compliance Unit (see Appendix H for standard conditions on Accreditation and Licences).

1.5.1 Evaluation of written applications

New and renewal applications for accreditation or licences are assessed by Department of Primary Industries staff, according to criteria developed by the Panel. Arising from these assessments, recommendations on the applications are made to the Panel. The Panel considers the recommendations and then makes recommendations on the applications to the Secretary.

The criteria against which the Panel assesses written applications are drawn from the legislation. Considerations include whether the AEC is properly constituted, whether its procedures are adequate, whether it is meeting sufficiently frequently to deal with the volume of work, and whether it is conducting inspections of the animals and facilities it supervises. The types and numbers of animals held, and their accommodation are also checked, and likely problem areas are flagged for follow-up at site inspection. Similarly, numbers and qualifications of animal care staff are assessed for adequacy.

Monitoring of animal care and use by the AEC is another area of assessment. Numbers of AEC inspections carried out must be provided. Questions on the source and destination of animals allow a double-check on compliance with the Act's provisions relating to animal supply.

[Form R- application for accreditation as an animal research establishment and licence as an animal supplier](#), and the [criteria for application assessment](#) are published on the Animal Ethics Infolink website.

1.5.2 Conduct of site inspections

Inspections are conducted by an inspector under the Animal Research Act 1985 (the Act). Members of the Panel can also accompany an inspector during inspections, in accordance with section 10 of the Act.

During inspections, establishments are assessed for compliance with the *Australian Code for the Care and Use of Animals for Scientific Purposes*, the Act, the *Animal Research Regulation 2010* and licensing conditions. The range of items assessed can include the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; physical facilities for housing and using animals; and the wellbeing of the animals held. This typically occurs through an assessment of written material and a site visit. Routine inspections are typically arranged in advance and usually require one to four days on site.

In response to the COVID-19 pandemic, many AEC meetings were held via videoconferencing. Therefore, videoconferencing was utilised by the inspector and Panel members for some inspections to facilitate attendance at AEC meetings.

Assessment of written material

Assessment typically begins before a site visit through an examination of documents provided by the establishment or individual. Examples of documents assessed include records of research applications approved by the AEC, AEC minutes, records of AEC inspections, operational procedures of the AEC and standard operating procedures.

This assessment is carried out by an inspector appointed under the Act. Panel members who have been nominated to accompany the inspector may also participate in this aspect of the inspection. This evaluation allows potential problem areas to be identified prior to a site visit.

Site Inspection

During the site inspection, the inspector and Panel members may examine animal housing and facilities, speak to researchers and animal care staff, review records of animal monitoring, and attend an AEC meeting. Issues identified by the inspection team are discussed with the AEC and representatives of the establishment during the inspection.

Inspection report

After the inspection, a report is prepared by the inspector with input from any Panel members that participated in the inspection. The report outlines issues identified and any additional recommendations from the inspection team. Reports are provided to the establishment as soon as possible following the inspection. Reports are also referred to a full meeting of the Panel for consideration, and any additional feedback from the Panel is then provided to the establishment.

Response to inspection reports

Establishments are asked to respond in writing to the inspection report. This response should address any recommendations and non-compliances identified from the inspection, and actions that have been taken in response to these. Responses are typically considered at meetings of the Panel, and an assessment is made of whether the responses are satisfactory. If necessary, further follow up with the establishment can be carried out, such as additional inspections.

1.6 The Animal Research Act in schools and TAFE NSW

The Animal Research Act allows the use of animals for educational purposes when there is a demonstrated educational benefit, when there is no suitable alternative, and when the least number of animals is used, with the least impact on their wellbeing. Although animals are used for educational purposes in many situations, their use in schools and TAFE colleges presents special issues, such as mechanisms for approval and monitoring of animal use across the State. Their use also presents opportunities to promote in students an understanding of the ethical and technical issues involved with the use of animals.

1.7 Administration

Executive support for the Panel and administration of the *Animal Research Act 1985* is by NSW Department of Primary Industries Animal Welfare and Compliance Units.

2. Report on work and activities

2.1 Administration and planning

Administrative functions have varied from activities such as assessments of Accreditation and Licensing, to formulating the Panel's strategic plan for 2020–21. The appendices to this annual report contain details of operational and strategic functions of the Panel. These include the dates of, and attendance at, Panel meetings (Appendixes A and B) and site inspections (Appendix C); the Animal Research Review Panel Strategic Plan 2020–21 (Appendix D) and Panel operating expenses (Appendix E).

2.1.1 Strategic plan July 2020 – December 2021

The Panel's 18-month strategic plan for 2020-21 identifies the primary goals of the Panel and strategies for achieving these goals and is provided in Appendix D.

2.1.2 Liaison with establishments and individuals

The Panel liaises with establishments and individuals to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles.

During the 2020-21 year, liaison was conducted via discussions during, and feedback after, site inspections. Additionally, recommendations were made in the process of assessing Accreditation and Licence applications.

2.2 Assessment of applications

During 2020-21 there were 201 Accredited Animal Research Establishments, of the 201, 71 animal research establishment do not house animals and undertake surveys and/or fauna surveys. There are also 38 holders of Animal Supply Licences.

During 2020–21 the Panel considered and made recommendations to the Secretary on:

- 1 new application for Accreditation
- 40 renewal applications for Accreditation
- 0 new applications for Animal Supply Licences
- 6 renewal applications for Animal Supply Licences.
- 11 extensions to existing Accreditation and/or Animal Supply Licences

2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the *Animal Research Act 1985* the definition of LD50 has been broadened.

Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister.

Applications for permission to conduct LD50 tests are evaluated by a Panel subcommittee. Members of the subcommittee in 2020–21 were Dr Russell, Dr O'Brien, Mr Meyers and Professor Phillips. The subcommittee makes recommendations to the Panel, which in turn advises the Minister.

In 2020–21 the subcommittee considered one application (five tests) from an Accredited Animal Research Establishment.

The testing is used in quality control during the manufacturing of vaccines and in the development of new vaccine formulations. Most of the tests are related to the manufacture of clostridial vaccines, used to protect livestock and companion animals against tetanus, enterotoxaemia, black leg and black disease that are rapidly fatal if contracted by unvaccinated animals.

The Panel recommended the Minister grant concurrence between 30 April 2021 to 30 April 2022 in accordance with the following conditions:

- 1) Data is provided in graphical form by 31 January 2022 with figures comparing 2019, 2020 and 2021 calendar years on the following:
 - a) The number of animals used for each quality control test in relation to a relevant measure to be determined by the establishment. The measure should provide information on the trends in numbers of animals used over time.
 - b) The number of animals used for development and research over time, with an explanation of the purpose – for example replacement of a test, refinement of a procedure.
 - c) The total number of animals produced in relation to numbers of animals actually used in tests.
 - d) The number of animals that die in tests and the number euthanised as an early end-point in tests.
- 2) Any application for Ministerial concurrence to conduct LD50 tests between April 2021 and April 2022 must be presented by the establishment to the NSW Department of Primary Industries by 31 January 2021.
- 3) The establishment must continue, in consultation with the AEC, to identify and implement refinements to lessen the impact of existing approved tests on animals and methods of reducing the numbers of animals used in existing approved tests or replacing animal tests with alternatives and reports upon these to the NSW Department of Primary Industries by 31 January 2022.

2.3 Assessment of changes to AEC membership

All establishments are required to advise the Department of changes to AEC membership. The Panel assesses and makes recommendations to the Department on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

The qualifications of AEC members are assessed in accordance with the requirements set out in the *Australian Code for the Care and Use of Animals for Scientific Purposes* and Panel Policy 9: *Criteria for Assessment of Animal Ethics Committee Membership*.

In the 2020–21 year the Panel assessed and made recommendations to the Department on the appointment of 72 members of Animal Ethics Committees.

2.4 Assessment of Animal Research Establishment AEC Annual Reports

The Animal Research Review Panel provides advice to the NSW Government on the use of animals in research and teaching in this State. As part of their annual Form L returns, each year all Accredited Animal Research Establishments and holders of Animal Research Authorities must submit a copy of their AEC Annual Report to the Department of Primary Industries.

AEC annual reports are written to inform the heads of the establishment of the activities of the AEC and to identify problems that need to be addressed. The reports also provide a means for self-assessment of the establishment's compliance with the animal research legislation and help identify measures needed to ensure ongoing compliance. This self-assessment is a central component of an establishments' responsibilities under NSW animal research legislation. Additionally, the preparation of a report also provides an opportunity for the AEC to reflect on its activities and self-assess its operations.

Each year, the Panel provides feedback on the annual reports to establishments and their AECs. For the 2020 reporting year, Panel members reviewed 62 AEC Annual Reports.

2.5 Subcommittees

The Panel appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full Panel for consideration. Activities of subcommittees in the 2020–21 year included:

- Evaluation of applications for LD50 testing (Dr Russell, Dr O'Brien, Mr Meyers and ProfessorPhillips)
- Rehoming animals (Ms Wallace and Dr Riley)
- Animal Ethics Committee training (Dr Riley, Professor Phillips, A/ProfessorRooney and Ms Wallace)

2.6 Statistics on animal use

The Animal Research Regulation 2010 requires accredited research establishments (other than schools) and animal research authority holders to record and submit information on the number of animals used in research each year.

The requirements for reporting on animal use provide data on the numbers of animals used in all research projects in NSW, reported against the purpose of the research and the types of procedures in which they were involved. The aim of collecting these statistics is to give some indication of the level of 'invasiveness' of the procedures on the animals and to provide data on the use of animals in research. Aspects of the system include the recording of:

- an animal in all projects in which the animal is used.
- animals for each year in which they are held in long-term projects.
- the types of procedures used (giving an indication of the impact of procedures) combined with the recording of the purpose of the research.

The categories used are based on those used on a national basis. Figures are collected on a calendar year rather than by financial year. The information is collated and published in [annual Animal Use Statistics reports](#) on the Animal Ethics Infolink website.

An additional category on the fate of animals was added for the 2019 reporting year onwards. Completion of this category is mandatory for reporting on the use of domestic cats and dogs and voluntary for other species.

In addition to information on numbers of animals used, information is collected on initiatives in the areas of reduction, replacement and refinement of animal use. A summary of this information is included in the annual Animal Use Statistics reports on the Animal Ethics Infolink website.

As an additional means of monitoring Accredited Animal Research Establishments, the annual reports of AECs are required to be submitted with the submission of annual statistics. The *Australian Code for the Care and Use of Animals for Scientific Purposes* requires that each AEC must submit a written report on its activities at least annually to the governing body of the institution for which it acts.

2.6.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the Panel. Lethality testing is defined as '*any animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die*'. Lethality tests include, but are not limited to, LD50 tests (see item 2.2.1). Figures on lethality testing are included in the annual Animal Use Statistics reports on the Animal Ethics Infolink website.

2.7 Support for Animal Ethics Committees

The Panel and the Department continue to use various means to support AECs in performing their duties. These means include the conducting of site inspections; the writing of policies, guidelines and fact sheets where a need is identified; the maintenance of a website dedicated to animal research issues ([Animal Ethics Infolink](#)) and the supply of advice over the telephone or by correspondence.

The Panel is used as a reference source by the State's AECs, for example as a source of information on successful policies developed at other institutions.

A deliverable of the Strategic Plan June 2020 – December 2021 is to develop a guideline for AECs on improved decision making with respect to research/teaching applications. The guideline is under development.

2.7.1 Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by several AECs. Categories C (Animal Welfare) and D (Independent) have presented the most difficulty. To help AECs find potential members, the Department maintains a list of names, contact details and the categories that individuals believe they can represent. This list is available to all NSW AECs.

2.8 Website: Animal Ethics Infolink

Development and maintenance of a website by the Panel and Department - 'Animal Ethics Infolink' - is aimed at assisting researchers, teachers and members of Animal Ethics Committees to access information about the operation of the animal research legislation in NSW. In addition to specific information about the legislation, including Panel policies and guidelines, this site provides general information about legislation in other states and countries and links to many sites from which useful information promoting the humane care and use of animals for scientific purposes can be sourced. The website also gives the broader community access to information about animal use for research and teaching in NSW.

The Animal Ethics Infolink site is accessible at www.animaethics.org.au.

2.9 Site inspections

In the 2020-21 financial year, 9 site inspections were conducted by an inspector appointed under the Act. Panel members accompanied the inspector during site inspections (Appendix C). Reports from all 9 inspections were presented to the full Panel for review and any additional feedback.

2.10 Policies and Guidelines

The Panel and Department produce policies and guidelines to aid researchers, AECs, research establishments, animal suppliers and members of the broader community to understand and comply with the requirements of the animal research legislation. These documents can be found by following the links from the Panel's website, [Animal Ethics Infolink](#) (see Appendix G for a list of guidelines and policies).

Policies and guidelines are developed or revised to fill needs identified by the Panel.

In 2020-21 two new documents were published:

- Fact Sheet 1 – [Environmental enrichment for Pigs](#) (October 2020)
- G27. [Research Animal Rehoming Guidelines for establishments and individuals involved in the care and use of animals for research and teaching in NSW](#) (December 2020)

In 2020-21 three guidelines were revised:

- G4. [Use of Animals undergoing surgical procedures for educational purposes](#) (revised August 2020)
- G16. [Animal Ethics Committee supervision of obtaining, breeding, keeping and supplying animals for use in research](#) (revised June 2021)
- G16A. [Supply of dogs and cats for use in research](#) (revised August 2020)

2.11 Initiatives in replacement, reduction and refinement

Information collected from the 'Annual Return on Animal Use' submitted by each research establishment includes information on techniques developed or used by the establishment to replace, reduce and refine animal use in research and teaching. The adoption of such techniques is actively encouraged by the Panel. Lists of the initiatives are published in the annual [Animal Use Statistics Reports](#) on Animal Ethics Infolink website.

2.12 Complaints

A statutory process for making complaints about animal research is set out in sections 22, 28 and 42 of the Act. Complaints must be made in writing to the Secretary, who refers the complaint to the Panel for investigation. The Panel is bound by the Act to investigate complaints made in this manner, and to furnish the Secretary with a report. The Secretary then makes a determination as per section 24, 28B or 44 of the Act. Both the complainant and the individual or establishment being investigated have a right to apply to the NSW Civil and Administrative Tribunal (NCAT) for administrative review of the determination.

In the 2020-21 reporting period, no statutory complaints were made under the Act.

APPENDICES

Appendix A: Dates of Animal Research Review Panel meetings

Meeting number	Date of meeting
239	16 July 2020
240	24 September 2020
241	3 December 2020
242	25 February 2021
243	6 May 2021

Appendix B: Attendance of members at Panel meetings

MEMBER	MEETING NUMBER				
	239	240	241	242	243
Professor Jacqueline Phillips (Chair)	*	*	*	*	*
Professor Annemarie Hennessy (Deputy Chair)	*	*	*	*	*
Professor Robert Mulley	*	*	*	*	A
Mr Anthony Croker	*	A	*	*	*
Mr Scott Meyers	*	A	*	A	*
Dr Sophie Riley	*	*	*	*	*
Ms Paula Wallace	*	*	*	*	*
A/Professor Keiron Rooney	A	*	A	*	*
Ms Sally Bannerman	*	*	A	*	A
Dr Damian O'Brien	*	*	*	*	*
Dr Benjamin Russell	*	*	*	*	A
Dr Alice Marshall	*	*	*	*	*

* = Present

A = Absent

Appendix C: Dates of Inspections attended by Panel members July 2020 – June 2021

Inspection number	Inspection date/s	Category of Panel member/s in attendance (section 6(2) of the Act)
1	7 July 2020	
2	28 August 2020	s6(2)(d) - Animal Societies' Federation
3	17 & 25 September 2020	6(2)(a) - NSW Vice-Chancellors' Committee; s6(2)(d) - Animal Societies' Federation
4	15 October 2020	s6(2)(c) - RSPCA NSW; s6(2)(f) - Minister for Education and Training
5	13 November 2020	
6	2 February 2021	s6(2)(b) - Medicines Australia; s6(c) - RSPCA NSW; s6(2)(g) - Minister for Primary Industries
7	7 May 2021	
8	13 May 2021	s6(2)(a) - NSW Vice-Chancellors' Committee; s6(2)(c) – RSPCA NSW; s6(2)(d) - Animal Societies' Federation
9	3 June 2021	s6(2)(a) - NSW Vice-Chancellors' Committee; s6(2)(d) - Animal Societies' Federation

Appendix D: Animal Research Review Panel Strategic Plan July 2020 – December 2021

Objective: Protect and promote the welfare of animals used in research and teaching
(What are we seeking to achieve?)

Performance measurement:
(How are we going to measure success?)

Success	KPI/Evaluation	Basis for Comparison	Status at 30 June 2021
High proportion of research establishments compliant with the Animal Research Act, Regulation and the <i>Australian Code for the care and use of animals for scientific purposes</i> .	Percentage and number of inspections that show acceptable compliance with regulatory requirements.	Performance over time.	In progress
High proportion of establishments are well informed and have access to information to enable them to improve animal welfare in research.	Percentage and number of establishments that report access to information and improved knowledge on follow up survey.	Performance over time.	In progress

Strategies:
(How are we going to get there?)

Strategy/Deliverable	Who	When	Output/ Level of activity	Status at 30 June 2021
Education / Training				
Develop guideline for AECs on improved decision making with respect to research/teaching applications	Panel / Animal Welfare	June 2021	Guideline published	In progress
Survey Establishments and AECs for education/training needs and delivery methods (needs analysis)	Panel / Animal Welfare	December 2020	Survey completed and analysed	Completed
Identify platforms and topics and develop	Panel / Animal Welfare /	March 2021	Implementation plan developed	Pending

implementation plan for Establishment and AEC education/training	Compliance			
Publish and publicise pig enrichment fact sheet	Panel / Animal Welfare	August 2020	Fact sheet published and publicised	Completed
Survey implementation of pig enrichment factsheet	Panel / Animal Welfare	October 2021	Survey carried out and assessed.	Pending
Develop supporting material to accompany rehoming guideline	Panel / Animal Welfare	December 2021	Supporting fact sheets developed	In progress
Industry liaison and communication				
Participate in prioritised inspections and provide feedback to institutions arising from site inspections and AEC meetings	Panel / Compliance	Ongoing	Participate and provide feedback	Ongoing
Review and provide feedback on inspection reports	Panel / Compliance	Ongoing	Review reports and provide feedback	Ongoing
Provide technical advice for timely resolution of complaints	Panel / Compliance	Ongoing	Provision of timely technical advice	Ongoing
Review options for Panel engagement with industry	Panel/ Animal Welfare / Compliance	March 2021	Completion of review	In progress
Legislation				
Participate in NSW Animal Welfare Reform through comment and advice	Panel	Ongoing as required	Provision of timely advice throughout reform program, as requested.	Ongoing

Appendix E: Animal Research Review Panel expenses

Note: The following figures do not include the time and costs incurred by individual Panel members—and met at their own expense—for work such as planning for the AEC members meeting, and input into the development of guidelines. In addition, support provided to members by their employing establishments (for example: salaries paid by government departments for their employees' time spent on Panel business) is not included in the figures.

Fees and retainers	6,435
Travel and subsistence	593
Stores (including catering) and printing	0
Freight and postage	0
TOTAL	\$7,028

Appendix F: Animal Research Review Panel policies and guidelines

(Available from <http://www.animaethics.org.au>)

Policies

2. Payment of External Members of Animal Ethics Committees (revised 4/5/17)
3. Activities prohibited under the NSW Prevention of Cruelty to Animals Act 1979 (revised 1/12/17)
4. Non-Research Animals at Accredited Animal Research Establishments (revised 1/12/17)
5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 31/1/20)
- 5A. Accredited Animal Research Establishment Support for Animal Ethics Committees (revised 8/5/14)
6. Differentiation between animal research and veterinary treatment (revised 8/5/14)
8. Establishment of Protocols for Grievance Procedures (revised 16/12/14)
9. Criteria for Assessment of Animal Ethics Committee Membership (revised 15/7/19)
10. Emergency Procedures
11. Formal Agreements between Accredited Research Establishments sharing Animal Ethics Committees
12. Frequency of Animal Ethics Committee Meetings (revised 31/1/20)
13. Inspections by Animal Ethics Committees
14. The use of restricted drugs and the conduct of restricted acts of veterinary science in animal research (revised 27/2/2014)
15. Orientation of New Members of Animal Ethics Committees
16. Conflict of Interest with Membership of Animal Ethics Committees (revised 31/3/20)

Guidelines

- G3. Collaborative Research between Accredited Animal Research Establishments (May 2018)
- G4. Use of Animals undergoing surgical procedures for educational purposes (revised Aug 2020)
- G5. Collection of Voucher Specimens (revised January 2020)
- G6. Use of Pitfall Traps (revised January 2020)
- G7. The use of non-indigenous vertebrate pest species in research (revised March 2020)
- G8. Teaching Artificial Insemination and Pregnancy Testing in Cattle
- G9. Radio Tracking and GPS Tracking (revised January 2020)
- G10. Wildlife Surveys (revised January 2020)
- G11. Guidelines for Tick Serum Producers
- G12. Animal Research Application Form (Model) (February 2000)
- G14. Guidelines for the Care and Housing of Dogs in Scientific Institutions (March 1999)

- G15. Blood Collection
- G16. Supervision of Animal Supply by Animal Ethics Committees (revised June 2021)
- G16a. Supply of dogs and cats for use in research (revised August 2020)
- G17. Training Personnel
- G18. Guidelines for the Housing of Rabbits in Scientific Institutions (August 2003)
- G19. Teaching Cervical or Vaginal Artificial Insemination of Sheep (draft)
- G20. Guidelines for the Housing of Rats in Scientific Institutions (December 2007)
- G21. Guidelines for the Housing of Guinea Pigs in Scientific Institutions (May 2006)
- G22. Guidelines for the Housing of Mice in Scientific Institutions (April 2012)
- G23. Guidelines for the Housing of Sheep in Scientific Institutions (June 2010)
- G24. Consideration of high impact projects by Animal Ethics Committees (December 2015)
- G25. Common issues encountered during inspections of animal research establishments (May 2018)
- G26. Animal Ethics Committee reporting and amendment application templates (March 2018)
- G27. Research Animal Rehoming Guidelines (December 2020)

Appendix G: Standard conditions for Accreditation and Animal Supply Licence

The following are standard conditions that were placed on establishments Accredited as Animal Research Establishments and Licenced as Animal Suppliers, if relevant to their activities. Additional conditions are added on a case-by-case basis.

Accreditation

That any site inspection is satisfactory.

Details of changes to Animal Ethics Committee membership (including the qualifications of new members and the categories to which they are appointed) must be provided to the Animal Welfare Unit of the NSW Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Secretary, Department of Industry.

Rabbits should be housed in groups in pens. Rabbits may only be housed in cages with the express permission of the AEC based on compelling evidence for the need to use such housing. Lack of space or facilities for pens should not be considered sufficient justification for the use of cages. Where rabbits are held in cages, these cages should be enriched by methods such as pair housing in double cages. (*Australian Code for the Care and Use of Animals for Scientific Purposes Clauses 3.1.5, 3.1.6, 3.2.13*) (See ARRP Guideline 18: Guidelines for the Housing of Rabbits in Scientific Institutions: <https://www.animaethics.org.au/policies-and-guidelines/animal-care>).

Unless otherwise approved by the Animal Ethics Committee, animals should be housed in accordance with the ARRP guidelines on animal housing for specific species found at: <http://www.animaethics.org.au/policies-and-guidelines/animal-care>.

Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.

Dogs should be housed in accordance with ARRP Guideline 14: Guidelines for the Care and Housing of Dogs in Scientific Institutions (<http://www.animaethics.org.au/policies-and-guidelines/animal-care>).

The Establishment must comply with NHMRC Principles and guidelines for the care and use of non-human primates for scientific purposes (<https://www.nhmrc.gov.au/health-ethics/animal-research-ethics/use-non-human-primates-scientific-purposes>).

Unless otherwise approved by the Animal Ethics Committee based on compelling evidence for the requirements of projects, housing for cats must include:

- A minimum floor area (not including shelves) of 1.5m²/ per cat and a minimum height of 2.0m.
- Shelves to enable cats to sit at varying heights must be provided.

In addition to these requirements, facilities for cats must at least meet the guidelines of the Council of Europe (2006) Appendix A. (<http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf>).

Unless approved by the Animal Ethics Committee ducks must be provided with access to water to enable bathing behaviour (see Council of Europe (2006) Appendix A <http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf>).

Unless approved by the Animal Ethics Committee, pigs should be provided with a solid floored area with bedding material for rooting and resting. (See Council of Europe Appendix A: <http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf>).

Unless otherwise approved by the Animal Ethics Committee, wildlife studies should be carried out in accordance with the ARRP guidelines on wildlife research found at: <http://www.animaethics.org.au/policies-and-guidelines/wildlife-research> .

Animals (other than exempt animals) may only be obtained from a licensed animal supplier (see <http://www.animaethics.org.au/policies-and-guidelines/animal-supply>).

It is essential that the AEC members are provided with a copy of the inspection report of {date} and that the AEC is involved in the assessment of, and provision of responses to, the conditions, recommendations and observations contained in this report.
(*Added after inspection*)

A response to conditions {xx} of the inspection report of {date} must be provided to the NSW Department of Primary Industries by {date—within 3 months of inspection report being sent}.
(*Added after inspection*)

Animals (other than exempt animals) must only be obtained from a licensed animal supplier.

Failure to comply with the terms, conditions, limitations or restrictions of this licence may result in the suspension or cancellation of the accreditation.

Must notify the Department of Primary Industries within 7 days of any changes unless otherwise specified in the Act or Regulation.

The accreditation holder ensures that the provisions of the Australian code for the care and use of animals for scientific purposes (the Code) are complied with in relation to carrying on of any activity authorised by the accreditation.

The accreditation holder must ensure that the provisions of the *Animal Research Act 1985* and Animal Research Regulation 2010 are complied with in relation to the carrying on of any activity authorised by the accreditation.

The accreditation holder must ensure, unless otherwise approved by the Animal Ethics Committee, that animals are housed in accordance with the ARRP guidelines on animal housing for specific species found at www.animaethics.org.au.

The accreditation only relates to the designated land described on it.

This accreditation is not transferable.

Animal Supply Licence

That any site inspection is satisfactory.

The documented procedures and methods of record keeping, as required under clauses 2.5.11, 2.5.12, 2.5.15 (vii) and 3.2.2 of the Australian Code for the Care and Use of Animals for Scientific Purposes, must be submitted by the supply unit to the AEC for approval.

To assist in monitoring the management of breeding colonies, the supply unit must provide regular reports to the AEC, for review, on the fertility, fecundity, morbidity and mortality of all breeding colonies. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.

To help ensure that overproduction is avoided, the supply unit must provide regular reports to the AEC, for review, on the number of animals culled and the reasons for these numbers. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.

Any breeding which involves animals which have been the subject of genetic modification (involving the introduction of foreign DNA into cells or whole animals) must comply with clauses 2.4.26, 2.4.27 and 3.3.24 of the *Australian Code for the Care and Use of Animals for Scientific Purposes*.

The licence holder must ensure that the provisions of the Animal Research Act 1985 and Animal Research Regulation 2010 are complied with in relation to the carrying on of any activity authorised by the licence.

The business must ensure that the provisions of the Australian code for the care and use of animals for scientific purposes (the Code) are complied with in relation to carrying on of any activity authorised by the licence.

This licence is valid for a 36-month period and is not transferable to another person.

The licence only relates to the designated land described on it.

Must notify the Department of Primary Industries within 7 days of any changes unless otherwise specified in the Act or Regulation.

Failure to comply with the terms, conditions, limitations or restrictions of this licence may result in the suspension or cancellation of the licence.