

Animal Research Review Panel Annual Report 2019 – 20



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Animal Research Review Panel Annual Report 2019 - 20

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More information

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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 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 2019–20 period, several membership terms concluded, resulting in a period of transition for the Panel. The membership of the Panel was:

Professor Andrew Dart (out-going Chair) (nominated by the NSW Vice-Chancellors' Committee; concluded 13 October 2019)

Professor Jacqueline Phillips (incoming Chair) (nominated by the NSW Vice-Chancellors' Committee; reappointed 12 November 2019)

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)

Dr Peter Rolfe (nominated by Medicines Australia; concluded 30 September 2019)

Dr Damian O'Brien (nominated by Medicines Australia; appointed 1 October 2019)

Distinguished Professor Annemarie Hennessy (Deputy Chair) (nominated by the Minister for Health; reappointed 14 October 2019)

Ms Sally Bannerman (nominated by the Minister for Education and Training; reappointed 6 March 2020)

Dr Elizabeth Arnott (nominated by the Minister for Primary Industries; resigned 24 April 2020)*

Dr Mike Fleming (nominated by the Minister for the Environment; concluded 13 October 2019)

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)

Dr Christina Zhu (nominated by RSPCA NSW; concluded 13 October 2019)

Mr Scott Meyers (nominated by RSPCA NSW; appointed 14 October 2019)

*Panel membership of the nominee for the Minister for Primary Industries was vacant for the remainder of the financial year.

Information on members of the Panel in 2019–20 is as follows:

Professor Andrew DART BVSc PhD Dip ACVS Dip ECVS (Chair)

Professor Dart is Professor of Equine Veterinary Science and Director of the Research and Clinical Trials Unit of the Faculty of Veterinary Science, the University of Sydney. He has held positions as Director of the Veterinary Teaching Hospital and Deputy Chair and Acting Chair of the Animal Ethics Committee of the University of Sydney. Professor Dart is a Registered Specialist in Equine Surgery and has spent time in private practice and as a Clinical Academic. Professor Dart was appointed to the Panel in 2008 and as Chair of the Panel in December 2010.

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 and Health Science, 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.

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 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 Peter ROLFE BVSc, PhD (Syd)

Dr Rolfe is an employee of Elanco Animal Health, a registered veterinary surgeon and has had a career in research and research management and in various public and private sector roles. He currently manages global programs for the research and development of innovative pharmaceuticals for use in farm and companion animals. Dr Rolfe's membership concluded on 30 September 2019.

Dr Damian O'BRIEN BVSc (Uni of Sydney)

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 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 the University of Western Sydney.

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 Elizabeth ARNOTT BVSc MVS MANZCVS (Small Animal Medicine & Animal Welfare) PhD

Dr Arnott was the Team Leader for Animal Welfare Policy at the Department of Primary Industries. She has worked in private veterinary practice for over 15 years, completing a Master of Veterinary Studies and attaining membership of the Australian and New Zealand College of Veterinary Scientists. Dr Arnott undertook research into working dog welfare and behavioural genetics to complete a PhD through the University of Sydney in 2018. She was appointed to the Panel in 2019 and resigned on 24 April 2020.

Dr Mike FLEMING BSc (Hons) ANU, PhD (Monash)

Dr Fleming had been a member of the Panel since February 2009. He is a Senior Team Leader with the Science Division of the Office of Environment and Heritage. Dr Fleming has conducted research in marsupial physiology, wildlife management and biodiversity survey. He has worked extensively in the Northern Territory and New South Wales. Dr Fleming's membership concluded 13 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 14 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. Dr Riley is also the legal researcher for the Centre for Compassionate Conservation at the University of Technology. 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.

Dr Christina ZHU, BVSc (merit) MANZCVS (Small animal surgery)

Christina Zhu joined the Panel in 2017. After graduating from the University of Sydney with a Bachelor of Veterinary Science, she worked in private practice, followed by a rotating internship at the University Veterinary Teaching Hospital after which she completed a clinical research Masters degree. In 2013 she became a Member of the surgery chapter of the Australian and New Zealand College of Veterinary Scientists. She is currently the Managing Veterinarian at RSPCA NSW. Dr Zhu's membership concluded on 13 October 2019.

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 12 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. 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.

1.3.4 Retirement of Panel Chair

The term of membership of Professor Andrew Dart, as Chair of the Animal Research Review Panel has concluded. Professor Dart was a member of the Panel from 2008 and Chair of the Panel from 2010. Under Professor Dart's period of leadership, activities and achievements of the Panel have included:

- Four successful Animal Ethics seminars
- Investigation of a complex complaint, with positive outcomes including refinements in procedures to reduce the impacts on animals, and improved Animal Ethics Committee operation, and ongoing monitoring by the Panel
- Investigation and recommendations on a complex formal complaint concerning a tertiary teaching establishment
- Investigation and recommendations on research carried out without Animal Ethics Committee approval involving multiple establishments
- Development of quideline documents including evidence-based housing quidelines for sheep and mice, Animal Ethics Committee assessment of high impact projects and a draft rehoming guideline
- Negotiations with individual establishments for housing standards for species including baboons, marmosets, cats and guinea pigs
- Panel recommendations for guinea pig housing upheld in an appeal to the then Administrative Decisions Tribunal
- Revision of Accreditation and Animal Supply Licence procedures including revised forms, revised criteria for assessment, and amendments to the Animal Research Act 1985
- Ongoing assessment of LD50 applications and liaison with the research establishment on the development of alternatives
- Maintenance of a site inspection schedule.

1.3.5 Appointment of new Panel Chair

The Hon Adam Marshall, Minister for Agriculture and Western New South Wales (the Minister), appointed Professor Jacqueline Phillips as Chair of the Panel. Professor Phillips brings to the role of Chair qualities including membership of the Panel since 2011, an extensive background in animal research, qualifications as a veterinarian and broad experience on high level committees and boards including as Chairperson.

Distinguished Professor Annemarie Hennessy has been reappointed by the Minister as Deputy Chair.

Animal Ethics Committees 1.4

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.animalethics.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 a limited number of 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 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.

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 typically referred to a full meeting of the Panel for consideration and then sent to the establishment.

Response to inspection reports

Establishments are required to respond in writing to the inspection report, and this response must address any issues and non-compliances arising from the inspection. 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 is carried out, such as additional inspections.

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.

Administration 1.7

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 operational plan for 2019–20. 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 2017–20 (Appendix D) and Operational Plan for 2019–20 (Appendix E); and Panel operating expenses (Appendix F).

2.1.1 Strategic plan 2017 - 20

The Panel's three-year strategic plan for 2017-20 identifies the primary goals of the Panel and strategies for achieving these goals and is provided in Appendix D.

2.1.2 Operational plan for 2019-20

The Panel Operational Plan for 2019–20, including performance status for each activity, is provided in Appendix E.

2.1.3 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 2019-20-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 2019-20 there were 167 Accredited Animal Research Establishments and 37 holders of Animal Supply Licences.

During 2019–20 the Panel considered and made recommendations to the Secretary on:

- 11 new applications for Accreditation
- 44 renewal applications for Accreditation
- 0 new applications for Animal Supply Licences
- 9 renewal applications for Animal Supply Licences.
- 9 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 2019–20 were Dr Riley, Dr Mulley and Professor Phillips. The subcommittee makes recommendations to the Panel, which in turn advises the Minister.

In 2019–20 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 on the following conditions:

- 1) Data is provided in graphical form by 31 January 2021 with figures comparing 2018, 2019 and 2020 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 2021.

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 2019–20 year the Panel assessed and made recommendations to the Department on the appointment of 71 members of Animal Ethics Committees.

2.4 **Assessment of Accreditation and Licence responses**

The Panel assesses and makes recommendations to the Department on responses from Accredited Animal Research Establishments and Licensed Animal Suppliers to conditions and recommendations arising from site inspection and/or placed at the time of Accreditation and Licence application.

In the 2019–20 year the Panel considered 12 responses from Accredited Animal Research Establishments and Licensed Animal Suppliers.

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 2019–20 year included:

- Evaluation of applications for LD50 testing (Dr Riley, Dr Mulley and Professor Phillips)
- Rehoming animals (Ms Wallace and Dr Riley)
- Animal Ethics Committee training (Ms Wallace, Dr Riley, Professor Phillips and A/Professor Rooney)

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.

For the 2019 reporting year an additional category on the fate of animals was added. 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.

Support for Animal Ethics Committees 2.7

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 holding of seminars for AEC members and researchers; 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.

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 this 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.animalethics.org.au.

2.9 Site inspections

In the 2019-20 financial year, Panel members accompanied an inspector during three site inspections (Appendix C).

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 2019-20 three policy documents were revised:

- P5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised January 2020)
- P12. Frequency of animal ethics committee meetings (revised January 2020)
- P16. Conflict of interest with membership of animal ethics committees (revised March 2020)

In 2019-20 six guidelines were revised:

- G5. Collection of voucher specimens (revised January 2020)
- G6. Use of pitfall traps (revised January 2020)
- G7. Use of non-indigenous pest species in research (revised March 2020)
- G9. Radio tracking and GPS tracking (revised January 2020)
- G10. Wildlife surveys (revised January 2020)

A draft factsheet on pig enrichment was approved to be circulated for targeted consultation.

The following were withdrawn from publication:

- G1. Opportunistic Research on Free-Living Wildlife
- G2. Captive Wildlife
- G13. Guidelines for the Production of Monoclonal Antibodies

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 legislated process for making complaints about animal research is set out in sections 22, 28 and 42 of the Act. Complaint 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 2019-20 reporting period, one complaint made under the Act was referred to the Panel for investigation. The Panel delegated its investigation of this complaint (in accordance with section 12 of the Act) to compliance officers in NSW Department of Primary Industries and inspectors appointed under the Act.

APPENDICES

Appendix A: Dates of Animal Research Review Panel meetings

Meeting number	Date of meeting
233	11 July 2019
234	19 September 2019
235	4 December 2019
236	20 February 2020
237	7 May 2020
238 (OOS)	12 June 2020

Appendix B: Attendance of members at Panel meetings

Meeting number

Member	233	234	235	236	237	238 (OOS)
Professor Jacqueline Phillips (Chair)	N/A	N/A	N/A	*	*	*
Professor Jacqueline Phillips	*	Α	*	N/A	N/A	N/A
Professor Andrew Dart (Chair)	*	*	N/A	N/A	N/A	N/A
Professor Annemarie Hennessy (Deputy Chair)	*	Α	*	*	*	*
Professor Robert Mulley	*	*	*	*	*	*
Mr Anthony Croker	*	*	Α	*	*	*
Mr Scott Meyers	N/A	N/A	Α	Α	Α	*
Dr Sophie Riley	*	*	Α	*	*	*
Ms Paula Wallace	*	*	*	*	*	*
A/Professor Keiron Rooney	N/A	N/A	*	*	*	*
Ms Sally Bannerman	*	Α	Α	*	*	*
Dr Elizabeth Arnott	*	*	*	*	N/A	N/A
Dr Damian O'Brien	N/A	N/A	*	*	*	*
Dr Mike Fleming	*	*	N/A	N/A	N/A	N/A
Dr Christina Zhu	*	*	N/A	N/A	N/A	N/A
Dr Peter Rolfe	*	Α	N/A	N/A	N/A	N/A
Dr Benjamin Russell	N/A	N/A	*	*	Α	*

^{* =} Present

A = Absent

Appendix C: Dates of Inspections attended by Panel members July 2019 – June 2020

Inspection number	Inspection dates
1	13 November 2019
2	5 February 2020
3	12 & 14 February 2020

Appendix D: Animal Research Review Panel Strategic Plan July 2017 – June 2020

* Numbers on the right refer to items from 2019/20 Animal Research Review Panel Operational Plan that address the strategies.

Goals and Strategies	
Goal 1: Effective and efficient implementation of the statutory requirements of the Animal Research 1985, the Animal Research Regulation 2010 and the Australian Code for the Care and Use of Animals for Scientific Purposes.	
1.1 Maintain a system to accredit and licence all establishments and individuals in NSW conducting research and teaching using animals.	1.1
1.2 Maintain a programme of site visits to effectively monitor compliance with the legislation.	2
1.3 Review the methods of conducting site visits and documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency.	
1.4 Identify and implement adjuncts to inspections to better ensure compliance with the legislation.	2.5
1.5 Monitor compliance with the Act, Regulation and Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.	1 2
1.6 Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.	
1.7 Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.	1.4
1.8 Maintain and review the system for collection and analysis of statistics on animal use for research and teaching, to ensure that it provides useful information which accurately reflects the use of animals, without imposing an undue administrative burden on institutions or Government.	2.5 5.1
1.9 Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.	1.2
1.10 Provide opportunities to the research, teaching, veterinary, animal welfare and lay communities to provide feedback on the activities of the Animal Research Review Panel and respond appropriately.	2 3
1.11 Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.	1.3
Goal 2: The principles, processes and responsibilities in the <i>Australian Code for the Care and Use Animals for Scientific Purposes</i> are actively embraced by all involved wherever animals are used.	
2.1 Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.	1 2 3 4
2.2 Promote an understanding of the roles and responsibilities of institutions in actively pursuing programmes for researchers and teachers that underpin their responsibilities under the Code.	1 2 3 4

2.3 Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes.	1 2 3
2.4 Promote and foster interaction between AECs and researchers/teachers.	2 3 4
2.5 Promote an appreciation of the ethos underpinning the Code through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care staff.	2 3 4
2.6 Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programmes.	1 2 3 4
2.7 By identifying problems and suggesting remedies, aid institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.	1 2 3 4
2.8 Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs.	1 2 3 4
2.9 Review the membership and operation of individual AECs to ensure they are operating effectively.	1.1
2.10 Develop and promulgate evidence-based guidelines to assist AECs, researchers and teachers to effectively implement the 3Rs.	4
2.11 Promote a critical review of the operation of AECs by the institution with a view to maximising their effectiveness.	2 4
Goal 3: Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the Australian Code for the Care and Use of Animals for Scientific Purposes.	
3.1 Promote an understanding of the roles and responsibilities of researchers/teachers through participation in education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	3 4
3.2 Maintain the "Animal Ethics Infolink" website as a resource for AECs, researchers and teachers and members of the community.	3.1
Goal 4: Methods that complement or replace animal use are used wherever possible.	
4.1 Encourage AECs to critically assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.	2
4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching.	2
4.3 Collate and disseminate information on alternatives to animal use.	3
4.4 Promote consideration of funding for development and validation of alternatives.	
Goal 5: Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals.	f
5.1 Encourage a critical review of the design of projects before applications are submitted to AECs.	2 3 4

5.2 Ensure close scrutiny by AECs of breeding programmes to minimise overproduction of	1
animals.	2
	3
5.2. Energy place constinut by AECs of the compatence of recoverhals to compact on selfic	4
5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific	1
procedures.	2
	3
5.4 Barrier 6 - 20 al a de como forma de como forma de la	4
5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.	1
	2
	3
5.5 Promote the critical evaluation by AECs and researchers of the impact of the type of	1
, , , , , , , , , , , , , , , , , , , ,	2
housing / holding on experimental animals and awareness of its implications for experimental	
results.	3
Goal 6: When animals are used in research and teaching, their well-being is promoted and there is anticipation, prompt recognition and alleviation of pain and distress.	<u> </u>
6.1 Promote the implementation of strategies which will foster the well-being of animals and	1
which will foster the development of appropriate risk management assessments related to pain	2
and distress in animals.	3
	4
6.2 Ensure that AECs and researchers/teachers focus on the possible impact of procedures at	1
the planning stage and implement appropriate strategies for monitoring and alleviation.	2
	3
	4
6.3 Promote awareness by researchers / teachers and animal care staff of signs of well-being,	2
pain and distress in animals.	3
	4
6.4 Promote the use of appropriate analgesia and anaesthesia by facilitating access by	2
researchers/teachers to information resources.	3
	4
6.5 Promote awareness of the effects of handling and other interactions with humans on	2
levels of pain and distress and the use of strategies to minimise adverse impacts.	3
6.6 Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress	2
	-
during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	
Goal 7:	
High standards of housing and routine care are established for animals used in research a teaching.	1 -
7.1 Evaluate housing and routine care through the ongoing site visit programme and	1
assessment of applications for Accreditation and Animal Supply Licence.	2
7.2 Develop and disseminate evidence-based guidelines for housing and routine care.	4
7.3 Actively participate in the development and review of appropriate national and international standards for housing and routine care.	4
Goal 8:	
Animals used are supplied in accord with the legislation	4.0
8.1 Identify areas of non-compliance through scrutiny of records during site visits and	1.2
investigation of complaints.	2
8.2 Develop and disseminate appropriate educational material.	3
8.2 Develop and disseminate appropriate educational material.	4
	1 -

Goal 9:	
The community (research, teaching, veterinary, animal welfare and lay) has access to	
information about animal use for research and teaching in NSW.	
9.1 Provide information in the annual report on ARRP activities and achievement and areas of	1.4
concern to the Animal Research Review Panel.	
9.2 Publish collated statistics on animal use on the Animal Ethics Infolink website.	2.8
	3.1
9.3 Identify options for disseminating information about specific issues of interest and concern	3
both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	4
9.4 Review and maintain a website for the dissemination of information.	3.1
9.5 Provide opportunities for and encourage the community (researchers, teachers,	3
veterinarians, animal welfare, lay) to have an input into legislative review, development of	4
standards for housing and care and policy development.	
9.6 Ensure that information about animal use provided by the Animal Research Review Panel	1.4
is in lay terms where appropriate.	3
9.7 Encourage institutions to provide information about their animal use direct to the general	
community.	
Goal 10:	
The approach to administration of animal research and teaching is harmonised between St and Territory regulatory and funding bodies.	ate
10.1 Promote interaction between State and Territory regulatory and funding bodies.	
The state of the s	

Appendix E: Animal Research Review Panel Operational Plan July 2019 - June 2020

- C = Compliance Unit
- AW = Animal Welfare Unit

Activity	Measure of Performance	Time Frame	Unit	Status
1. Mandatory				
Review incoming applications for accreditation and licence	Recommendation to the Secretary	Licensing and Accreditation Unit to manage an effective and efficient licensing program within the statutory requirements of the Animal Research Act 1985.	С	Complete
1.2 Investigate formal complaints	Report to the Secretary	Interim or final recommendations within 3 months	С	Complete
1.3 Review incoming applications to conduct LD50 tests	Recommendations to the Minister	3 months	С	Complete
1.4 Prepare annual report for 2018-2019	Report submitted to the Minister	December 2019	AW	Complete
2. Inspections / Monitoring/ Statistics			_	
2.1 Conduct site visits of accredited animal research establishments on a 4-yearly basis (for those establishments in-State, active and with own AEC)	Number of establishments inspected Number of days for inspections	Ongoing	С	Ongoing – 4 AREs, 5 days. Delays due to COVID-19.
2.2 Inspect new establishments applying for accreditation prior to or within 6 months of accreditation (for those establishments in-State, active and with own AEC)	Number of new establishments inspected	Ongoing	С	Ongoing – no new establishme nts met these criteria in 2019-20
2.3 Review and send inspection reports	Reports sent	Within 3 months of inspection	С	Complete
2.4 Follow up "problems" identified at inspection or on review of applications for accreditation or licence	Problems rectified	Within 12 months	С	Complete
2.5 Investigate informal complaints	Recommendation to NSW DPI	Interim or final recommendations within 3 months	С	Complete
2.6 Assessment of 2018 AEC annual reports	Assessment carried out	October 2019	AW	Complete
2.7 Assess qualifications of new AEC members	Recommendations to the Secretary	Develop and implement system enhancements that promote regulatory compliance in line with legislated requirements	С	Complete
2.8 Prepare statistics report on animal use for 2018	Report prepared	December 2019	AW	Complete
3. Education				
3.1 Maintain Animal Ethics Infolink website	Site maintained	Ongoing	AW	Site under review
3.2 Disseminate information via the Animal Welfare email circular	Information included in the circulars	Ongoing	AW	Complete
3.3 Input into education and training initiatives	Input when need identified	Ongoing	AW / C	Pig enrichment fact sheet drafted.
4. Policies and guidelines				

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4.1 Develop policies/ guidelines where strong need identified	Developed as need identified. GL 27: Rehoming finalised	June 20	AW	1 Developed, publication pending.
4.2 Revise current policies and guidelines	Continue programme of revision.	Ongoing	AW	8 Revised
5. Legislation				
5.1 Participate in legislation review	Provide comment	Dependent on progress of the review	AW	Participated in stakeholder meeting.
5.2 Commonwealth – cosmetic testing ban	Consider legislation amendments	Schedule dependent on action by Commonwealth to progress ban	AW	Consultation by Commonwe alth delayed due to COVID-19

Appendix F: 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	4,945
Travel and subsistence	911
Stores (including catering) and printing	452
Freight and postage	63
TOTAL	\$6,371

Appendix G: Animal Research Review Panel policies and guidelines

(Available from http://www.animalethics.org.au)

Policies

- 2. Payment of External Members of Animal Ethics Committees (revised 4/5/17)
- P3. Activities prohibited under the NSW Prevention of Cruelty to Animals Act 1979 (revised 1/12/17)
- P4. 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)
- P10. Emergency Procedures
- P11. Formal Agreements between Accredited Research Establishments sharing Animal Ethics Committees
- P12. Frequency of Animal Ethics Committee Meetings (revised 31/1/20)
- P13. 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)
- P15. Orientation of New Members of Animal Ethics Committees
- P16. Conflict of Interest with Membership of Animal Ethics Committees (revised 31/3/20)

Guidelines

- G3. Individuals and Institutions Engaged in Collaborative Research (May 2018)
- G4. Use of Animals in Post-graduate Surgical Training
- 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 (March 2002)
- G17. Training Personnel
- G18. Guidelines for the Housing of Rabbits in Scientific Institutions (August 2003)
- G19. Teaching Cervical or Vaginal Artificial Insemination of Sheep
- 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)

Appendix H: 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.animalethics.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.animalethics.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.animalethics.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/healthethics/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.animalethics.org.au/policies-and-guidelines/wildlife-research.

Animals (other than exempt animals) may only be obtained from a licensed animal supplier (see http://www.animalethics.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.animalethics.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.