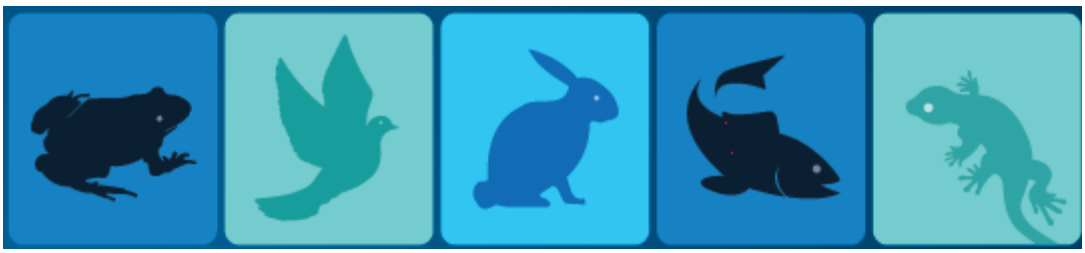
NSW GOVERNMENT Department of Primary Industries

Animal Research Review Panel

Annual Report 2014 -15



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Animal Research Review Panel Annual Report 2014-15

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More information

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Letter to the Minister

NSW GOVERNMENT | Department of Primary Industries

ANIMAL RESEARCH REVIEW PANEL

3 December 2015

The Hon Niall Blair MLC
Minister for Primary Industries
Minister for Lands and Water
52 Martin Place
SYDNEY NSW 2000

Dear Mr Blair

In accordance with Section 11 of the Animal Research Act 1985, the Animal Research Review Panel presents its annual report covering the period 1 July 2014 to 30 June 2015.

Yours sincerely

Professor Andrew Dart
Chair, Animal Research Review Panel

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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 (ARRP) 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. The Code is reviewed regularly by the Code Reference Group, under the auspices of the National Health and Medical Research Council (NHMRC). The Code Reference 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 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. Staff of the Animal Welfare Unit, NSW Department of Primary Industries 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 ARRP, 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 ARRP under section 9 (d) of the Act since it commenced.

1.3.3 Membership

The Panel consists of 12 members appointed by the Minister on the basis of 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): two nominees.

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

During the 2014–15 period the membership of the Panel was:

A/Professor Andrew Dart (Chair) (nominated by the NSW Vice-Chancellors' Committee)

Dr Regina Fogarty (Deputy Chair) (nominated by the Minister for Primary Industries)

Dr Magdoline Awad (nominated by RSPCA NSW)

Mr Peter Batten (nominated by the Minister for Education and Training; resigned November 2014)

Dr Mike Fleming (nominated by the Minister for the Environment)

Professor Annemarie Hennessy (nominated by the Minister for Health)

Ms Emma Hurst (nominated by the Animal Societies' Federation)

Professor Anne Keogh AM (nominated by the Animal Societies' Federation)

Professor Robert Mulley (nominated by the NSW Vice-Chancellors' Committee)

Mr David O'Shannessy (nominated by RSPCA NSW)

Professor Jacqueline Phillips (nominated by the NSW Vice-Chancellors' Committee)

Dr Peter Rolfe (nominated by Medicines Australia)

Information on members of the Animal Research Review Panel in 2014–15 is as follows:

Professor Andrew DART(Chair) BVSc PhD Dip ACVS Dip ECVS
Dr 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. Dr Dart is a Registered Specialist in Equine Surgery and has spent time in private practice and as a Clinical Academic. Professor Dart was appointed as Chair of the ARRP in December 2010.

Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland). Dr Fogarty is the Director of the Office of Agricultural Sustainability and Food Security, a policy group within the Department of Primary Industries. Dr Fogarty has been actively involved in animal welfare issues in previous positions with the Department as Manager of NSW Agriculture's Animal Welfare Unit; as Program Leader, Intensive Livestock Products; and as Veterinary Officer (Pig Health). Dr Fogarty joined the ARRP in 2003 as the nominee of the then Minister for Agriculture.

Dr Magdoline AWAD BVSc MACVSc(Animal Welfare) GradCert Mgt(Prof Prac) CMAVA
Dr Awad is a nominee of the RSPCA (NSW). After graduating with a Veterinary Science degree from the University of Sydney, Dr Awad worked in small animal private practice before joining the RSPCA NSW in 1996 as a Veterinarian. She was Deputy Chief Veterinarian from 2004-2008 and currently holds the role of Chief Veterinarian. In 2008 she became a Member of the Animal Welfare Chapter of the Australian College of Veterinary Scientists. She has a particular interest in Shelter Medicine. She was involved in the development of the CAWS Programs (Community Animal Welfare Scheme), Indigenous Dog Health Programs as well as the Pets of Older Persons Program (POOPS) for RSPCA NSW. She became a member of the ARRP in 2008.

Mr Peter BATTEN BSc (Wool and Pastoral Sciences) (UNSW), Dip Ed (Technical) (Sydney CAE)
Mr Peter Batten was Director of the TAFE NSW – Training and Education Support – Industry Skills Unit – Orange and Granville. He has 30 years' experience in vocational education and training with TAFE NSW including positions dealing with the welfare of animals in teaching including Program Manager Extensive Agriculture, Industry Specialist Livestock Production and Wool and Teacher of Agriculture. Mr Batten joined the ARRP in 2008 as the nominee of the Minister for Education and Training.

Dr Mike FLEMING BSc (Hons) ANU, PhD (Monash)
Dr Fleming is a nominee of the Minister for the Environment and has been with ARRP 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.

Professor Annemarie HENNESSY BMdSu, PhD

Professor Hennessy was previously a member the ARRP from 2008 to 2010. She was re-appointed in January 2014. 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 Emma Hurst BA(Psy), PGDip(Psy), M(HealthPsy) .
Ms Hurst is a registered psychologist who has worked in the areas of adolescent mental health, aged care, child therapy, addictions, and health promotion research. Ms Hurst has worked in a range of settings such as mental health services, universities, and specialist early intervention services. She is particularly interested in the promotion of animal advocacy and runs a research animal rehoming service. Ms Hurst was appointed to the Panel in 2014 as a nominee of the Animal Societies Federation.

Professor Anne Keogh AM MBBS (hons), MD, FRACP, FCSANZ, FPVRI
Professor Anne Keogh is a nominee of the NSW Animal Societies Federation. She is the Senior Heart Transplant Cardiologist St Vincent's Hospital Sydney, Head of Human Clinical Research in heart failure and pulmonary hypertension, and Joint Head Clinical Research at the Victor Chang Cardiac Research Institute. She is Conjoint Professor of Medicine University of NSW, Director of two binational registries, and sits on multiple global and national scientific advisory boards. She has been Trustee of Medical Advances without Animals from 2006, and has worked with a broad range of Australian and international animal welfare groups for 20 years, Australia Day Ambassador for 7 years, past president International Society of Heart and Lung Transplantation and past president of the Pulmonary Hypertension Society of Aust and NZ which she formed in 2010. She was awarded the Order of Australia (AM) in June 2012 for services to transplantation, heart failure and animal welfare.

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 the University of Western Sydney, and has extensive experience in husbandry and management of farmed livestock, particularly pigs and deer. More recently he has engaged in research on a range of wildlife species.

Mr David O'SHANNESSY, BSAgr.
Mr O'Shannessy is the nominee of the RSPCA (NSW). Since completing an Agricultural Science degree he has been employed as an inspector with RSPCA NSW and for a period of time was a sales representative for a veterinary pharmaceutical company. He was appointed RSPCA Chief Inspector in May 2005 and was appointed as a member of the ARRP in January 2005.

Professor Jacqueline Phillips. BVSc Hons (Uni of Syd), PhD (ANU)
Professor Phillips is a nominee of the NSW Vice-Chancellors' Committee and was appointed to the ARRP in 2010. Professor Phillips is a registered veterinarian who has worked in small animal and mixed practice. She has served on Animal Ethics Committees as a Category A member at the Australian National University (ACT) and Murdoch University (WA) . She is a Professor of Neuroscience in the Faculty of Medicine and Health Science, Macquarie University.
Her research is in the areas of hypertension and renal disease.

Dr Peter ROLFE BVSc, PhD (Syd)
Dr Rolfe is a nominee of Medicines Australia. He 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.

1.4 Animal Ethics Committees

At the institutional 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 on the basis of 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 institution, 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. They 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*, 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 involved with the establishment, animal research or the supply of animals for research

Category D: an independent person who does not fit the requirements of the other categories, is not associated with the institution 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 should 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). This policy was revised in December 2014. In examining applications from establishments for accreditation as animal research establishments, the membership of AECs are assessed to ensure they are of acceptable composition. The Panel also assesses, and makes recommendations to the Secretary, on the suitability of all new appointments to AECs. All new AEC appointments must be approved by the Secretary. 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.

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 Industry, who has statutory authority for the issue of accreditation and licences and for imposing, altering or removing conditions of accreditation or licence.

Accreditation and licences are usually issued subject to a condition that any site inspection is satisfactory and to a condition requiring the reporting of changes in AEC membership to the Secretary for approval. Other conditions may also be stipulated, as relevant to the operation of each establishment. (See Appendix K 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 Animal Welfare Unit 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 Panel may convene an Applications Subcommittee to facilitate the assessment of new applications. The subcommittee is convened on a “needs” basis. Where no need is identified by the Animal Welfare Unit for input by the Applications Subcommittee, recommendations are made by the Unit directly to the Panel.

A small number of applications are also viewed directly and considered by the full Panel. These include applications from individuals or organisations about which the ARRP has particular concerns, or situations where the application is sufficiently different from the norm to raise policy implications.

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. Details of AEC inspections carried out must be provided. Questions on the source and destination of animals allow the Panel to double-check compliance with the Act’s provisions relating to animal supply.

1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether establishments and individuals are complying with the legislation. The *Australian Code for the Care and Use of Animals for Scientific Purposes* provides the criteria against which establishments are assessed. The range of items assessed includes: the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing and using animals. An evaluation is also made of the wellbeing of the research or breeding animals.

Audit visits are arranged in advance and usually take from 1 to 4 days per site. Large establishments with multiple sites can take up to 2 weeks to inspect. Information about inspections conducted in the 2014–15 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

Assessment begins before site inspection with an examination of written material provided by the establishment or individual. This includes lists of the research applications considered by the AEC and people issued with Animal Research Authorities, AEC minutes, the AEC annual report, and records of inspections conducted, together with information about the procedures of the committee and the institutional policy on the committee's operation and decisions.

The examination is carried out by an Animal Welfare Unit Veterinary Inspector and the Panel members who have been nominated to participate in the inspection. This pre-inspection evaluation allows likely problem areas to be identified and a general idea to be gained of how the establishment is operating.

On the day(s) of the inspection the inspection team initially looks at the animals and the facilities and talks with researchers and animal care staff. This examination includes assessing a broad range of items such as the physical condition of animals, animal care and management, and records related to the animals held. After examining animals and facilities, the inspection team sits in on a scheduled meeting of the AEC, which allows it to view the operation of the AEC and the interaction of its members. At the end of the meeting, time is taken to discuss with the AEC issues arising from the inspection and to solicit feedback from AEC members. Additional important considerations are how the committee liaises with researchers and whether it has developed its own policies or guidelines for procedures of particular concern, such as blood collection techniques, methodology for monoclonal antibody production, and standards for wildlife transportation and the recognition and relief of pain.

A meeting is usually held with the head of the institution at the beginning or end of the inspection. Any serious concerns are immediately referred to the institution at the appropriate level.

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the Panel has considered the report, recommendations may arise to impose additional conditions on the accreditation or licence. For example, a condition may be that appropriate post-operative procedures must be implemented.

In addition to conditions for accreditation or licence (which are mandatory and must be implemented), the Panel report usually contains a number of recommendations—for example, for more effective operation of the AEC, for improvement of the management of research within the establishment, or for improvement of the animal facilities. Implementation of recommendations is not mandatory, but the institution is required to advise on how it has responded to the recommendations. If the recommendations have not been implemented, then the reasons for this must be explained.

Inspection reports also provide an opportunity for the Panel to commend the institution, individual researchers or animal attendants for initiatives that raise the standards of the overall operation of the research facility or for techniques or facilities that enhance the welfare of research animals.

The Panel also conducts revisits to institutions (and individuals) that have been inspected previously and where particular concerns were raised during the inspection. The primary purpose of these revisits is to evaluate the responses to the recommendations and conditions imposed.

The Panel aims to carry out full audit visits for all institutions approximately every 4 years, as well as unannounced visits by inspectors to follow up problems. Reinspections concentrate more on procedures rather than facilities, unless new facilities have been built. Announced and unannounced spot checks and visits to look at specific aspects of operation may be carried out between full visits.

1.6 The Animal Research Act in schools and TAFE

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

The Animal Welfare Unit is a section within the NSW Department of Primary Industries. The functions of the Animal Welfare Unit cover:

* animal research issues under the *Animal Research Act*, including providing executive services to the Panel
* general animal care and cruelty issues under the *Prevention of Cruelty to Animals Act,* including the operation of the Animal Welfare Advisory Council under the Minister for Primary Industries
* animal display issues under the *Exhibited Animals Protection Act*, including the operation of the Exhibited Animals Advisory Committee
* Departmental animal welfare activities.

The Animal Welfare Unit can be contacted at:

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161 Kite Street
Locked Bag 21
ORANGE NSW 2800
Phone (02) 6391 3149

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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 2014–15. The appendixes to this annual report contain details of many of the operational and strategic functions of the Panel.

These include the dates of, and attendance at, Panel meetings (Appendixes A and B); dates and attendance of Panel members at inspections (Appendixes C and D); the Animal Research Review Panel Strategic Plan 2014–17 (Appendix E) and Operational Plan for 2014–15 (Appendix F); and Panel operating expenses (Appendix I).

2.1.1 Strategic plan 2014 – 17

During 2014-15 the Panel revised its 3-year strategic plan. The plan identifies the primary goals of the Panel and strategies for achieving these goals.

Details of the plan are given in Appendix E.

2.1.2 Operational plan for 2014-15

The Panel Operational Plan for 2014–15, including performance status for each activity, is provided in Appendix F.

2.1.3 Liaison with organisations and individuals

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

During the 2014-15 year the main method of liaison was via discussions during, and feedback after, site inspections. Additionally recommendations were made in the process of assessing Accreditation and Licence applications.

There was ongoing communication with an Accredited Establishment following the investigation of a complaint, to enable the assessment of the effectiveness of measures put in place to deal with the issues identified.

2.2 Assessment of applications

In 2014–15 there were 145 Accredited Animal Research Establishments and 45 holders of Animal Supply Licences.

During 2014–15 the Panel considered and made recommendations to the Secretary on:

6 new applications for Accreditation

26 renewal applications for Accreditation

3 renewal applications for Animal Supply Licences.

3 extensions to existing Accreditations 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 NSW *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 for Primary Industries. Applications for

permission to conduct LD50 tests are evaluated by an Panel subcommittee. Members of the subcommittee in 2014–15 were Professor Dart and Dr Fleming. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2014–15 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. The majority 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. One of the tests is required for quality control of batches of equine salmonella vaccine, used to protect horses against salmonellosis. The Panel recommended the Minister approve the application on the following conditions:

1) Data is provided in graphical form by 31 January 2016 with figures comparing 2013, 2014 and 2015 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 euthanased as an early end-point in tests.

2) Any application for Ministerial concurrence to conduct LD50 tests between April 2016 and April 2017 must be presented by the establishment to the Animal Welfare Unit by 31 January 2016.

3) The establishment continues, 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 Animal Welfare Unit by 31 January 2016.

2.3 Assessment of changes to AEC membership

All establishments are required to advise the Animal Welfare Unit of changes to AEC membership. The Panel assesses and makes recommendations to the Secretary 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 (http://www.animalethics.org.au/policies-and-guidelines/operation/criteria-for-assessment)*.

In the 2014–15 year the Panel assessed and made recommendations to the Secretary on the appointment of 66 members of Animal Ethics Committees.

2.4 Assessment of Accreditation and Licence responses

The Panel assesses and makes recommendations to the Secretary 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 2014–15 year the Panel considered 40 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 2014–15 year included:

* Evaluation of applications for LD50 testing (Professor Dart and Dr Fleming)
* Preparation for the 2015 Animal Ethics Seminar (Dr Fogarty (sub-committee Chair), Professor Dart, Professor Keogh, Ms Hurst and Professor Hennessy)
* Complaint investigation ((Professor Dart – Chair, Ms Hurst, Professor Keogh and Professor Mulley)
* Rehoming animals (Ms Hurst (sub-committee Chair), Dr Fogarty and Dr Awad).

2.6 Statistics on animal use

The Animal Research Regulation 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:

1. The recording of an animal in all projects in which the animal is used.
2. The recording of animals for each year in which they are held in long-term projects.
3. The recording of 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 to be used on a national basis. Figures are collected on a calendar year rather than by financial year.

Appendix G of this report summarises animal usage in 2014.

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 provided in Appendix H.

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. In the 2014-15 year, the Panel carried out an assessment of these reports, and provided feedback to the AECs and institutions.

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 Appendix G of this report.

2.7 Support for Animal Ethics Committees

The Panel and the Animal Welfare Unit 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.

In compiling the statistics on animal use for the 2013 reporting year it was discovered that a teaching procedure involving major surgery on rats (opening the abdomen) with recovery, and maintenance for a period prior to euthanasia, had occurred. The establishment was contacted for further information. The enquiries revealed that the AEC had not been aware of this use of rats, and would not have considered the procedure justified. The Panel assessed that the AEC's processes for the consideration and approval of teaching using animals required significant revision to ensure all teaching using animals was properly considered in accordance with the *Australian Code for the care and use of animals for scientific purposes*. A number of recommendations were made to the establishment and progress with implementation was followed up.

Ms Emma Hurst, via the Animal Welfare League, offered to assist with rehoming research animals. Information on this was circulated to Accredited research establishments and a number took the opportunity to liaise with Ms Hurst to rehome animals no longer required for research.

2.7.1 Register of candidates for AEC membership

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

2.7.2 Animal Ethics Seminar

In the 2014-15 year, planning was finalised for a seminar for members and executive officers of AECs and animal researchers, to be held in September 2015. In an effort to ensure that the programme for the seminar would meet the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided and has been used, in conjunction with comments gathered from evaluation forms completed at previous seminars, to structure a programme accordingly. The members of the Panel subcommittee working on this project were Dr Fogarty, Professor Dart, Professor Keogh, Ms Hurst and Professor Hennessy. Other members of the Panel have assisted with ideas for the programme and contacting potential presenters. The Australian Catholic University again generously agreed to host the meeting at its North Sydney Campus. Information

on previous seminars and the 2015 seminar can be found at the Animal Ethics Infolink website at: http://www.animalethics.org.au/animal-ethics-committees .

2.8 Website: Animal Ethics Infolink

Development and maintenance of a website by the Panel - '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 website has been developed and is maintained in conjunction with the Animal Welfare Unit. The Animal Ethics Infolink site is accessible at www.animalethics.org.au .

2.9 Site inspections

A list of dates of site inspections undertaken in 2014–15 is provided in Appendix C, and a list of Panel members attending is given in Appendix D. There were 14 establishments inspected over a period of 18 working days. The length of these inspections ranged from one day to four days.

The Panel aims to carry out a routine inspection of each Accredited Animal Research Establishment approximately every 4 years to maintain personal contact with establishments, AECs and researchers, and to carry out a complete audit of establishment operation under the *Animal Research Act 1985*.

The Panel places a major focus on reviewing the operation of AECs, to ensure that AECs, researchers and establishments understand their responsibilities under the Animal Research Act and the Code. The conduct of research procedures and the conditions in which animals are held also receive close scrutiny during site visits.

The inspection schedule was delayed in 2015 due to the retirement of the main Inspector in the Animal Welfare Unit, Dr Peter Johnson.

2.10 Policies and guidelines

The Panel and Animal Welfare Unit 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 J for a list of guidelines and policies).

New policies and guidelines are produced to fill needs identified by the Panel.

During the 2012-13 year an issue was raised with the Panel about publication of the results of a study using baboons for shoulder surgery. As the research had occurred 20 years previously, it was decided there was no value in investigating the particular study. However, the Panel agreed that it raised the broader issue of how AECs make judgements about the value of research, especially for projects with high impacts on the animals involved. It was decided that the development of a guideline document on this issue could be of assistance to AECs. In developing this guideline it was intended that steps would include assessing existing literature and carrying out a survey of AECs for feedback. In the 2013-14 year a review of literature on how AECs make judgements about the value of research was carried out. The Panel considered the literature review and developed a series of questions from this that were distributed to

Animal Ethics Committees. The results of the survey were collated to assist in the development of the guideline document. In the 2014-15 year a new guideline document was developed:

Guideline 24: Consideration of high impact projects by Animal Ethics Committees.

The following policies and guidelines were revised during 2014-15:

Policy 8: Grievance procedures

Policy 9: Criteria for assessment of Animal Ethics Committee membership

Guideline 10: Wildlife surveys

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. A list of some of the initiatives can be found in Appendix H.

2.12 Complaints

A formal process for making specific complaints about animal research is set out in sections 22, 28 and 42 of the *Animal Research Act 1985*. The process allows any person to make such a formal complaint. The complaint must be made in writing to the Secretary, who refers the complaint to the Panel for investigation. The Panel is bound to investigate formal complaints and to make recommendations to the Secretary for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or establishment being investigated have a right of appeal to the Administrative Decisions Tribunal.

The Panel also has a policy of responding to informal complaints. These may involve varying degrees of investigation, from formal interviews to requests for documents or unannounced visits to animal holding facilities. Complaints may arrive from a variety of sources: the RSPCA may refer matters that fall outside its jurisdiction; Panel members may raise matters brought to their attention by members of the community; public concern may be expressed in the media; and complaints may be raised in direct correspondence to the Minister for Primary Industries, the Panel, or the Animal Welfare Unit.

A summary of the complaints considered in the 2014–15 reporting period is as follows:

Impacts of a research project and interactions between the AEC and the research group
A complaint was received about a long-running research project at an Accredited Animal Research Establishment. The complainant raised a number of concerns including:

* The impact of the research on the animals
* The large number and frequency of requests for amendments to the approved project
* The possibility that a significant change in the project had been made without seeking the approval of the AEC and the length of time taken to investigate this
* Poor communication between the research group and the AEC.

The complaint was investigated by the Panel by means including: the formation of a subcommittee to consider information, the review of extensive documentation requested from

the establishment, the interview of representatives of the research group, members of the AEC and the complainant, and the viewing of research procedures directly and via video recording.

As a result of the investigation and the Panel's report on this to the Secretary, a number of measures were put in place to assess and reduce impacts on the animals, simplify the applications from the research group to the AEC and improve communication between the research group and the AEC. The effects of these measures have been the subject of ongoing monitoring by the Panel, including by the assessment of monthly reports from the AEC on its dealings with the research group.

Enquiry on the justification of a study

An enquiry was received seeking the Panel's opinion on the justification for a published study in the context of the Australian Code for the care and use of animals for scientific purposes. The Panel formed the opinion that the study could be ethically justified but that the outcomes were open to query based on the study design. With the approval of the enquirer, a summary table of concerns that had been submitted was forwarded to the responsible AEC, for its information and assistance in critical appraisal of applications.

Care and management of cattle

A complaint was received from a person who was dissatisfied with the outcome of a complaint they had made to an Accredited Animal Research Establishment concerning the care and management of cattle. Information was sought from the establishment on the investigation of the complaint and the outcomes. The information provided indicated that the response was prompt and thorough and had included the AEC's consideration of all the matters raised. None of the allegations had been able to be substantiated. However, as a result of the concerns raised, measures had been put in place to improve communication for the management of sick and injured animals.

APPENDIXES

Appendix A: Dates of Animal Research Review Panel meetings 2014–15

Meeting number	Date of meeting
208	29 July 2014
209	9 October 2014
210	11 December 2014
211	26 February 2015
212	7 May 2015

Appendix B: Attendance of members at Panel meetings 2014–15

	Meeting number				
Member	208	209	210	211	212
Professor Andrew Dart (Chair)	*	*	*	*	*
Dr Regina Fogarty (Deputy Chair)	A	*	*	*	*
Dr Magdoline Awad	*	*	*	*	*
Mr Peter Batten	A	*	N/A	N/A	N/A
Dr Mike Fleming	*	*	*	*	*
Professor Annemarie Hennessy	A	A	*	A	A
Ms Emma Hurst	*	*	*	*	*
Prof Anne Keogh	*	A	*	A	*
Professor Robert Mulley	*	*	A	A	*
Mr David O'Shannessy	*	*	*	*	*
Professor Jacqueline Phillips	A	*	*	A	*
Dr Peter Rolfe	A	A	*	A	A

* = Present

A = Absent

Appendix C: Dates of Inspections July 2014 – June 2015

Dates
9 July 14
16 July 14
23 – 25 July 14
6 August 14
7 August 14
14 August 14
14 – 15 August 14
18 August 14
20 August 14
1 September 14
2 – 3 September 14
10 – 11 September 14
25 September 14

Appendix D: Attendance of Panel members at site inspections 2014–15

Member	Days
Professor Andrew Dart (Chair)	3
Dr Regina Fogarty (Deputy Chair)	1
Dr Magdoline Awad	4
Mr Peter Batten	-
Dr Mike Fleming	2
Professor Annemarie Hennessy	-
Ms Emma Hurst	4
Professor Anne Keogh AM	-
Professor Robert Mulley	5
Mr David O'Shannessy	3
Professor Jacqueline Phillips	-
Dr Peter Rolfe	-

Appendix E: Animal Research Review Panel Strategic Plan July 2014 – June 2017

* Numbers on the right refer to items from 2014/2015 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 Act 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 3
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.	1.5
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 *Australian Code for the Care and Use of Animals for Scientific Purposes* 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.	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.	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.	2 3
2.4 Promote and foster interaction between AECs and researchers/teachers.	2 3
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.	2 3 4
2.7 By identifying problems and suggesting remedies, provide assistance to institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.	2 3
2.8 Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a programme of meetings of members and Executive Officers of AECs and participating in AEC meetings during site inspections.	2 3.2
2.9 Review the membership and operation of individual AECs to ensure they are operating effectively.	1.1 2
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 critically to assess the adequacy of researchers’/teachers’ attempts to identify alternatives to animal use.	2 3
4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching.	2 3
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.**	
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	2

of animals.	3 4
5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.	2 3 4
5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.	2 3 4
5.5 Promote the critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.	2 3 4
Goal 6: **When animals are used in research and teaching, their well-being is promoted and there is the anticipation, prompt recognition and alleviation of pain and distress.**	
6.1 Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals.	2 3 4
6.2 Ensure that AECs and researchers/teachers focus on the possible impact of procedures at 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, pain and distress in animals.	2 3 4
6.4 Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.	2 3 4
6.5 Promote awareness of the effects of handling and other interactions with humans on levels of pain and distress and the use of strategies to minimise adverse impacts.	2 3 4
6.6 Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	2
Goal 7: **High standards of housing and routine care are established for animals used in research and teaching.**	
7.1 Evaluate housing and routine care through the ongoing site visit programme.	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.	5.1
Goal 8: **Animals used are supplied in accord with the legislation**	
8.1 Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.	1.2 2
8.2 Develop and disseminate appropriate educational material.	3 4
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 achievements, areas of concern to the Animal Research Review Panel and statistics on animal use.	1.4 1.5
9.2 Identify options for disseminating information about specific issues of interest and	3

concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	4
9.3 Review and maintain a web site for the dissemination of information.	3.1
9.4 Provide opportunities for and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into legislative review, development of standards for housing and care and policy development.	3 4
9.5 Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.	
9.6 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 State and Territory regulatory and funding bodies.**	
10.1 Promote interaction between State and Territory regulatory and funding bodies.	

Appendix F: Animal Research Review Panel Operational Plan July 2014 – June 2015

Activity	Measure of Performance	Time Frame	Status
1. Mandatory			
1.1 Review incoming applications for accreditation and licence	Recommendation to the Secretary	3 months (new) 2 months (renewal)	Applications reviewed.
1.2 Investigate formal and informal complaints	Recommendation to the Secretary	Interim or final recommendations within 3 months	Complaints investigated and recommendations made.
1.3 Review incoming applications to conduct LD50 tests	Recommendations to the Minister	3 months	Applications reviewed and recommendations to Minister.
1.4 Prepare annual report for 2013-2014	Report submitted to the Minister	December 2014	Report submitted December 14.
1.5 Prepare statistics on animal use for 2013	Statistics collated	December 2014	Statistics collated .
2. Inspections / Monitoring			
2.1 Conduct site visits of accredited animal research establishments on a 3 – 4 yearly basis (for those establishments in-State, active and with own AEC)	Number of establishments inspected Number of days for inspections	Ongoing	14 18
2.2 Inspect new establishments applying for accreditation prior to or within 2 months of accreditation (for those establishments in-State, active and with own AEC)	Number of new establishments inspected	Ongoing	N/A
2.3 Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent.
2.4 Follow up “problems” identified at inspection or on review of applications for accreditation or licence	Problems rectified	Within 12 months	Problems followed up as per “Site inspection/ Accreditation responses” section of ARRP agendas.
2.5 Assessment of 2013 AEC annual reports	Assessment carried out	October 2014	2013 reports assessed and feedback provided to establishments.
2.6 Assess qualifications of new AEC members	Recommendation to the Secretary	Ongoing	Qualifications assessed and recommendations made to Secretary.
3. Education			
3.1 Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2 Plan 2015 Animal Ethics Seminar	Planning implemented	June 2015	Planning implemented.
4. Policies and guidelines			
4.1 Develop policies/ guidelines where strong need identified (maximum of 2) 4.2 Develop guideline to assist AECs in assessing research value / justification.	Developed as need identified. Develop draft for comment	 December 2014	1 New. Guideline developed.
4.3 Revise current policies and guidelines	Continue programme of revision.	Ongoing	3 revised.
5. Additional			
5.1 Continue liaison with NHMRC	Contact with NHMRC maintained	Ongoing	Comment on guideline content.

Appendix G: Animal use statistics 2014

Note: Statistics on animal use are collected on a calendar-year basis.

The following graphs, one for each **purpose** (see table below) show the numbers of animals used against the category of **procedure** (1–9; see below). The categorisation of procedures aims to give some indication of the 'invasiveness' or 'impact' of the work on the animals involved. **Species** are grouped as indicated below.

Some animals (e.g. those used to teach animal-handling techniques) are used in a number of projects. Animals that are re-used are counted in each project for which they are used. In welfare terms, this gives a more meaningful indication of animal use.

The system includes the collection of statistics on the observation of free-living animals. This causes a large number of animals to be recorded in procedure category 1 ('observation involving minor interference'). For example, an aerial survey of birds can include many thousands of individual animals.

After the graphs, statistics are given on the lethality testing performed in 2014.

Animal species categories used for collection of data

Laboratory mammals	Mice
	Rats
	Guinea Pigs
	Rabbits
	Hamsters
	Ferrets
	Other laboratory mammals (not primates)
Domestic mammals	Sheep
	Cattle
	Pigs
	Horses
	Goats
	Deer
	Cats
	Dogs
	Other domestic mammals
Birds	Poultry
	Exotic Captive
	Exotic Wild
	Native Captive
	Native Wild
	Other birds
Aquatic animals	Fish
	Cephalopods (reporting not mandatory)
	Crustaceans (reporting not mandatory)
Amphibians	Amphibians
Reptiles	Lizards
	Snakes
	Turtles and Tortoises
	Other reptiles

Primates	Marmosets
	Macaques
	Baboons
	Other primates
Native mammals	Macropods
	Possums and gliders
	Native rats and mice
	Dasyurids
	Wombats
	Koalas
	Monotremes
	Bandicoots
	Bats
	Other native mammals
	Seals
	Whales and dolphins
Exotic feral mammals	Camels
	Cats
	Cattle
	Goats
	Hares
	Horses
	Mice
	Pigs
	Rabbits
	Rats
	Dingo/Wild Dogs
	Foxes
	Other exotic feral mammals
Exotic zoo animals	Exotic zoo animals

PURPOSE
1. Stock breeding Breeding protocols to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the protocol in which they go on to be used).
2. Stock maintenance Holding protocols for animals maintained for use in other protocols. These animals may be maintained under an ethics authority because they require special management. If they are not held under an authority (e.g. normal stock animals kept mainly for commercial production, but occasionally used in research), then they are counted in the protocol only where they are used for teaching/research. *Examples:* *Fistulated ruminants that are maintained under a holding protocol for use in other short-term feeding trial protocols* *A non-breeding colony of diabetic rats held for research in other protocols*
3. Education Protocols carried out for the achievement of educational objectives. The purpose of the protocol is not to acquire new knowledge but to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment. *Examples* *Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis*
4. Research: human or animal biology Research protocols that aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology.
5. Research: human or animal health and welfare Research protocols that aim to produce improvements in the health and welfare of animals, including humans.
6. Research: animal management or production Research protocols that aim to produce improvements in domestic or captive animal management or production.
7. Research: environmental study Research protocols that aim to increase the understanding of the animals' environment or its role in it, or aim to manage wild or feral populations. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio-tracking, or capture and release. *Examples* *Pre-logging or pre-development fauna surveys*
8. Production of biological products Using animals to produce products other than e.g. milk, meat, eggs, leather or fur. *Examples* *Use of a sheep flock to donate blood to produce microbiological media* *Production of commercial antiserum* *Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals* *Quality Assurance testing of drugs*
9. Diagnostic procedures Using animals directly as part of a diagnostic process. *Examples* *Inoculation of day-old chicks with Newcastle Disease virus to determine virulence* *Blue-green algae toxicity testing* *Water supply testing using fish*
10. Regulatory product testing Protocols for the testing of products required by regulatory authorities, such as the APVMA. **If the product testing is not a regulatory requirement (e.g. if it is part of a Quality Assurance system only), those animals should be included in the appropriate Purpose category selected from above.** (This would normally be Purpose Category 8 in the case of QA testing.) *Examples* *Pre-registration efficacy or toxicity testing of drugs and vaccines*

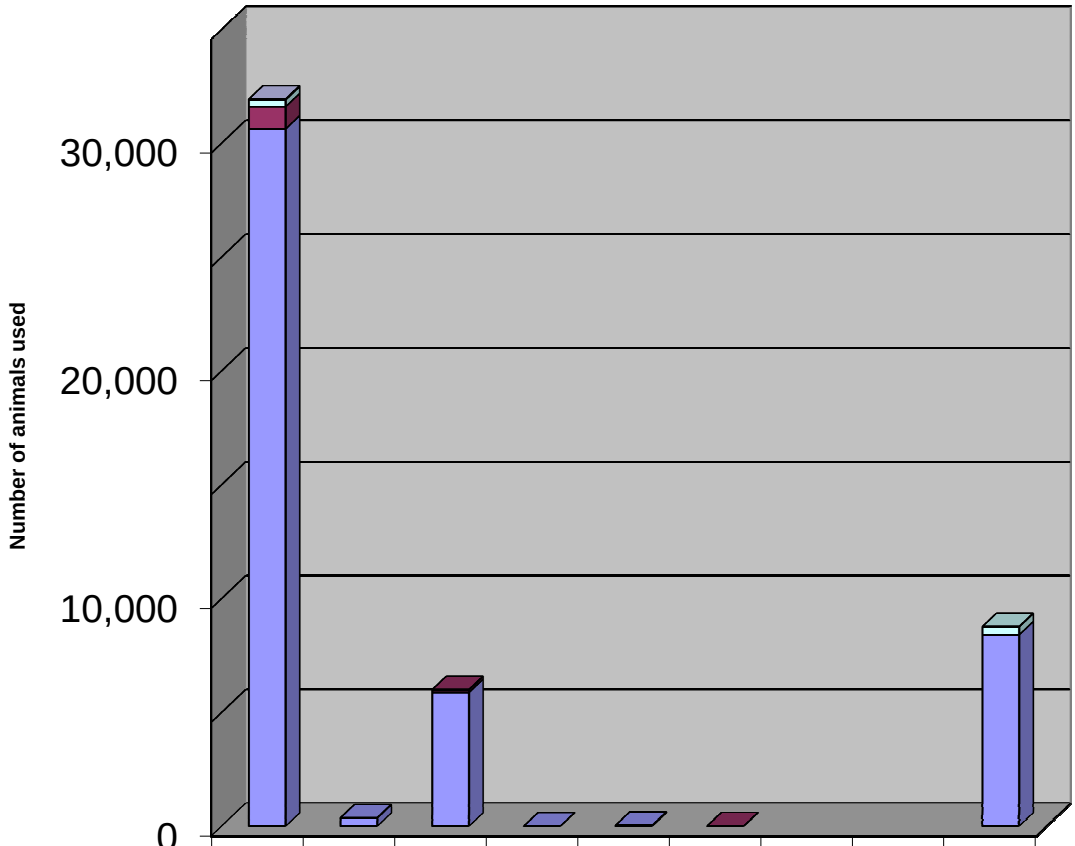
Data collection: procedure categories and guidelines used for classification

1: Observation involving minor interference	**6: Minor physiological challenge**
Animals are not interacted with, or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.	Animal remains conscious for some, or all, of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress, or any pain/distress is quickly and effectively alleviated.
2: Animal unconscious without recovery	**7: Major physiological challenge**
Animal is rendered unconscious under controlled circumstances (i.e. not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal, which is then killed without regaining consciousness.	Animal remains conscious for some, or all, of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress that is not quickly or effectively alleviated.
3: Minor conscious intervention	**8: Death as an endpoint**
Animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling.	This category applies only in those rare cases where the death of the animal is a planned part of the procedures. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, the procedure may be placed in category 6 or 7.
4: Minor surgery with recovery	**9: Production of genetically modified (GM) animals**
Animal is rendered unconscious with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture by using chemical restraint methods is also included here.	This category is intended to allow for the variety of procedures that occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes **all** animals used in GM production, other than the final progeny, which are used in a different category of procedure.
5: Major surgery with recovery	
Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Postoperative pain is usually considerable and at a level requiring analgesia.	

The following graphs (one for each purpose) show the numbers of animals used against the category of procedure (Categories 1 to 9).

Purpose: Stock Breeding

Breeding protocols to produce new teaching or research stock.
Only includes the animals used to produce progeny, NOT the final progeny.

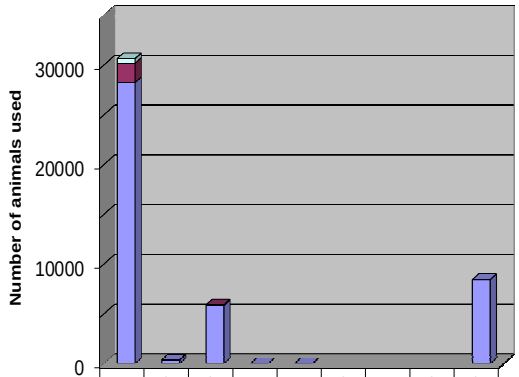


	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam	25								
Primates									
Reptiles									
Amphibians									
Aquatic	299								350
Birds									
Domestic	974		116			10			
Lab Mam	30630	371	5880	4	36				8421

Refer to following page for a further breakdown of species.

Purpose: Stock Breeding

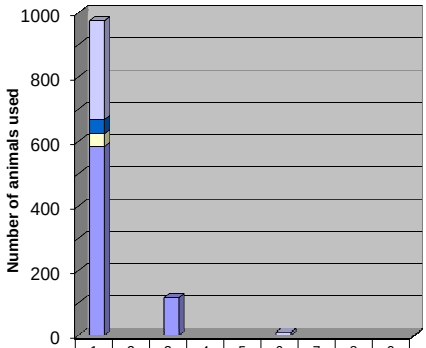
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	454								
Guinea Pig									
Rat	1936		52						
Mouse	28240	371	5828	4	36				8421

Purpose: Stock Breeding

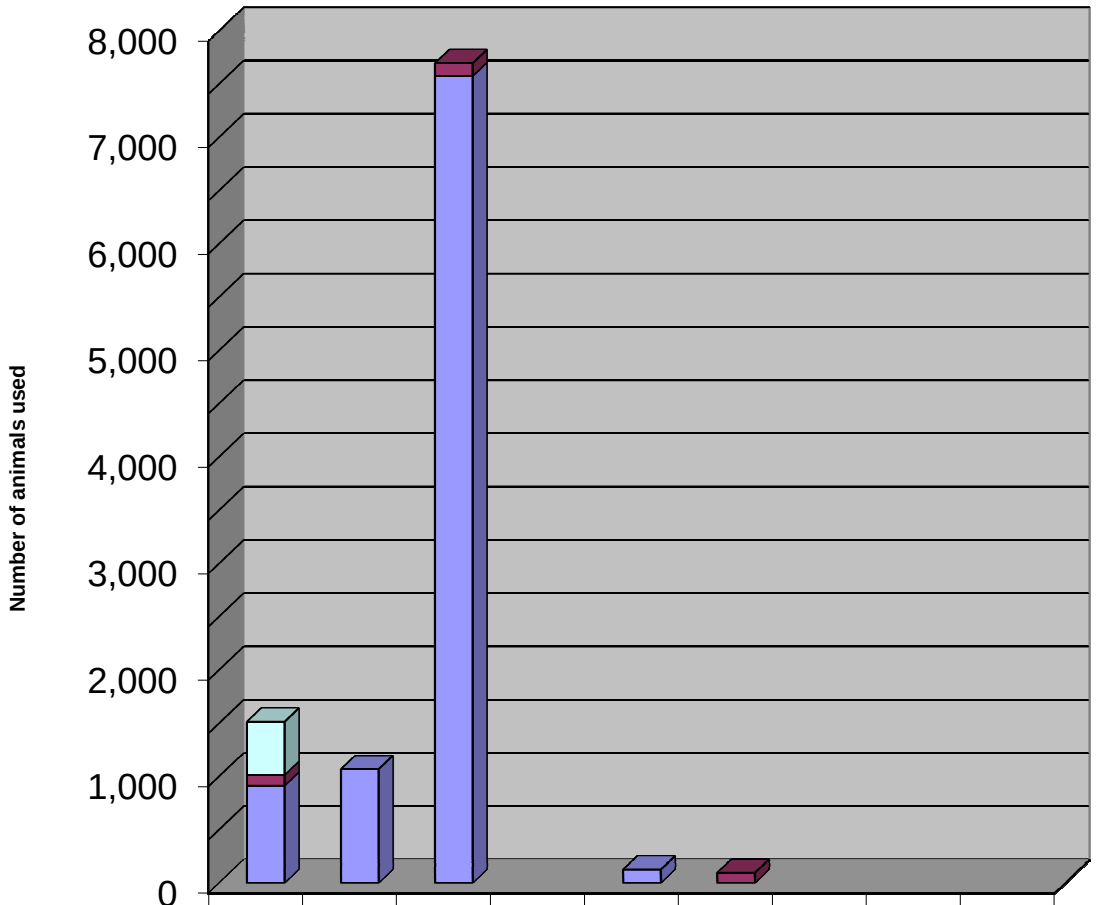
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	306					10			
Cats	44								
Deer									
Goats									
Horses									
Pigs	40								
Cattle									
Sheep	584		116						

Purpose: Stock Maintenance

Holding Protocols for animals maintained for use in other protocols.



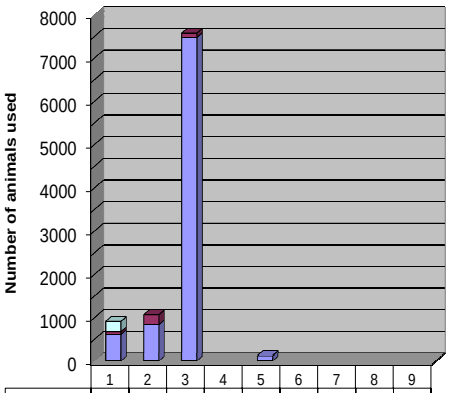
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam									
Primates									
Reptiles									
Amphibians									
Aquatic	500								
Birds									
Domestic	101		119			96			
Lab Mam	914	1068	7575		127				

Procedure

Refer to following page for a further breakdown of species.

Purpose: Stock Maintenance

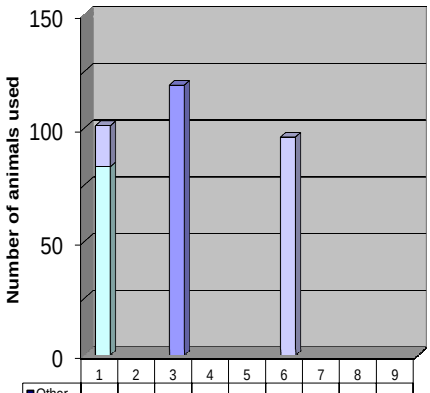
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	236								
Guinea Pig									
Rat	60	229	96						
Mouse	618	839	7479		127				

Purpose: Stock Maintenance

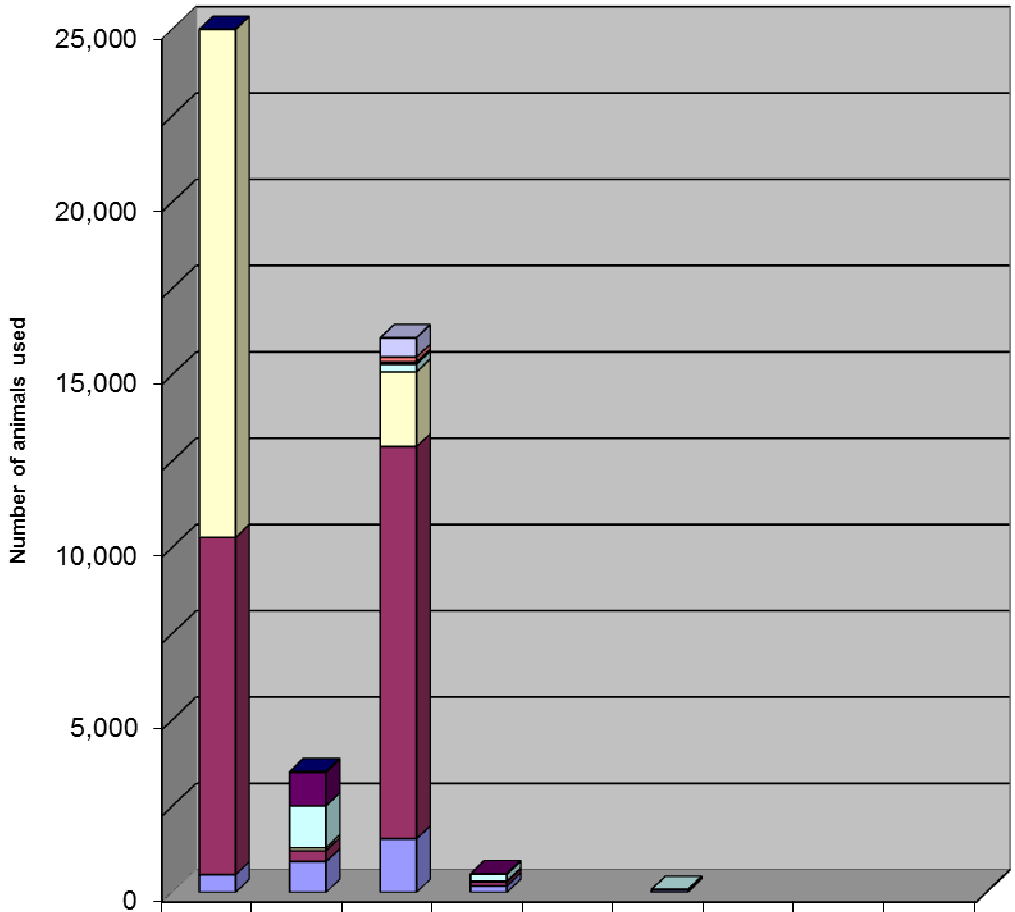
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	18					96			
Cats									
Deer									
Goats									
Horses	83								
Pigs									
Cattle									
Sheep			119						

Purpose: Education

Protocols carried out for the achievement of educational objectives, including interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.



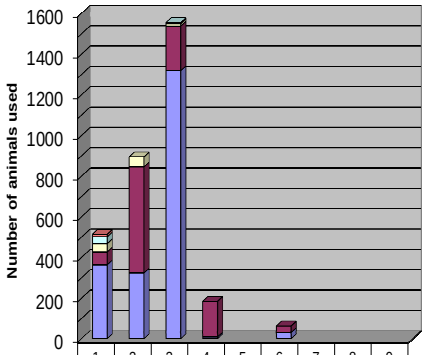
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	123	4							
Nat Mam	4,659	10	556						
Primates	4								
Reptiles	643		146						
Amphibians	1,418	974	56	10					
Aquatic	3,493	1,214	227	201		20			
Birds	27,913	86	2,167	20					
Domestic	9,770	311	11,358	122					
Lab Mam	514	895	1,555	185		63			

Procedure

Refer to following page for a further breakdown of species.

Purpose: Education

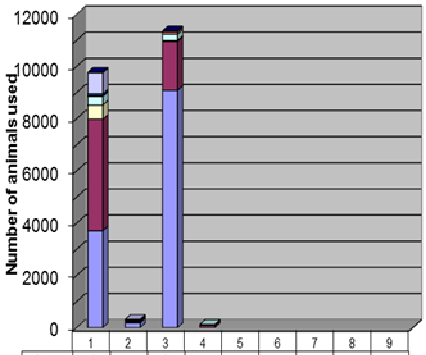
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret	12								
Hamster									
Rabbit	34		5						
Guinea Pig	40	49	11						
Rat	64	522	220	176		32			
Mouse	364	324	1319	9		31			

Purpose: Education

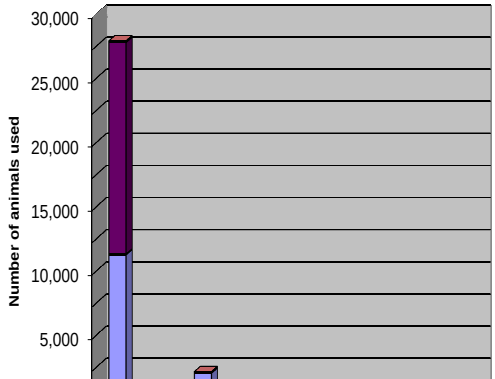
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other	13		8						
Dogs	803	45	25						
Cats	80	1	2						
Deer			88						
Goats	22	6							
Horses	333	11	243	30					
Pigs	541	48	31						
Cattle	4269	13	1873	92					
Sheep	3709	187	9088						

Purpose: Education

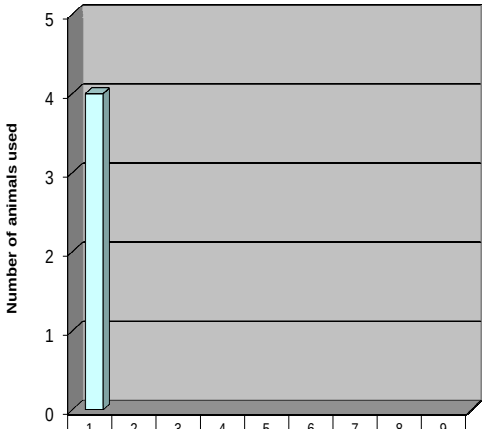
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other	115		12						
Native Wild	16,474		103						
Native Captive	61								
Exotic Wild									
Exotic Captive	2	56		20					
Poultry	11,261	30	2,052						

Purpose: Education

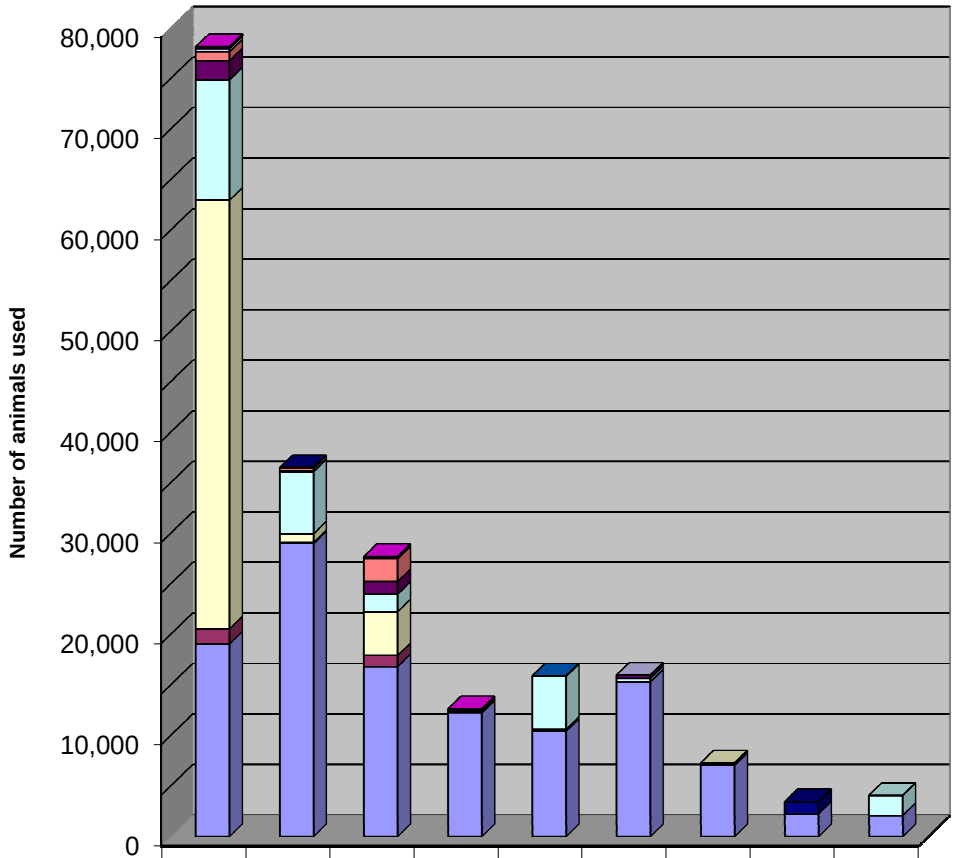
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other	4								
Baboons									
Macaques									
Marmosets									

Purpose: Research - Human or Animal Biology

Research protocols which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involoved in physiology, biochemistry and pathology.

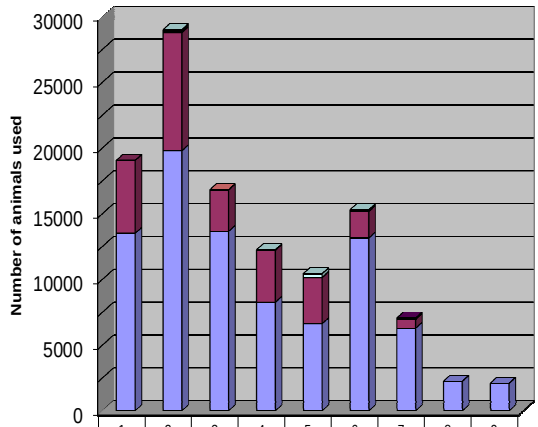


	1	2	3	4	5	6	7	8	9
Exotic Zoo	47		3	67					
Exotic Feral	133	23						1200	
Nat Mam	320	55	202	106		24			
Primates				9	2				
Reptiles	871	278	2249	33		6			
Amphibians	1914	61	1257	1	49	304			
Aquatic	11897	6131	1727		5220	315			1970
Birds	42414	864	4331	65			220		
Domestic	1498	109	1106	115	200	34	7		
Lab Mam	19054	28993	16817	12242	10422	15290	7051	2240	2090

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Biology

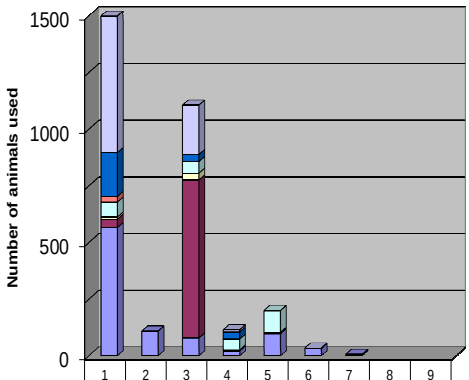
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret			2						
Hamster							84		
Rabbit		86	4	26	265	36	12		
Guinea Pig		130		10	21	92			
Rat	5547	8984	3150	3,937	3,504	2011	665		
Mouse	13507	19793	13661	8269	6632	13151	6290	2240	2090

Purpose: Research - Human or Animal Biology

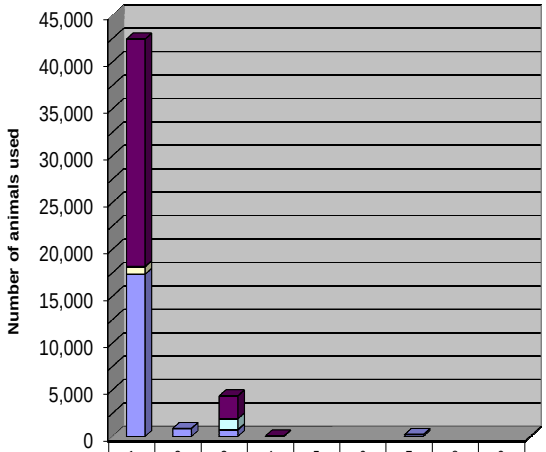
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	601		218	10		2			
Cats	194		31	31					
Deer	25								
Goats									
Horses	65		51	48	96				
Pigs	10		30						
Cattle	37		697	4	6				
Sheep	566	109	79	22	98	32	7		

Purpose: Research - Human or Animal Biology

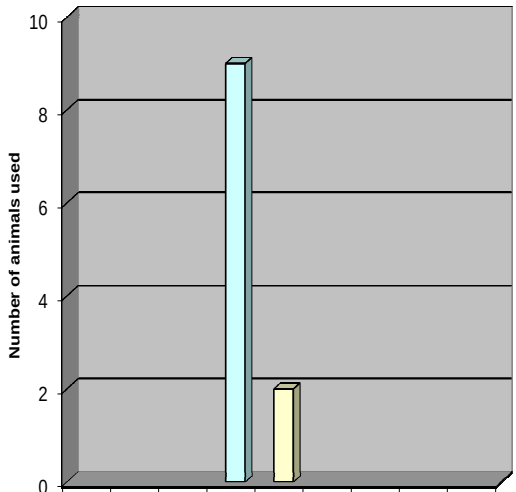
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild	24,259		2,429	36					
Native Captive	54		1,149	24					
Exotic Wild	777		53						
Exotic Captive				5					
Poultry	17,324	864	700				220		

Purpose: Research - Human or Animal Biology

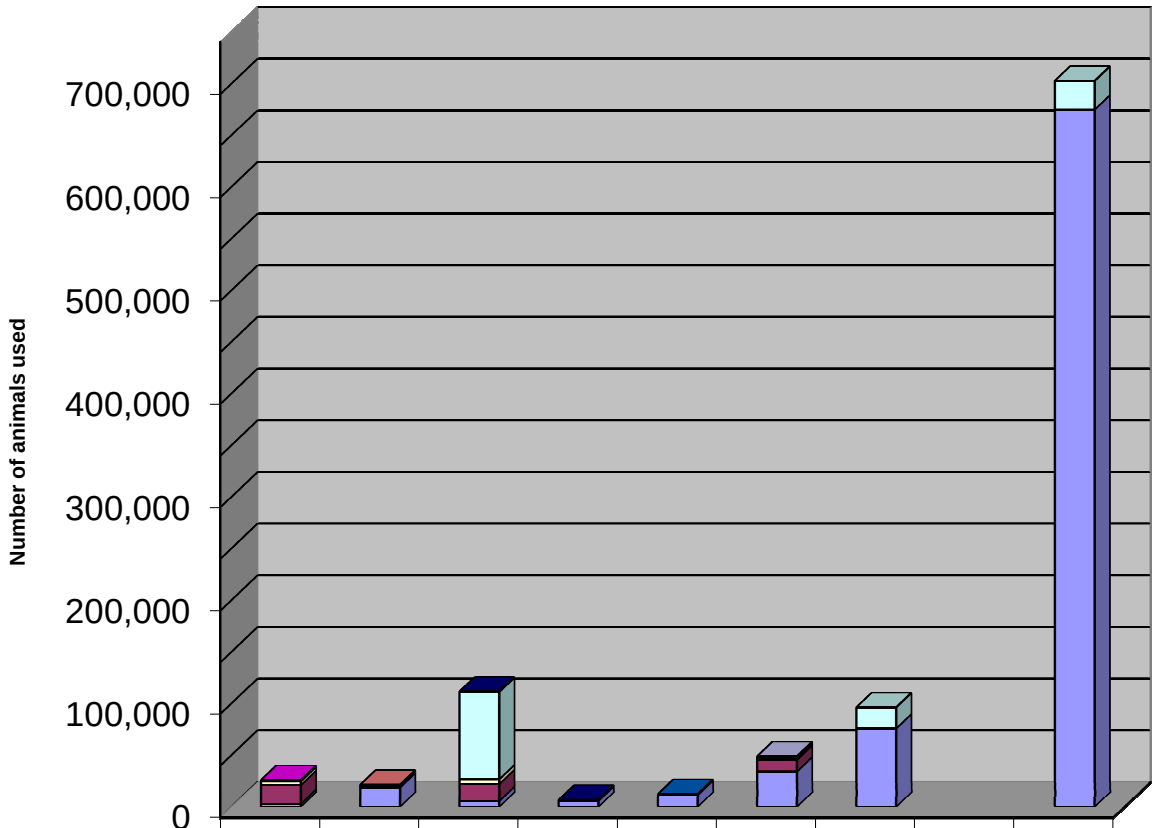
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other				9					
Baboons					2				
Macaques									
Marmosets									

Purpose: Research - Human or Animal Health & Welfare

Research protocols which aim to produce improvements in the health and welfare of animals, including humans.

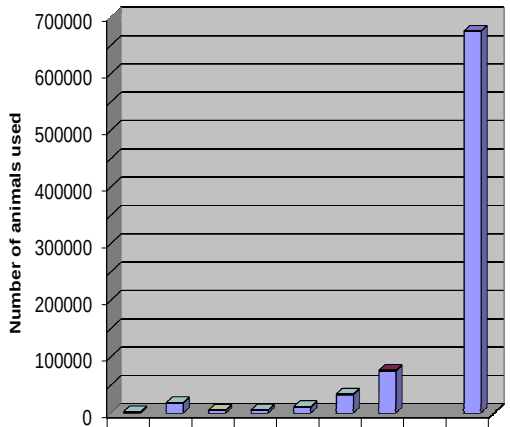


	1	2	3	4	5	6	7	8	9
Exotic Zoo	28								
Exotic Feral	500		31	10					
Nat Mam	30		290	43		102			
Primates			13	5	7				
Reptiles	9	10	44						
Amphibians					91				
Aquatic	636	2400	84447	394		1200	20313		27716
Birds	3646	53	4723	1		2090	50		
Domestic	18103	33	16336	277	684	11210	12		
Lab Mam	2824	18706	5631	5898	11542	34147	75721		674913

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Health & Welfare

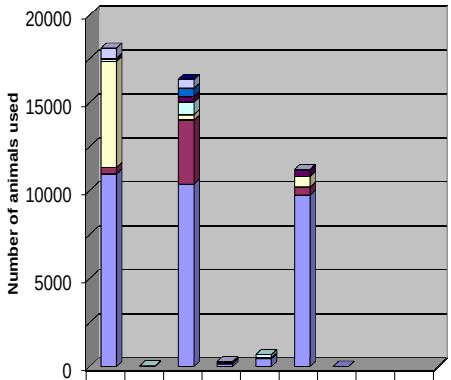
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	86	2		6	3	13			
Guinea Pig	2	21	13		6	18			
Rat	179	427	437	393	899	1148	1,230		
Mouse	2557	18256	5181	5499	10,634	32,96	74491		674913

Purpose: Research - Human or Animal Health & Welfare

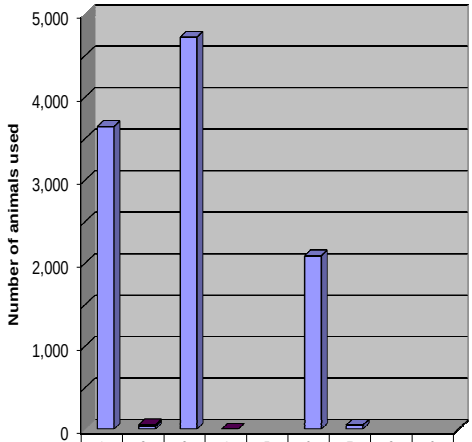
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other			17						
Dogs	567		492	29		27			
Cats	96		488	6					
Deer									
Goats			303			376			
Horses	92	3	712	71	169				
Pigs	6023	12	308		70	596			
Cattle	379		3638	10		453			
Sheep	10946	18	10378	161	445	9758	12		

Purpose: Research - Human or Animal Health & Welfare

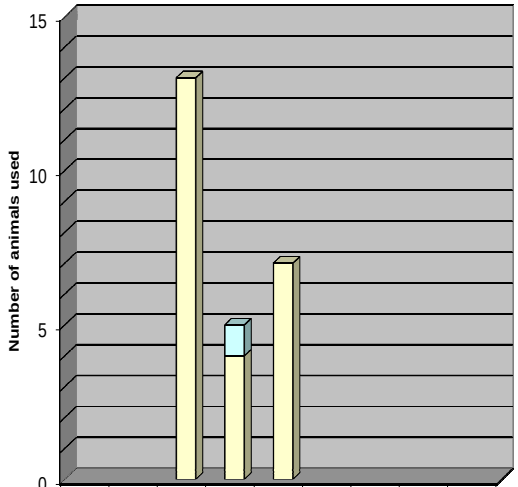
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild		20		1					
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry	3,646	33	4,723			2,090	50		

Purpose: Research - Human or Animal Health & Welfare

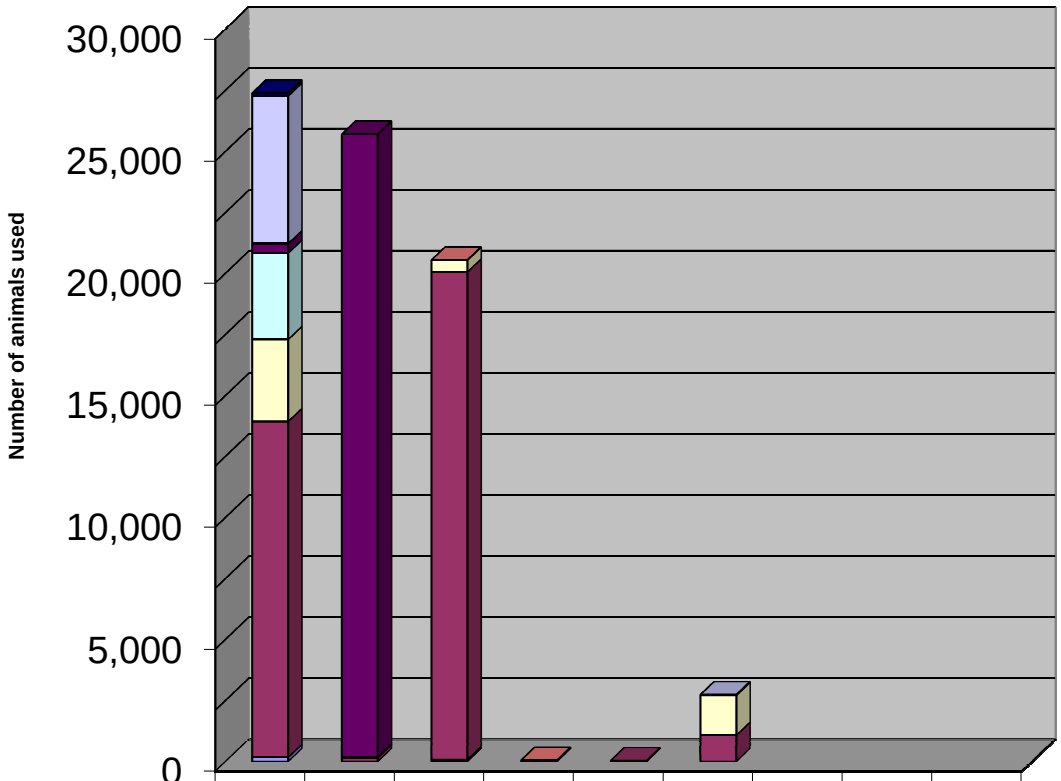
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other				1					
Baboons			13	4	7				
Macaques									
Marmosets									

Purpose: Research - Animal Management or Production

Research protocols which aim to produce improvements in domestic or captive animal management or production.



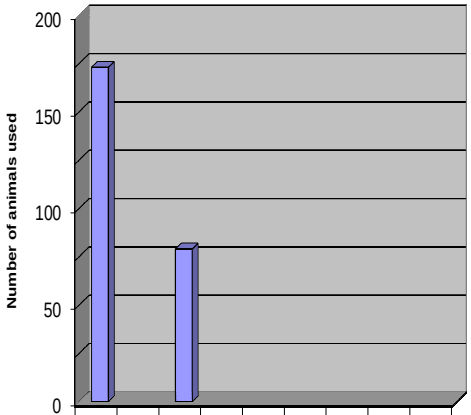
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	114								
Nat Mam	6041					23			
Primates									
Reptiles	27		2	1					
Amphibians	371	25500							
Aquatic	3531	27		35					
Birds	3355	12	479			1628			
Domestic	13765	158	19977	12	31	1081			
Lab Mam	173		79						

Procedure

Refer to following page for a further breakdown of species.

Purpose: Research - Animal Management or Production

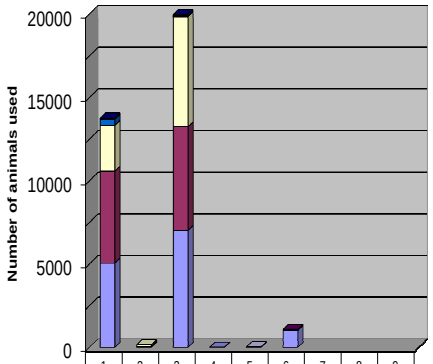
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat									
Mouse	173		79						

Purpose: Research - Animal Management or Production

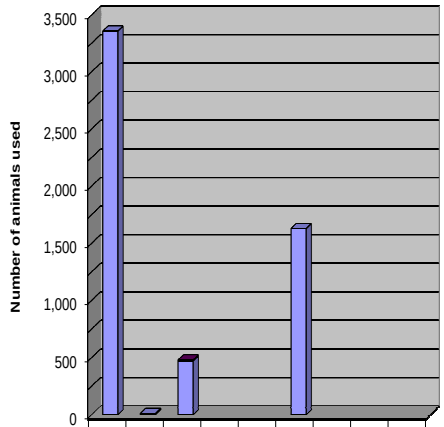
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other	56		41						
Dogs			4		27				
Cats	363								
Deer									
Goats			71			16			
Horses	12		8			6			
Pigs	2747	100	6597						
Cattle	5519		6221			36			
Sheep	5068	58	7035	12	4	1023			

Purpose: Research - Animal Management or Production

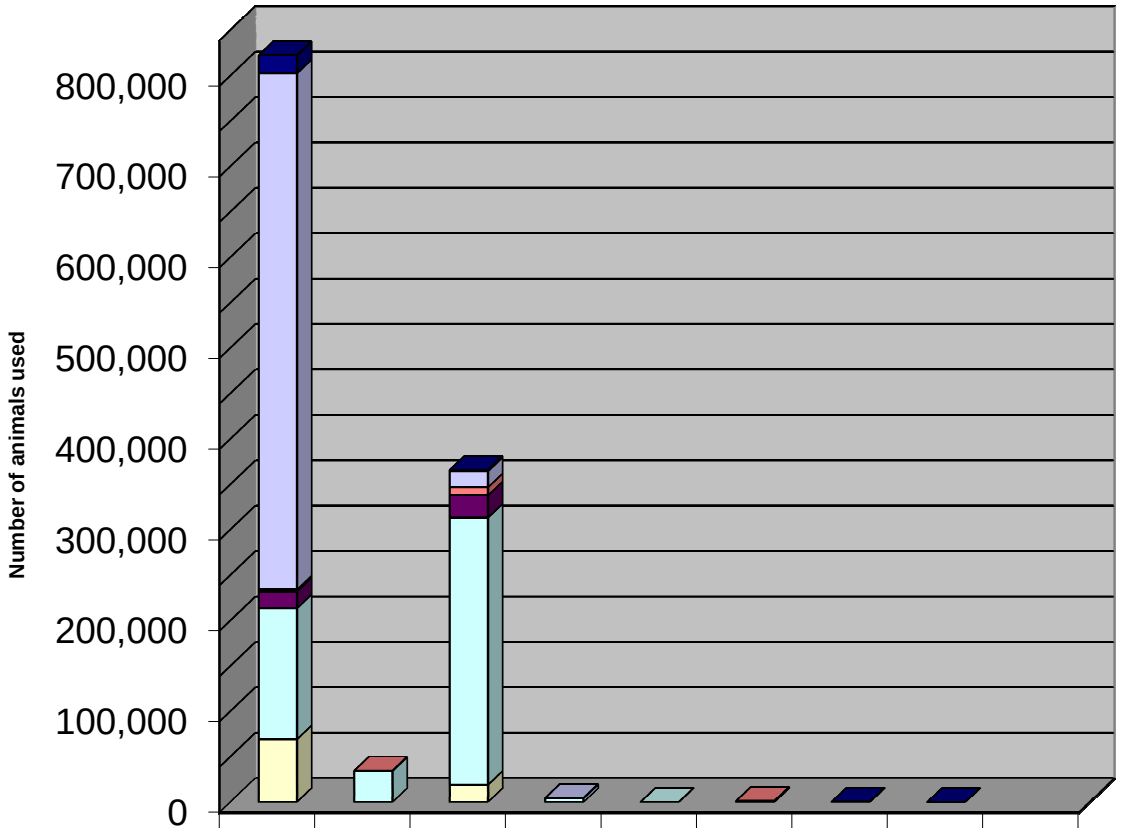
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild			9						
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry	3,355	12	470			1,628			

Purpose: Research - Environmental Study

Research protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations.



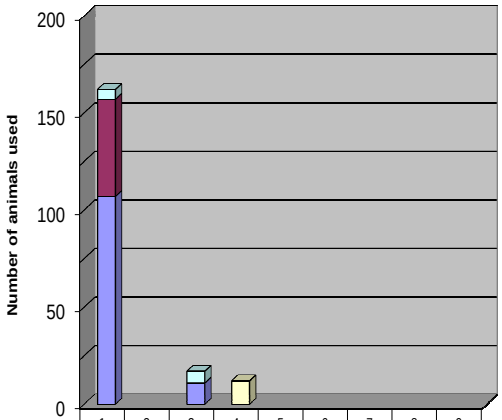
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	19733		1300				17	18	
Nat Mam	568502		17604	124					
Primates	1								
Reptiles	2152	4	8929			141			
Amphibians	18403	112	24819			84			
Aquatic	144296	34163	293985	4,338	141	1080			
Birds	68844	120	18895			73	379		
Domestic	233		220		4				
Lab Mam	162		17	12					

Procedure

Refer to following page for a further breakdown of species.

Purpose: Research - Environmental Study

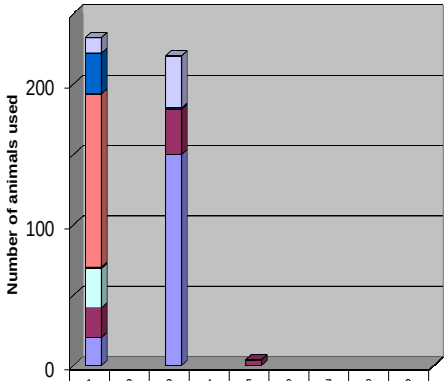
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	5		6						
Guinea Pig				12					
Rat	50								
Mouse	107		11						

Purpose: Research - Environment Study

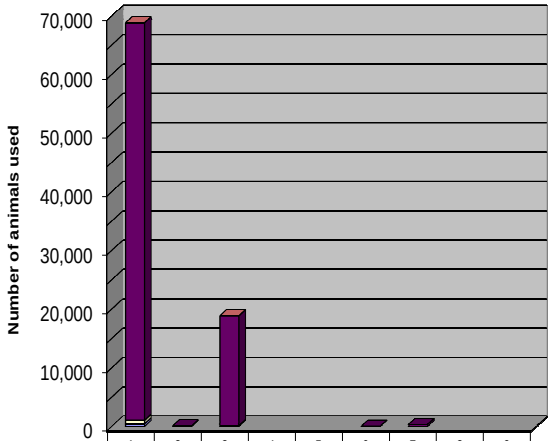
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	11		37						
Cats	29		1						
Deer	123								
Goats	1								
Horses	28								
Pigs									
Cattle	21		32		4				
Sheep	20		150						

Purpose: Research - Environment Study

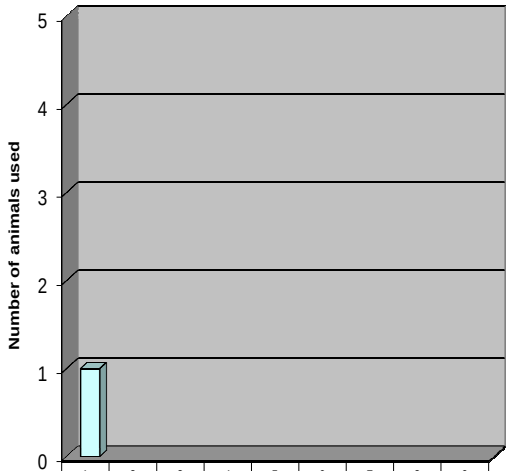
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other	1		6						
Native Wild	67,733	120	18,684			73	379		
Native Captive	33		101						
Exotic Wild	595		104						
Exotic Captive									
Poultry	482								

Purpose: Research - Environment Study

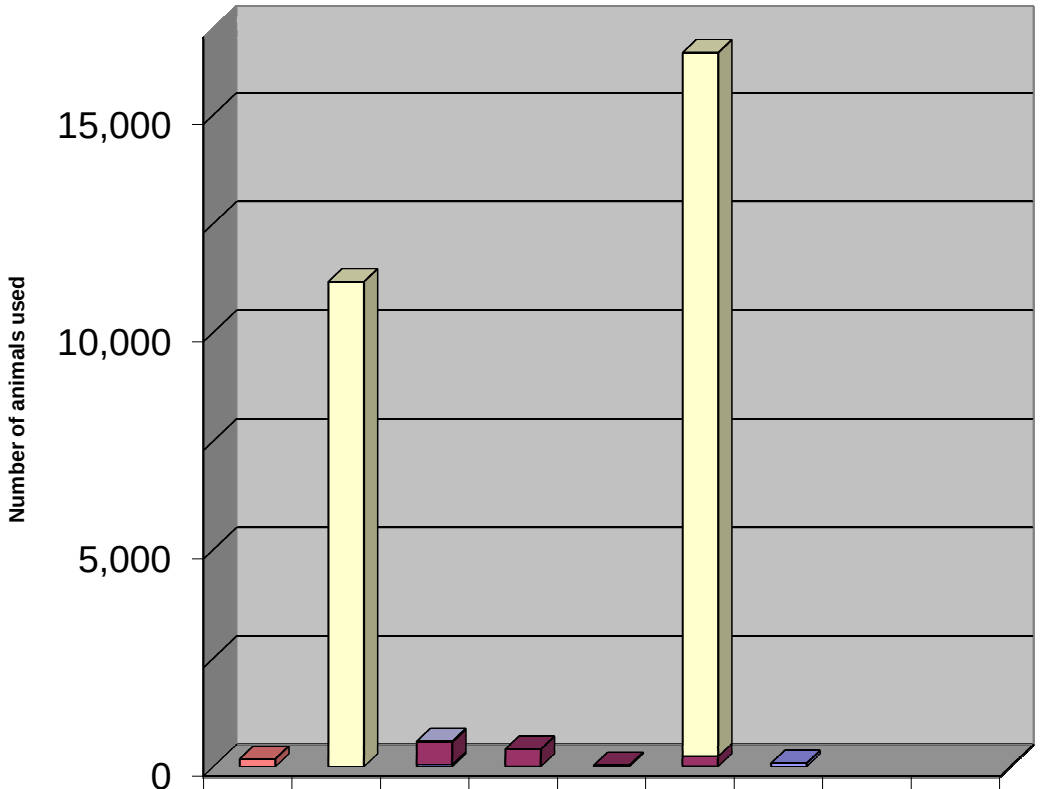
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other	1								
Baboons									
Macaques									
Marmosets									

Purpose: Production of Biological Products

Use of animals to produce products (other than normal milk/meat/egg, etc).



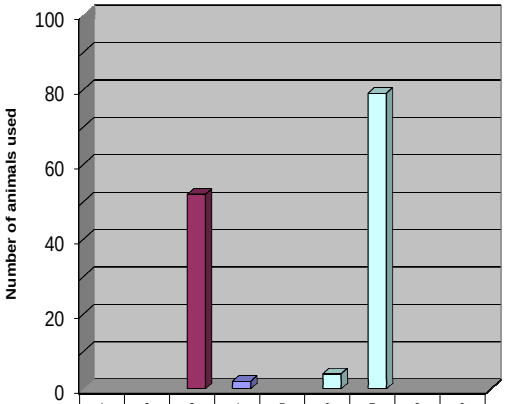
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam			6						
Primates									
Reptiles	180								
Amphibians									
Aquatic									
Birds		11161	15			16193			
Domestic			510	401	32	235			
Lab Mam			52	2		4	79		

Procedure

Refer to following page for a further breakdown of species.

Purpose: Production of Biological Products

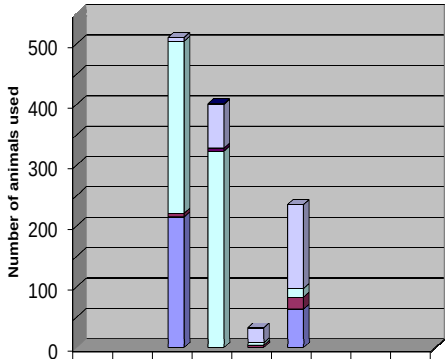
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit						4	79		
Guinea Pig									
Rat			52						
Mouse				2					

Purpose: Production of Biological Products

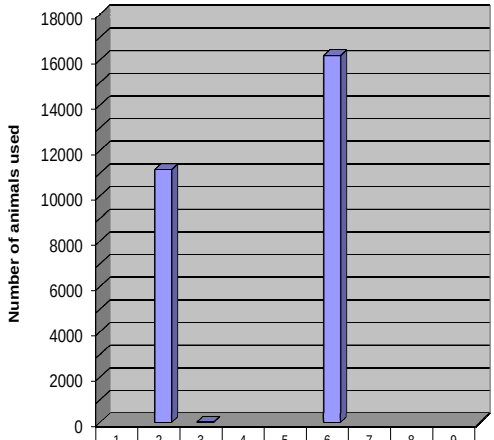
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other				1					
Dogs			6	72	24	138			
Cats									
Deer									
Goats				5					
Horses			283	323	4	14			
Pigs									
Cattle			6		4	20			
Sheep			215			63			

Purpose: Production of Biological Products

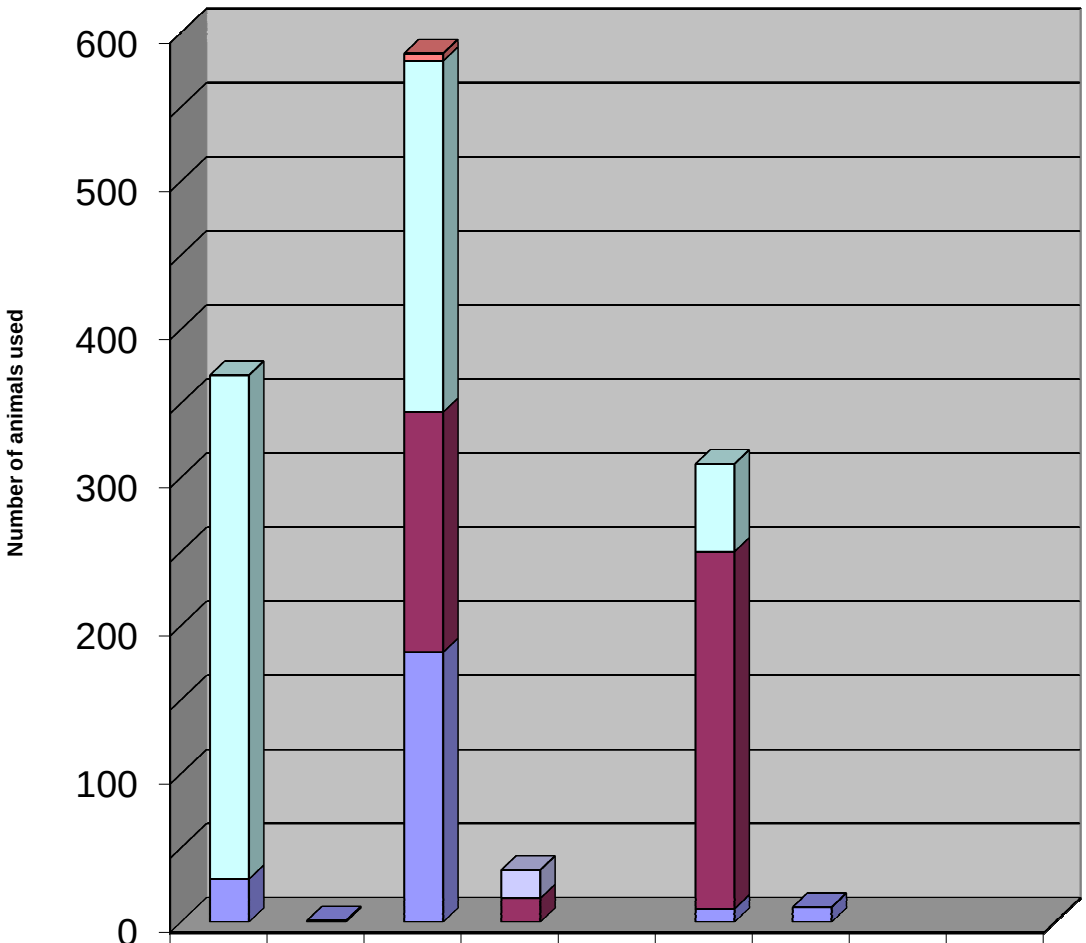
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild									
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry		11,161	15			16,193			

Purpose: Diagnostic Procedures

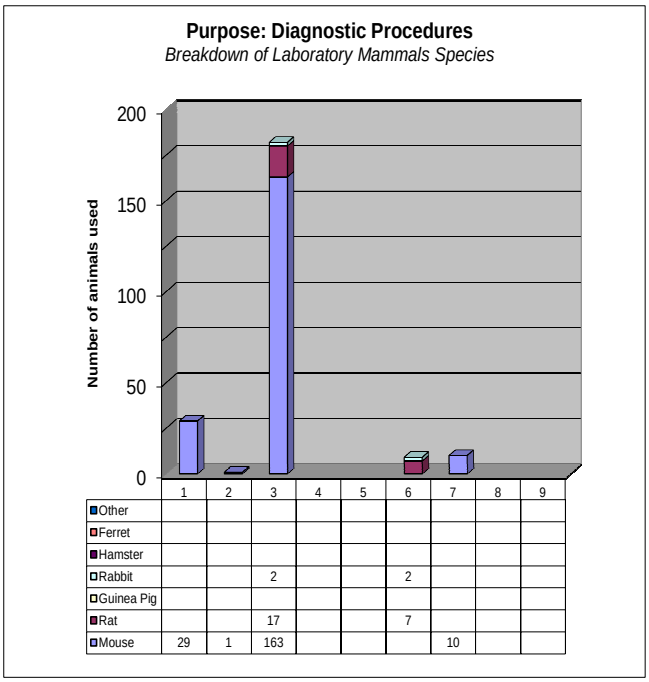
Using animals directly as part of a diagnostic process.

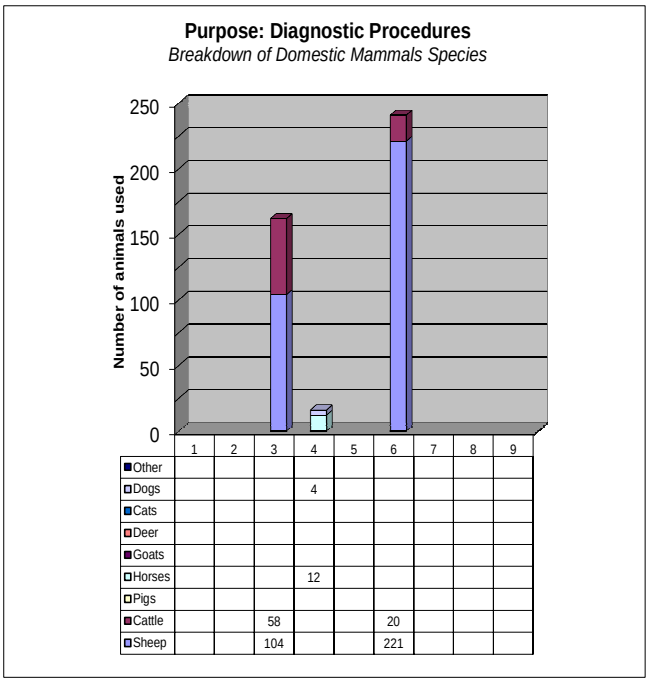


	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam				19					
Primates									
Reptiles			5						
Amphibians									
Aquatic	340		237			59			
Birds									
Domestic			162	16		241			
Lab Mam	29	1	182			9	10		

Procedure

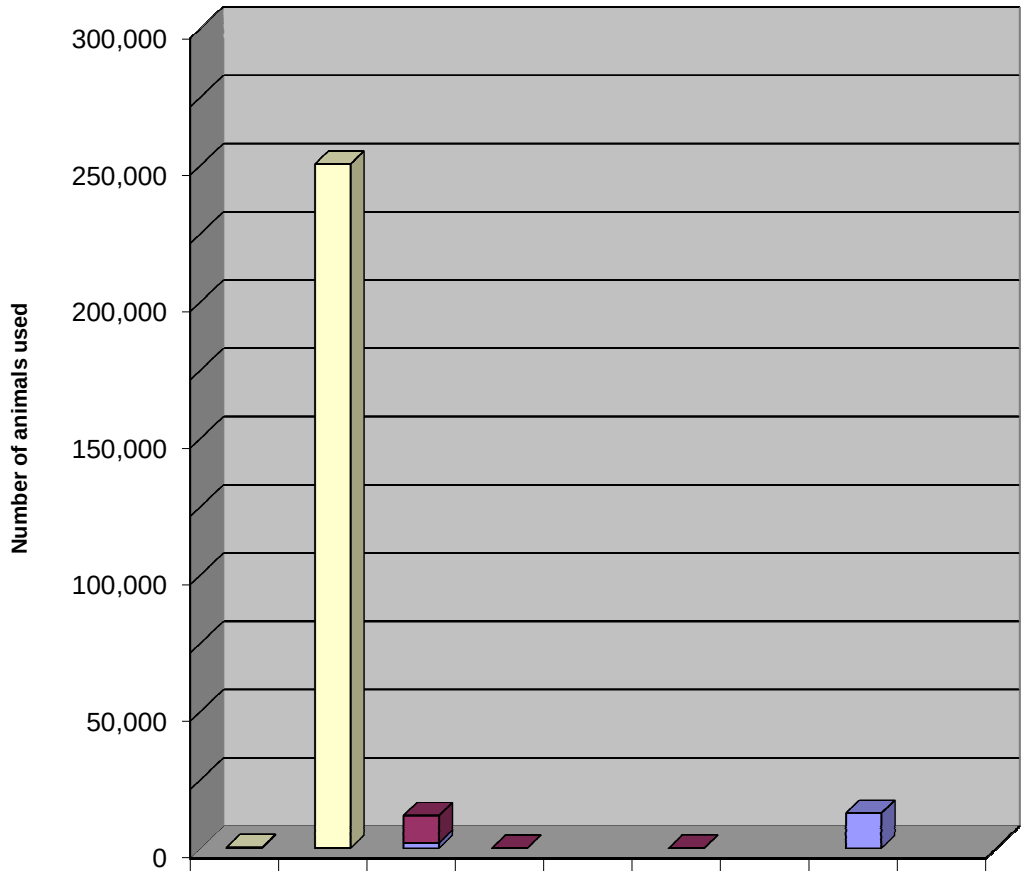
Refer to following page for a further breakdown of species.


Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species
Number of animals used
200
150
100
50
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 2 2
Guinea Pig
Rat 17 7
Mouse 29 1 163 10


Purpose: Diagnostic Procedures
Breakdown of Domestic Mammals Species
Number of animals used
250
200
150
100
50
0
1 2 3 4 5 6 7 8 9
Other
Dogs 4
Cats
Deer
Goats
Horses 12
Pigs
Cattle 58 20
Sheep 104 221

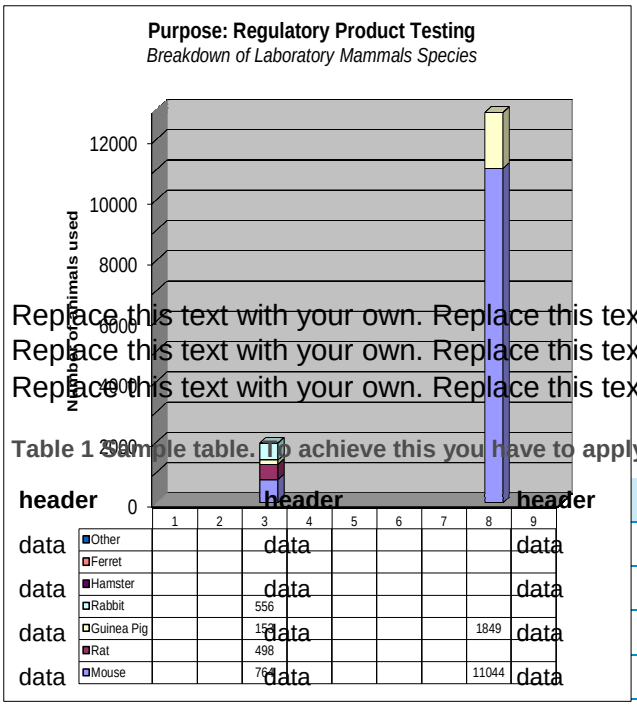
Purpose: Regulatory Product Testing

Protocols for the testing of products required by regulatory authorities.



	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam									
Primates									
Reptiles									
Amphibians									
Aquatic									
Birds	21	250540							
Domestic	286	60	10008	26		80			
Lab Mam			1971					12893	

Refer to following page for a further breakdown of species.



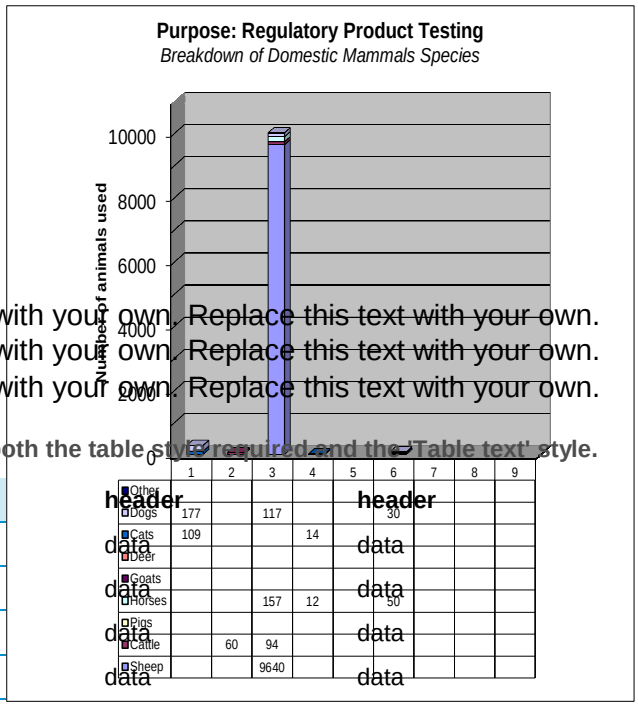


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Table 1 Sample table. To achieve this you have to apply both the table style required and the 'Table text' style.

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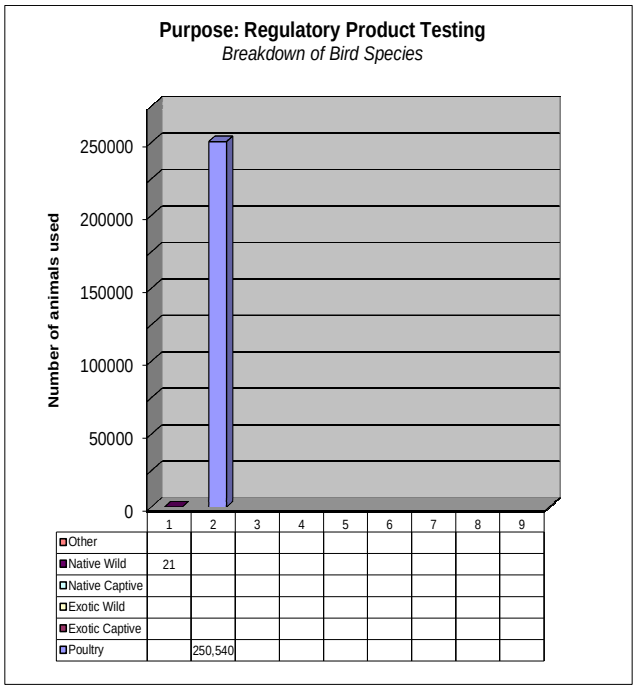

LETHALITY TESTING – 2014

The *Animal Research Act 1985* defines a 'lethality test' as *'an 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.

The following are the figures reported on animal use for lethality testing in 2014.

Species	Number used	Number died/ euthanased	Procedure	Justification	Alternatives
Guinea Pigs	1,752	392	Vaccinated animals are challenged with test organism in order to demonstrate protection and hence vaccine efficacy.	Assessment of in-process or development material to determine suitability for further manufacture.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release
Mice	1,671	822	L+ titration in mice: Susceptible animals are challenged with test toxin in order to determine potency of antigen preparation.	In-process testing of production and development antigen growths to allow stop/go decision during manufacturing process.	This test is based upon regulatory requirements for the assessment of in-process products. There are no alternatives available at this time however the establishment has embarked on a long-term program to develop *in vitro* assays which may be used to replace existing *in vivo* assays subject to regulatory approval of these replacement assays.
Mice	4,634	1,397	Serum neutralisation test in mice:	Regulatory testing required to demonstrate	This test is based upon

			Susceptible animals are challenged with test toxin/antibody dilutions to determine antibody titre.	efficacy (potency) of vaccines prior to release. Testing of stability batches and new product formulations.	regulatory guidelines. There are no alternatives available at this time however the establishment has embarked on a long-term program to develop *in vitro* assays which may be used to replace existing *in vivo* assays subject to regulatory approval of these replacement assays.
Mice	3,224	1,430	Total Combining Power test in mice: Susceptible animals are challenged with test antigen/toxin/antibody dilutions to determine potency of antigen preparations.	In-process testing of vaccine constituents to allow evaluation of suitability for further manufacture.	This test is based upon regulatory requirements for the assessment of in-process products. There are no alternatives available at this time however the establishment has embarked on a long-term program to develop *in vitro* assays which may be used to replace existing *in vivo* assays subject to regulatory approval of these replacement assays.

Mice	120	40	Challenge of vaccinated mice with target organisms to demonstrate efficacy of vaccine.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release.	No alternatives available at this time.
Feral goat *Capra hircus*	Unknown *Depends on attendance of free-living feral goats at a feeding structure where a toxic bait may be delivered*	1	Field trials using a variety of targeted feeding structures and non-lethal or lethal bait types.	Negative impacts associated with overabundant pest herbivore species are legally well accepted, with feral goats *Capra hircus* listed as a key threatening process under the Commonwealth *Environment Protection and Biodiversity Conservation Act 1999*. Additionally, herbivore and environment degradation caused by feral goats and deer are listed as Key Threatening Processes in New South Wales under Schedule 3 of the *Threatened Species Conservation Act 1995*. Despite these listings, control techniques for these species appear limited, particularly when compared to the number of techniques available for other pest species. Ongoing field trials continue to identify the potential for further development of a target selective, humane and cost efficient method as an additional technique for controlling overabundant herbivore pest species.	The purpose of this research is to devise a humane targeted method for killing free-living feral goats. There are no alternatives to lethality testing.
Mice (Mus musculus, strain C57BL/6L)	85	82	In order to assess the contribution of specific bacterial and host factors to disease,	The contribution of specific virulence factors to the pathogenesis of microbial pathogens can	No current alternatives exist, which effectively mimic

			virulence genes are essentially 'knocked-out' or their function inhibited, and this is then used to compare the virulence of the knock-out strain and the parental wild-type strain in an animal disease model. Moribund mice were euthanized. At the end of the 10 day experiment, all remaining mice were euthanized.	only be assessed in a live animal model of virulence. As mucosal and tissue barriers as well as a functioning immune system are required, these studies can only be conducted in live mammals ie mice.	the mucosal and tissue barriers as well as a functioning immune system observed in mammals.
Mice	2716	2361	Mice were infected with the rodent malaria parasite at the dose 1x103 infected red blood cells by intraperitoneal injection. Signs for disease develop between 7 to 10 days post inoculation. Mice which developed signs of severe anaemia (increase breathing) or neurological signs (fitting, coma) or which were unable to right themselves at physical checks three times daily were euthanized by cervical dislocation. Some animals die between checks. 355 Surviving animals are retained for breeding and genotyping.	Malaria is a disease that kills more than 1 million children annually. In endemic areas, some people die from malaria while others survive the infection. Unfortunately, we still know little about the mechanisms underlying the host resistance to malaria infection. In order to better understand this complex phenomenon, we have performed a largescale ENU (N-Ethyl-N-Nitrosourea) dominant mutagenesis screen for genes that when mutated, render normally susceptible mice resistant to malaria. From this screen we have discovered genes controlling haematological and immunological pathways that are novel determinants in the host response to malaria infection. The major goals of this project are to 1) determine the biological basis of the resistance causing mutations, and 2)	Unfortunately, there is no other existing model to replace the need to carry out the malaria infections in mice, although our group is utilising cutting-edge sequencing technologies and combination with other experiments to reduce the number of mice to infect with the malaria parasite.

				validate the genes as potential antimalarial targets.	
Mice	429	386	429 mice were infected with the rodent malaria parasite at the dose 1x103 infected red blood cells by intraperitoneal injection. Signs for disease develop between 7 to 10 days post inoculation. Mice which developed signs of severe anaemia (increase breathing) or neurological signs (fitting, coma) or which were unable to right themselves at physical checks three times daily were euthanized by cervical dislocation. Some animals die between checks. 43 Surviving animals were retained for breeding and genotyping.	This project aims to uncover why children in endemic areas die from malaria infection while other survive. Using a murine model of malarial infection, we are aiming to uncover the host genetics contribution to malaria resistance. Ten cohorts of mice were used to investigate the role of the red blood cell and platelets on resistance to malaria infection including cerebral malaria, We have found that the platelets play a crucial role to combat the infection and we in the process of determining the mechanisms of resistance to be able to translate our findings into a clinical practice. We have also found novel drug therapeutic targets throughout our experiments. 8 survivor mice were retained for breeding.	Unfortunately, there is no other existing model to replace the need to carry out the malaria infections in mice, although our group is utilising cutting-edge sequencing technologies and combining multiple experiments to reduce the number of mice to infect with the malaria parasite.
Mice	10	10	9 – Diagnostic	To identify the presence of algal toxins in portable water supplies that can be detrimental or dangerous to human health.	The establishment is actively seeking advice on a new method of testing that does not require the involvement of animals however, these methods are yet to be determined appropriate and in accordance

	with State and Water legislation.

Appendix H: Examples of methods used to implement the '3Rs'

The following are practical examples of strategies used to implement the '3Rs' (Replacement, Reduction and Refinement in animal use). These examples have all been reported by accredited establishments for the 2014 reporting year. They deal with 'Replacement' (of animals with other methods), 'Reduction' (in the number of animals used in specific protocols) and 'Refinement' (of techniques used to reduce the impact on animals).

Replacement, Reduction and Refinement
Introduction of co-joined cages (linked by tunnel to house two guinea pigs together in the one area (1800cm^2)
The establishment is still committed to the development of in-vitro testing to reduce the use of animals for our vaccine testing. A research scientist has made steady progress on this large project throughout 2014. Further to the *in-vitro* program, the AEC and Animal Services department has an on-going action to investigate whether several of our animal tests can be reduced and refined. We are in the process of determining whether we can eliminate the need for including additional rabbits on test, currently included in case any of them have to be removed from the study for any reason. The protocol for including 12 rabbits should be able to be reduced to 10 rabbits, saving 2 rabbits per test. The AEC also was responsible for a reduction in the number of guinea pigs used as part of the *C.chauvoei* challenge test. Previously extra control guinea pigs were used to determine the accuracy of the challenge dose. As this is now very stable these guinea pigs will no longer be used. In the case of refinement, we are also investigating whether vaccines containing the drug moxidectin can be tested on guinea pigs prior to the addition of moxidectin. This refinement would be beneficial to the guinea pigs because it is apparent that the moxidectin causes them to become lethargic and unwell for a few days post vaccination. The test is not being performed to evaluate the potency of moxidectin, so if the regulator agrees to the change then this would be a significant improvement to the welfare of the guinea pigs. The establishment is also considering the option of re-homing a small number of guinea pigs per year. The Animal Welfare League has offered to find homes for suitable guinea pigs and will manage the transportation and re-homing with the strictest of confidence. Suitable guinea pigs would only be those that go over weight according to the trial inclusion criteria, or ex-breeders who are no longer required to partake in the breeding program.
Reduction: Additional information of flystrike data collected on animals being used in the castration and tail docking experiment. Reduction in animal use with observations of flystrike on animals in a castration trial. Reduction: A reduction is achieved by using animals in a study to collect blood samples to supply a pool of serum for use as control samples in laboratory assays. This reduces the need to use additional animals for blood collection. Refinement: All the steers will be tested, then the steers with non-extreme temperament will then be selected for use in the experiment (n=36). The pre-selecting of steers with non-extreme temperament is considered a refinement. Refinement and Reduction: By adding a new on-sheep activity logger to the trial and using the

same sheep as the HOBO device is considered a reduction and refinement as this avoids the need for a separate trial using more animals to test activity logger (reduction), and also adds new data to the trial (refinement).

Refinement: Poplar twigs of about 5 cm diameter have been trialled as enrichment for the housed sheep. Leaves and side branches were removed to avoid change of and undue interference with the prescribed diet. The poplar stems have been mounted horizontally in head height with hinged clasps, allowing the manipulation and movement of the twigs. On follow-up inspection the sheep were observed to bite and move the twigs. Rate of acceptance and interaction was high, with all twigs showing signs of biting.

Reduction:

Control groups are shared whenever logistically possible and negative control groups are reused to reduce the number of chickens used.

Use surplus SPF males from the breeding farm for *Eimeria* oocyst production. The increased yields from these older surplus birds have reduced chick requirements by 2 to 10 times.

Refinement:

Monitoring system (DAS) installed in 2013 to monitor bird temperatures off site.

Increased scratching trays have been implemented along with more frequent changing of butcher's paper.

1. Accommodation of research horses in a large paddock on a professional horse spelling/pre-training farm.
2. Rehoming of retired research horses to suitable new owners.
3. Spontaneous collection of naturally voided urine for the purpose of drug analyses.
4. In-vitro simulation of the equine metabolism of designer anabolic steroids using horse liver.

Reduction and Replacement

The use of bioinformatics and cell lines minimised the number of rodents used under range of projects.

The retention of an advisor to the AEC on alternatives to animal use.

The launch of the Innovative Methods & Alternatives to Animals Research Unit.

The commissioning of a new optical imager and micro CT has reduced the number of rodents required in a number of studies; allowing the imaging of tumours at different time points rather than the dedication and sacrifice of multiple animals to every time point.

Refinement

Use of camera traps as a less invasive method of monitoring wildlife in the field.

Use of flexi cameras to ensure minimal disturbance of animals in hollows and next boxes.

Use of temperature microchips to assist in the identification of humane endpoints for rodents.

Use of hessian bags and ceramic roof tiles over treadle traps in the field minimises stress and exposure to weather during trapping.

- The number of animals has been optimised for the minimal number necessary to provide statistically significant results. By using the correct number of animals for a study reduces the need for replication and thereby reduces the overall number of animals used.

- The experimental protocol has built in safeguards to insure the comfort and health of the animal. In the experiments, the only instances of possible discomfort are the weekly hearing tests. Animals are anesthetized by a single IP injection of ketamine/xylazine, given eye lubricant to avoid keratitis, and placed on heating pad to maintain body temperature during the procedure. Recording sessions rarely last more than 90 minutes.

- Mice are deeply anesthetized for ear or brain surgery where the structure of interest is injected with a dye for tracing neural connections within the brain. Mice will be given adequate anaesthesia and analgesia, and monitored for signs of distress during and after surgery. Buprenorphine is administered SC upon completion of the tracer injection.

- The use of the same background strain of all knockout mice in our laboratory means that all knockouts can be compared to the same group of wild type animals. This reduces the number of wild type animals we need to study.

- We put our animals through an extensive phenotypic analysis of energy homeostasis, whereby several parameters of energy homeostasis are measured in the same mouse. Procedures are spaced over an interval of 4 weeks to allow recovery from each measurement. This reduces the number of animals we need to use in our experiments.

- We use analgesics after surgery, and local anaesthetic and mineral oil during tail blood sampling to reduce discomfort during the glucose or insulin tolerance tests. Mineral oil is used to reduce friction while we are milking the tail for blood.

- We will reduce the overall number of animals used by: conducting control cohort studies to compare responses in GM and non-GM C57BL/6 strains. If baseline responses are similar between these control groups we can eliminate the need for one of the control groups when using GM and non-GM lines. This approach has the potential make a substantial impact on usage. Furthermore we can contribute to reduction of institute animal usage by sharing access to tissues with other researchers.

- The injection of trypan blue into donor transplant females and our cell transplant experiments with retroviral gene expression. The injection of trypan blue allows us to visualise the epithelium in a live mammary gland so that we can guarantee that transplant has been successful in the host animal, therefore avoiding wasting of experimental animals.

- The mammary primary cell transplant with retroviral transgene expression allows us to investigate the effect of gene over-expression in the mammary gland without the generation of transgenic mice. Finally the use of mammary transplantation to produce many test glands from a single donor animal avoids producing a large breeding colony. This technique is particularly useful for rare genotypes, and greatly reduces animal usage in these cases.

- The training and skill of technicians is important in minimising stress on the animals. The work of the technicians is constantly being reviewed under regular checks made as part of the quality control programme.

- Grip strength meter testing should have no potential impact on the animals as it is a relatively non-invasive procedure. However, mice refusing to grip the bar or showing signs of

exhaustion or distress during the procedure will not be assessed further.

- Distress due to treadmill testing, may occur as evidenced by squealing or refusal to run further. Mice showing signs of distress will be removed from the treadmill and precluded from further assessment.

- The development of on-site DNA preparation of tissue for genotyping, the bar coded tracking of samples from collection through the genotyping process minimises the number of repeat samples required and minimises errors. Reducing errors in genotypes reduces unwanted breeding and wastage. Environmental enrichment such as the inclusion of domes and nesting material and well as the practice of minimising single housing promotes animal welfare.

- We only use animals where there is no alternative, but where necessary, animal experiments will be guided by replacement experiments, for example, in complex 2D and 3D tissue culture and the proposal for 3D-organotypic models (which are a vital component of this project). We currently tissue share and utilise shared samples to create 3D-organotypic assay to mimic in vivo condition whenever possible/appropriate for investigation. Utility of these intermediate 3D assays helps to inform in vivo investigation thereby minimising animal use at early stage of study.

- Rats are handled regularly, which should reduce stress at the time of performing the procedures. During the procedure animals will be handled for as little time as possible to reduce any unnecessary stress. We will collect several tissues (e.g. fat, liver, muscle) from the same animals to allow a reduction in the total number of animals needed for these studies

- Primary cell cultures will be used to test multiple stimuli and endpoint responses. This will ultimately reduce the numbers of animals used for experimentation. In addition, myoblasts will be stored in liquid nitrogen for ongoing use.

- We are using a BP-2000 Visitech System to perform blood pressure measurements. This setup is designed to minimize the stress level for animals. It is equipped with a heating plate to give the rats warmth which reduces stress and also facilitates tail vein bleeding (as blood flow is increased). Furthermore animals will be trained in undergoing the procedure as well as being gently handled. In order to shorten the time that rats will have to be restrained, rats will be pre-warmed with a heat lamp/pad before the procedure.

- Blood glucose level is determined by a glucometer reading. With the improved device which we have purchased, we are able to detect BGL with 1ul of blood versus 10ul with the previous device.

- In the time course study and wherever possible in the other studies, donor mice will donate adipose tissue to more than one recipient, in order to minimise the number of donors required.

- We have used C57Bl/6 in the past but C57Bl/6 females did not produce litters with large enough numbers of pups thus requiring us to use more pregnant female mice. We therefore

switched to using QS pregnant females that produce larger litters. This reduces the number of adult female mice we use.

- There is a small but consistent occurrence of vaginal malformations (vaginal septa and imperforate vagina) in the females of the C57Bl/6 strain, which is the predominant inbred strain in our facility. Our estimate across our colonies would be 2-7%, depending on the particular mouse line. We have incorporated into the training of new animal care staff, and regularly reinforce, that a check for these conditions should be a standard part of the welfare check of the animals and that no females that have obstructions of the vaginas be used in mating pairs. By this, we hope to avoid deaths of the mothers in birth (dystocia) or distress to females on mating. Mice introduced into the facility from other sources are also routinely checked for these conditions if they are to be used for breeding.

- We have optimised tissue culture methods to replace animal studies with in vitro studies. Pancreas perfusion method optimizes islet yield beyond simple pancreas removal and digestion. As in the past, efforts will be made to share tissues. Application of EMLA cream prior to tail bleeding.

- It has been suggested that a low (sub-anaesthetic) dose of MS-222 can reduce handling stress in fish so we will evaluate this in our facility. The aim of this pilot study is to determine whether luciferase and fluorescence based non-invasive imaging methods are a viable option for reducing the number of fish used in research.

- We will reduce the total amount of pain or stress caused to the animals by refining our surgical technique. After surgery we will provide one 2 oz cup of MediGel®CPF, a dietary supplement containing the NSAIDs carprofen (Rimyadyl), in this form it can be readily consumed to ensure an effective dose of 5mg/kg/day. Thus the mice can have access ad libitum to analgesics.

- We have implemented an optimised procedure for intraductal injections. Our original intraductal surgery involved opening the animal with a ‘Y incision on the ventral abdomen to examine and confirm the injection of cells through the mammary epithelium (with the injection into the nipples). The new technique does not involve the standard ventral Y incision and movement of skin back to see the mammary gland. Instead mice are shaved finely and carefully to allow good visibility through the skin and only the superficial tip of the nipple is removed to allow the injections. This technique has the following advantages to the previous technique:
    - No cutting or stretching of the skin
    - No glue or staples required
    - Less time under anaesthesia
    - Quicker recovery
    - Higher engraftment rate

- Whenever possible, in vivo imaging will be used to take serial measurements of tumour progression/regression. We will be using a xenogen IVIS device. In vivo imaging assists us in minimising the number of mice used by allowing the collection of large amounts of data from individual mice. Furthermore, the quantitative nature of the data reaches statistical significance faster than with non-quantitative measurements.

- We will use tissue culture models as much as possible to study the molecular basis of cancer

and treatment responsiveness. Use of a xenograft model reduces the number of mice needed to show an effect of drug treatment. Subcutaneous transplantation also generate a single tumour focus, whereas tumour susceptible GM mice can often generate multiple tumours.

- Provision of anaesthesia to minimise risk of injections into wrong spot during hCG injections in frogs. Provision of routine post-op analgesia and development of computer models and use of mammalian cell lines where possible to minimise use of animals

- Sub cutaneous injection of adjuvant will be used in order to reduce the discomfort to the animal associated with ip immunization. We will use wildtype mice generated through breeding of heterozygotes as controls whenever possible.

- We will group house or provide companion animals for mice whenever possible. All researchers are appropriately trained in animal handling techniques to ensure minimal distress. The studies are complemented by in vitro studies using primary human cells.

- The vast majority of methods in this project simply require the generation of embryos by natural breeding methods and therefore generate little or no stress to the animals. Furthermore, the use of zebrafish as a vertebrate model system can be defined as an act of replacement as the embryological and larval studies outlined in this project do not require interventions that would be necessary in mammalian species to gather and generate embryos. This is because zebrafish are externally fertilised and the fish will be bred by natural methods to produce embryos that can be collected outside the mother. In addition, embryos and larvae will be manipulated mostly before the free feeding stage, consistent with the notion of refinement. Use will also be made of ‘Fishnet” a virtual atlas of zebrafish development, accessible online, this reduces the need for histology studies of wildtype animals.

- Multi-modal analgesia will be used in all surgical procedures (ketoprofen and bupivacaine)

- Silicone gavage tubes will be used as these, combined with competent technique ensure no trauma to the oesophagus

- We have designed our experiments to minimise the number of animals. Although we are now obliged by necessity to perform breeding, which generates more animals than purchasing, we will use every animal possible within the bounds of the experimental design, and will stop breeding as soon as we have generated enough experimental animals. We also intend to use tissues from excess animals as extra samples in downstream validation experiments, so these animals will not be wasted.

- In order to reduce the number of rats for serum extraction we will use rats coming from neonate collection that in normal conditions would be culled without any further use. Using these rats for serum extraction will allow us to reduce the number of rats requested in this project. We will also reduce the number of animals by mating female rats again to produce further litter for harvest of neonatal cardiomyocytes.

- In mice colonies, the use of the recipient mother as sentinel for the rederived pups spares

the offspring from blood collection by tail nick for health screening.

- Use of a vasectomy procedure which accesses the vas deferens through an incision in the scrotal sac rather than laparotomy, which is likely to be less painful.

- Use of a subcutaneous implant to replace the ovariectomy procedure, which is less invasive.

- The use of a non-surgical embryo transfer procedure which does not require anaesthetic.

- Whenever possible mice used as studs and embryo donors for cryopreservation are to be sourced from stocks indicated as unusable by researchers. Although less efficient in terms of production of embryo number from females (older females don't produce high numbers of embryos), and optimal collection of mice (numbers of embryos with the desired genotype may accumulate more slowly), this avoids the need for extra breeding for this activity and gives a purpose to mice that have been unavoidably produced in breeding schemes, but aren't useful for experimental procedures.

- Stud males can be used for several purposes, such as timed mating for generating timed embryo stages, or for continuing the breeding of a line, as well as used for rederivation or cryopreservation purposes. This ensures the males have as much contact with females as possible and reduced the total number required.

- When mice are euthanased, tissues are halved and used for both flow cytometric and histological analysis and blood is collected after death for serum antibody analysis. Other tissues such as bone marrow or lymph nodes may be shared between researchers such that the maximum amount of data/information can be obtained from a single mouse. These procedures minimize the number of animals used.

Replacement:

- Use of audio-visual material such as videos, slides, interactive computer programs;
- Use of abattoir specimens and cadavers;
- Use of plant tissue as a replacement for animal tissue for certain enzymatic assays;
- Routine husbandry procedures to be performed on animals coordinated with teaching activities;
- Use of animals killed in road accidents.
- The use of differentiated stem cells rather than cells derived from primary cultures derived from animal tissue.

Refinement

- Improvements to animal housing and management;
- Training of researchers;
- Use of monitoring checklists to identify, action and report adverse events and the development of an adverse event form.
- The use of less invasive procedures e.g. sand pads rather than trapping.
- Use of an Observational Only - Field Research Form (No Trapping, Handling or Spotlighting).

Reduction

- Sharing of tissue among researchers;
- Obtaining more data from the use of fewer animals by combining objectives.

Close scrutiny of the numbers of animals requested in applications and progress reports to the Committee.

Refinement

Minimise movement and activity around the colonies as much as is practicable. Any activity that requires entry into or near the colony will be conducted in such a way that minimal stress and disturbance is caused to the birds.

1. Development of mailing list to better facilitate tissue sharing among researchers
2. Training of researchers in current best practise techniques
3. Use of models, e.g. Koken rat, for training
4. Transfer of excess animals from one project to another
5. Re-use of animals among multiple projects
6. Improved peri- and post- operative analgesia to reduce pain from surgery
7. Development of in vitro techniques to replace the use of animals.
8. Use of ex vivo assays to minimise adverse impact on animals.
9. Teaching projects utilise computer practicals to reduce the number of animals used.
10. Conduct pilot studies to ensure the least number of animals are used to obtain statistically valid data.
11. Use of modern trapping techniques and equipment to minimise potential for animal injury. Use of smaller, less invasive tags for identification.
12. Use of in vivo imaging technology to perform repeated measurements on the same animals over the course of an experiment, resulting in a significant reduction of animals used.
13. Increased awareness and use of environmental enrichment.
14. Experimental results used for computational modelling.
15. Combination of experiments so that only a single “control” group is used

Statistical analysis/justification to ensure only the minimum number of animals are used has become a requirement of every AEC application

A roof was built over one of the regularly used facilities to make the sheep yards all weather.

Reduction

For pen and field studies the APVMA guidelines stipulate the minimum number of animals per treatment group. This minimum was always the number used. Wherever possible in pen studies control groups were shared between studies to reduce the number of animals required.

We make available samples that are collected opportunistically (under AEC approval) from collection animals and wildlife under our care or that have died. Access to this important material reduces the need for additional interference with animals and has benefited many collaborative researchers through the years.

Reduction

- Increased emphasis on strategies to reduce animal numbers used in studies
- Use of pilot studies to reduce animal numbers
- Continuing to encourage researchers to share tissues.
- Feedback on study design to ensure studies are scientifically and statically valid
- Recommend to use of new scanning techniques in tumour development to track tumour development non-invasively, collect more data from the same animal therefore reduce the animal numbers
- Encouragement and use of cryopreservation technologies to freeze embryos/sperm so that fewer animals are required for genetic modification breeding programmes

Refinement

- Routine use of analgesic as a pain relief following surgical procedures
- Use of i-button to monitor temperature and humidity in animal cages
- Use of tamoxifen chow to replace multiple intraperitoneal injections to induce genetic modification
- Continuing emphasis on environmental enrichment such as red plastic houses for rodents and group housing to reduce stress Recommendation of smallest gauge of needle sizes where possible
- Use of appropriate anaesthetics to reduce stress and pain for collection of blood where possible and surgeries
- Continuing use of subcutaneous slow release pellets and/or osmotic pumps to replace multiple intraperitoneal injections
- Continuing use of pilot studies for new disease models to be performed under the observation of University Veterinarians before further experiments can proceed
- Continuing use of pilot studies and reporting to the AEC
- Refinement of humane endpoints – using a reduced clinical score on the Monitoring sheets with increased monitoring at a score of 1
- Use of imaging to develop humane endpoints for tumour progression
- Consider use of 14G needle to pass catheter instead of extensive blunt dissection

Replacement

- Recommendation of in vitro studies using scavenged tissues/organs from other experiments or abattoir before conducting studies on whole animals where possible
- Recommendation to use embryos, hatchlings or larval forms fish before they become capable of independent feeding for relative replacement instead of using whole animal as a model

The current application and annual reporting form for Animal Care and Ethics protocols seek explicit references to the 3 Rs. The above and meetings help identify examples of good practice in relation to 3 Rs. Included here are some examples from currently approved projects:

Refinement	**Reduction**
Only “circle” hooks have been used to minimise hook ingestion. In most cases this has worked. The use of Nets was avoided from the outset because of the negative impacts of this fishing method.	None – the minimum number of breeders is set by DPI to ensure sufficient genetic variation amongst progeny.
	An application for change of protocol was submitted and approved by ACEC in 2014. The proposed change was to maximise the outcomes of the research while minimising the number of animals used. This was achieved by combining the control groups of the two studies that spared 16 mice. The success rate in developing type 2

	diabetes by high fat diet in this round of study was higher than before. Therefore additional 24 diabetic mice were used to carry out a further intervention trial in Study Two (with samples obtained 48 hours after the intervention).
Most often, bat boxes were monitored from the ground by shining a torch into the open bottom box designs or using a pole camera for closed bottom designs. This reduced the need to handle bats.	
We are now using infra-red cameras extensively to conduct surveys. We have replaced the use of cage traps with cameras on the student field survey. We are using cameras to conduct more widespread surveys for long-nosed potoroos.	I have not reduced the number "used" but the greater reliance on cameras has reduced the number of medium-sized mammals physically captured and handled.
Survey methods such as 'call play-back' are used where applicable. This is a recognised fauna survey technique that, when undertaken according to recommended guidelines, has minimal disruption on native fauna in the survey area.	
There was significant refinement in the process prior to killing to ensure the fish were completely anaesthetised and did not suffer. Time out of the water, prior to killing, was also minimised to reduce any stress. Fish were handled carefully and with knotless nets.	

Reduction:

- Within the CLiK Knockdown project, two separate studies were initially planned (32 sheep per study), but these were combined into one study (48 sheep in total). By avoiding the replication of two treatment groups this reduced the total number of sheep by 16.
- New method for collecting fluke eggs has been established, instead of euthanasing sheep to collect the fluke eggs they are sieved from the faeces.

Refinement:

- During a fish study of 288 fish the number of fish bled per group was reduced to 12 out of 18 in each group as it was deemed they would have enough samples without bleeding all fish.

Replacement: Wherever possible, researchers must utilise all methods that obviate the need to use animals including literature searchers to ensure what they intend to do is not unnecessarily

repeating work already undertaken elsewhere. The Committee encourages the use of animal tissues (where suitable) derived from animals euthanased in other projects to establish suitability and technique preliminary to considering full animals studies eg the use of eyes removed from mice humanely killed from other protocols to study retinal cell collection technique.

Reduction: Detailed experimental design utilising the expertise of a bio-statistician to ensure the appropriate number of animals are used to provide sufficient power to achieve the stated objectives is encouraged by the AEC.

Careful planning to only breed sufficient animals to supply research studies and to maintain breeding colonies or source animals as required from external suppliers.

Refinement: The care and wellbeing of all animals held for research (and teaching) purposes is paramount and all efforts to minimise distress and suffering and provide a suitable environment with appropriate enrichment is advocated by the AEC. Close monitoring of animals is essential for the early detection of pain and suffering post procedure and researchers must initiate appropriate treatment to alleviate or minimise suffering.

The protocol was amended to include an extra treatment group, thereby replacing the need to conduct two separate studies and reducing the number of dogs used.

A submission was made to the APVMA on the proposed Preamble for the WAAVP guidelines in respect of efficacy testing of acaricides for paralysis ticks contesting that a) two studies were required and b) ‘an adequate number of treated and control animals are necessary for each study and group sizes should be justified’, arguing that an arbitrary number could encourage sponsors to commence studies with more animals than is needed to demonstrate statistical significance. The arguments were not accepted.

The number of dogs used for a project was reduced to 16 following reassessment of the protocol. 27 dogs had been approved in the ARA application.

SOP Blood Collection-Dogs and Cats were revised to include sections 4.6 Volumes and section 4.5 Animal Wellbeing, referencing NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes (2008), in University of Newcastle ACEC guidelines on Blood Collection in Animals-Methodology (2012) and with input from the AEC.

A Canine and Feline Environmental Enrichment plan has been developed and was approved in August.

The new entomology lab will be equipped to conduct *in vitro* trials of compounds prior to *in vivo* testing and conduct acaricide/pesticide monitoring programs.

New and improved technology has continued to be developed during the year, in an attempt to improve the efficiency of stored serum processing to hopefully reduce the numbers of animals used in the production process.

An example of refinement includes: The operation of the backpack electrofisher only by highly trained and experienced researchers. The researcher involved has over 3 years of professional experience using this method. Also, in order to avoid any risk to non-target vertebrates, if any of these are seen in the sampling reach, electrofishing will cease until the area is clear of non-target animals.

In terms of reduction, the number of fish identified, temporarily held, and returned to the stream is dependent upon both the abundance of fish at the survey sites, and the degree of fishing effort that is required to determine (with a certain level of statistical confidence) the species present

and their relative abundance. To minimise the impact of the research on fish, no more than the necessary degree of fishing effort to achieve robust results will be used.

- A protocol investigating human biology is using the minimal number of mice possible according to statistical analysis to provide significance during parameter comparison according to data in their previous study using this model. The researchers noted that they had refined the model based on previous studies.
- Researchers conducting an assessment of the population status of a protected seahorse species are returning the seahorses to their natural habitat and are using existing survey methods.
- Researchers used power calculations using data from similar studies and to use the minimal number of animals to produce statistical significance in this model. Brains were divided for different procedures, halving the number of rats used. The researchers used the smallest injury parameters that provide a demonstrable brain injury as measured on several outcome measures, to ensure the least dysfunction to the rats.
- Researchers aiming to develop compassionate approaches to coexisting with kangaroos in rural landscapes are using the minimum subset of individual kangaroos will be identified with tags /collars, in order to describe movements of groups of animals and individuals within the study area. Capture by darting and sedation for fitting of collars (auto -release at 6 weeks) and WID tags provide minimum interventions, for high returns on data (defining home - ranges and movements), with study longevity and strategic management outcomes.
- Researchers conducting a project aiming to determine whether a peptide causes the general suppression of mammalian immune responses are using the number of mice based on industry standards for this established assay to assess immune functionality. This protocol will involve the intraperitoneal delivery of either a parasite peptide or KLH antigen, both of which are non -toxic and not expected to induce any side effects, thus ensuring minimal suffering to animals.
- In a study about asthma onset and progression, the researchers have kept the mouse group sizes to eight mice per group. They have observed a low degree of variation in their models and these small numbers have allowed them to obtain statistical significance previously. They have included a wildtype group in every experiment so that the data is always paired (there can be some small variation in responses between experiments that arise from different batches of allergen for instance, although these do not affect the overall phenotype). In this project they have only included one group of wildtype mice to reduce animal use. They have selected the strains with lack of specific pattern recognition receptors related to the cause of allergic asthma. They are also using the current best practice for all of our experimental procedures
- In a project aiming to cultivate the leishmania parasite, the researchers have included Centers for Disease Control (CDC) insect traps to potentially increase their insect catch without having to rely on direct aspiration of insects from kangaroos and wallabies. This means that they can reduce the contact with these animals by relying on traps. Using only hand raised and captive animals means that the researchers have selected a group that is used to human contact and will not be placed under stress by their presence. They operate with the park rangers close by. The animals are familiar with the rangers who care for them daily. Their presence is likely to keep the animals calm while the researchers work.
- A project measuring aspects of water bodies found in urban situations and identifying what frog species live there are using call surveys (playback calls) instead of frog capture surveys. This eliminates any potential physical harm that could come from frog capturing and greatly reduces stress.
- The researchers are conducting observations of detector dog behaviour which takes place during normal police dog training hours and does not exceed their normal workload. The use of several blood detection dog teams reduces the work and time required for each animal. To minimise stress the training takes place at their respective training units where the dogs are accustomed to the training environment. The researchers are not directly interacting with the dogs to reduce stress to the dogs.

- In a project about obesity, power calculations have been undertaken using data from similar studies. The researchers are using the minimal number of mice to achieve statistical significance in this model. All the tissues will be divided for different procedures, reducing the number of animals used.
- In this project, researchers are evaluating the effects of warmer water temperatures on the metabolic and behavioural ecology of seahorses. Replacement is not possible as this project directly assesses impacts on the seahorses and how this species may respond to environmental warming. The minimum number of animals required for sufficient statistical analysis has been utilised. The researchers collaborated with other researchers who have conducted similar studies to implement further refinements were possible.
- This research involves the observation of dingoes. The researcher is working in collaboration with zoo keepers, dingo handlers, rangers and experts to minimise impact on dingoes and to guide her in the research.
- The researcher is conducting observations of White -Cheeked Honeyeaters and is setting cameras up outside of peak feeding times with no human interference. The ladder and camera units are conspicuous to avoid collisions. The ladder is also weighted down to avoid potential falling from wind.
- In a project investigating whether Mosquitofish and nutrients affect algal blooms, the researchers are using minimal numbers possible to ensure fish remain present for the duration of the experiment. The animals will be housed in experimental pond ecosystems. The experimental ponds are designed to replicate natural ecosystems as closely as possible.
- The researchers are determining the potency and duration of the anti -inflammatory effect of a specific protein. The preliminary work to get to this stage of the research was conducted using cell lines, but the researchers now need to test the peptide against a complete inflammatory response which can only occur in vivo. They have chosen the group number (n=10) mice based on recommendations by the pharmaceutical industry. By using this number the researchers will have sufficient data from one experiment and will not require repeating any analysis.
- Researchers investigating continuous maternal cigarette smoke exposure promoting the development of allergic sensitisation and the subsequent development of asthmatic features are using power calculations, using data from a previous study using the same maternal cigarette smoke exposure model . The researchers will use the minimal number of animals to allow the identification of statistically significant changes in this model. Additionally, the left and right lungs will be used for different procedures (histology and mRNA assays) in randomly, halving the number of animals used.
- In a teaching protocol on cell fractionation, the researchers have reduced the number of animals used from 4 per class of 40 students to 2 per practical class. This is the minimum number of animals needed to provide sufficient liver material for the class to adequately perform their experiment.
- Researchers aiming to identify the cause of the inflammation in the airways have kept their group sizes to eight mice per group. They have observed a low degree of variation in their models and these small numbers have allowed them to obtain statistical significance previously. Mice will be anesthetized to minimize struggling and sneezing during the intranasal routes of delivery. Volumes administered via the intranasal route are small compared with those of other routes (20 -60 µl); this is to minimize the potential for suffocation and death.
- Researchers developing simple habitat enhancements for wharf pontoons to increase the recruitment of estuarine fishes are using the minimum number of experimental and control reefs necessary to test the hypotheses.
- In a project developing a mouse specific species of Cryptosporidium and producing a range of phenotypically defined strains whose genome will be characterised, the initial determination of purity and application of genetic characterisation will be used to determine the level of polymorphism within the parasites populations. This will help reduce the number of isolations attempted.

Research in NSW involves

(i) Collection of blood samples from dogs in NSW that are being sampled for other purposes associated with active Veterinary cases.
(ii) Collection of blood samples from Koalas presenting to the Koala Hospital in NSW as a result of illness or trauma. Samples are collected under anaesthesia and only if the treating Veterinarian considers that there is no foreseeable negative impact on the animal.
(iii) Collection of biopsy samples from that fish that are being caught as by-catch by commercial fishermen
(iv) Observation of rabbit culls in NSW to audit the process and provide recommendations to improve animal welfare.

Replacement

- Pegs used to simulate fingerlings when teaching fish counting and bagging techniques
- Use of heads of sheep, cattle, goats and pigs, sourced from abattoirs, for use in training of humane destruction of animals.
- Faux fur remnants used to practise clipping.
- Use of legs from horse carcasses sourced from local abattoirs for use in shoeing and/or hoof health.
- Mannequins, audio-visual materials, taxidermised and preserved specimens were used as substitutes for live animals where the learning outcomes were able to be met by substitute means.
- Ear-tagging of sheep was practised on cardboard and leather.
- Injection pads were used to practise medication injection for a range of species.
- Replicating blood sampling using cat catheters, sponges and red cordial.
- Computer simulated racing and mechanical horse for horse riding and racing training.

Refinement

- During shearing training the learner shearer begins by shearing only part of the sheep, with the professional shearer completing the task, to reduce handling time, injury and stress.
- Horses are monitored for behavioural changes and replaced regularly. Horse usage is rotated to prevent overuse.
- Instruction to students on their obligations and responsibilities with regard to animal welfare during enrolment/induction period. Students are required to provide written acknowledgement of their understanding.
- Using treats as substitution for medication.
- Prior to field work activities, students were familiarised with both the animals and the research techniques to be used. This included visits to zoos, aquaria and museums, demonstrations of the use of equipment and DVDs showing the use of research methods. Actual field work was kept to a minimum.
- Reduction of lamp size to less intense light; use of red light covers for spotlighting activities.
- For native animals, handling is conducted by the licensed person only, with students observing the techniques.

Reduction

- Simulated penning of sheep by demonstration.
- Use of ultrasound equipment to capture images (cattle) for replay to students.
- Keeping a minimum number of animals on campus required to simulate a mini colony.
- The number of occasions that an animal is handled was minimised, eg lambs are tagged and drenched at the same time to avoid having to re-capture.
- Undertaking research activities in association with another organisation eg university,

National Parks and Wildlife, rather than conducting additional activity for the same purpose.
- Timetabling of classes is coordinated so that activities are spread over the semester, to avoid over-use of the same animal.
- Appropriate animal to student ratio.

Examples of reduction

1 Using soiled bedding sentinels instead of contact sentinels for health monitoring.
2 Alternately testing pooled faecal samples (non-lethal) and serology (terminal bleed) for health testing instead of culling animals at every time point.
3 Projects without specific breed requirements were able to use excess mice from a breeding colony instead of ordering in mice from external suppliers.

- Continued use of remote controlled infrared digital cameras and acoustic recording devices instead of, or in addition to, trapping to detect species presence or absence.
- Phasing out of toe clipping in small mammals.
- Trial of unmanned aerial drones for conducting waterbird surveys rather than manned aircraft (noise) or foot-based surveys (disturbance to habitat).
- Use of secure outdoor enclosures furnished with native habitat for rearing endangered frogs in the location of their natural range instead of the artificial environment of indoor tanks at a breeding facility.

Replacement of Animals:

The establishment has been developing *in vitro* assays to replace *in vivo* assays that require animal use. In 2014, research scientists developed and validated an *in vitro* assay for the measurement of neutralising antibodies to *Cl.septicum* toxin. This effort has saved more than 11,000 mice otherwise used in those assays.

Reduction and Refinement of Animal Use:

1. Project teams consist of scientists, biometrician, veterinarians and regulatory colleagues who will perform rigorous assessment of each and every clinical and laboratory study to ensure the study designs are scientifically sound, animal use justified and animal numbers are adequately powered. Justification of animals use and number of animal use ate one of the essential requirements of the study protocols. Biometrician always involved in the power calculation of the study to determine the appropriate animal number for each study to ensure the study design archives desired outcomes and avoid repetition of studies due to lack of power.
2. The establishment has recently developed an intradermal challenge model for erysipelas in pigs in which multi strains were tested on single pig without causing extra distress or pain to the animals. This helps a 4-fold reduction in animal numbers compared to the traditional challenge models which require single injection/strain/pig. This refined challenge model will be used in future vaccine efficacy trials.
3. Another approach is refine and reduce animal numbers in a study is maximise the use of negative controls within the other treatment groups without impacting the scientific outcomes. For example when efficacy of two vaccines is assessed in a study, one vaccine control group will serve as a negative for the second vaccine group and vice versa. Similar approach was used in the Eryvac potency assays that saved 128 mice otherwise required for the assay in 2014.
4. As an R&D organisation one of the establishment's core cultures is to implement '3'R practices. Recognition is via an annual Global awards and in 2014, one of the research teams was awarded a 3R award in recognition for the development an *in vitro* assay.

- Minimum animal numbers have been used in all projects.
- Animals are re-used where possible. In particular many animals euthanized after reaching a pre-determined study end point have had tissues taken for histological studies different to the primary study in which the animals was used. Cadavers are kept frozen/formalin preserved

for 1-2months following euthanasia for the opportunity to re-use the animals for histological studies.
- Cryopreservation (sperm storage) of knock-out mice in each breeding colony was implemented in 2014 to secure lines in case of breeding difficulties, disease outbreak or emergency/disaster (eg fire etc) and allows reduced numbers to be kept.

Example of replacement

- Use of computer simulation in a teaching subject in place of rats and cats
- Use of museum specimens in practicals
- Use of deceased feral birds in a teaching subject and existing fur pelts for heat transference models

Examples of techniques adopted to refine procedures

- Use of remote underwater video instead of trapping and releasing fish as a less intrusive research method
- Use of pilot studies to refine techniques before large numbers of animals are used.
- Rehoming of 30 Australian Bass from a protocol.

Examples of techniques adopted to reduce the number of animals used

- The practice of sharing tissue from deceased rats and mice with other researchers eg blood, skin, brains, lenses, livers and hearts
- Transfer of unused animals between protocols instead of order additional animals
- Training protocol makes use of excess rats and mice that have not been used for experiments and that would otherwise be euthanased to train researchers in various technique, thus minimising number of animals required in their research applications and providing Certificates of Competency

It is a prerequisite for all applications to address the 3Rs as part of tier AEC application and for the AEC to specifically review theses parts of the application. This process resulted in the identification of a number of improvements for animal welfare and usage through replacement, reduction and refinement.

Reduction:

- The establishment maintains and whenever possible generates a tissue bank, so that tissues not required for immediate use, can be preserved for future.
- Where animals are used in teaching, animals will be allocated to small groups of students rather than to individual students.
- When designing a project investigators often refer to previous or similar studies to ensure that work is not being unnecessarily duplicated.
- A pilot study is often employed by an investigator before proceeding further.
- Investigators seek the advice of a biostatistician where appropriate.
- Experiments are sometimes run in parallel using just one control group.
- Pooling of samples is undertaken whenever possible.
- Animals on campus are overseen by a central breeding and management system.

Refinement:

- Refinement of experiments is based on previous experiments and research outcomes.
- The capture of native animals and aquatic life is always undertaken with minimal interference to the animals. Animals are released as soon as data has been collected, at the point of capture, and at a time when environmental conditions are most suited.
- All procedures are carried out by competent, qualified technicians or experienced investigators/staff, following AEC-approved SOPs and industry best practice.
- Inexperienced personnel work under the direct supervision of experienced personnel until

competent.
- The use of timed release mechanisms on GPS collars removes the need for recapturing animals in wildlife studies.
- Pitfall traps are provided with shelter materials (sand, leaf litter, cloth and PVC piping) for animals awaiting release. Traps are checked early each morning and each evening to avoid animals spending more time than necessary in captivity.
- Insect surface sprays are used around pitfall traps to reduce possible irritation from ants, for example.
- A number of experiments have been designed to measure physiological parameters employing minimal handling of animals, while others are purely observational.
- Where appropriate, animal behaviour is captured using motion detection cameras placed at a distance so as not to disturb animals.
- Exposure times for testing behavioural responses in experiments are limited to as short a time as possible.
- Attention is paid to good housing, care, feeding, handling, transport, and monitoring of each species at all times.
- Wherever possible, social isolation of animals undergoing experimentation is avoided
- Proper attention is paid to monitoring for all procedures.
- The AEC always tries to ensure that projects are designed to reduce the need for repeat procedures, and stress on animals.
- Data loggers for data collection to avoid strict confinement of animals.
- Use of captive wildlife is preferred to use of wild specimens as they are accustomed to human presence.
- Invasive techniques are revised as new information becomes available.

Replacement:

- Studies are co-ordinated where possible to enable the sharing of tissues and surplus animals by other investigators or as a teaching resource.
- Conducting a pilot study has proved to be helpful before moving to larger scale experiments.
- Undertaking observational studies rather than capturing animals has proved useful in a number of instances.
- Similarly implanted tracking devices have assisted in wildlife studies.
- Where applicable in vitro studies are used. Results from previous studies are used to reduce the number of animals required for some experiments.
- Animals are used in conjunction with, and complemented by, computer simulations. Video recording of the experiment or behaviour for future use.

Researchers are required to apply the 3Rs (replacement, reduction and refinement) at all stages of their research. Some researchers report on field work that involves mainly observation and low impact to animals within the study. Where research involves housing animals and performing procedures, researchers report the use of extensive in vitro experiments prior to the use of animal models, conducting power analyses to identify the least amount of animals required for experimentation to achieve statistical power, the use of highly skilled personnel and housing of animals in a safe, stress free environment where they can socialise. Animals are provided with clean food and water as well as environmental enrichment. Any procedures performed on the animals are conducted away from other animals to minimise any distress, and strategies addressing the minimisation of pain are incorporated into protocols reviewed by the AEC.

Following is a list of specific examples of strategies to address the 3R's reported by researchers this year:

Reduction

- Use of a contralateral ear in the animal as a control. This halved the number of animals

needed for this type of study. By synchronising breeding and infection experiments, we had been able to reduce the number of mice that had been predicted by more than 24.
- To reduce numbers the unsampled animals from the initial pair maintained as the cage mate for the new sentinel. Overall this reduces numbers of mice euthanased annually.
- Better RNA extraction techniques meant that the number of mice required to purify RNA can be reduced four-fold to obtain necessary quantities of RNA for experimentation
- In vitro studies complementing this in vivo studies are still ongoing, but the murine model is still vital to our research
- When possible, one control group is used for several simultaneous experiments
- Numbers have been reduced from 20,000 larvae to 4,800 larvae because of optimisation of husbandry practices.

Replacement

- The automated behavioural apparatus was chosen for this study in order to minimise the use of animals. Small group sizes yielded data that could be analysed statistically, which would not have been possible with conventional testing.
- We use zebrafish as an act of refinement and replacement. Since we work mostly with embryos, these develop externally and are available in large clutches.
- All peptides used in this protocol have previously been validated by other Program Grant Chief Investigators and only optimal candidate peptides are investigated in animal models.

Refinement

Minimise suffering and distress through use of:

- Anaesthesia, namely Isofluorane, for most procedures
- We have refined tagging and transmitter attaching process through practice and it is now a quick and streamlined process that causes minimal distress to the animal. Small injection volumes and finer needles
- Utilizing the post-mortem tissues in the animals to help refine techniques being developed in other studies (such as optically clearing brain and bone tissue)
- Utilised non-invasive faecal sampling to determine the hormonal competence of animals in response to the contraceptive treatment. This method of sample collection is significantly less invasive than using blood sampling to determine hormone concentrations.

Replacement

- Continue to use replacement methods, such as ADinstruments or the use of earthworms, for teaching projects that previously used toad or rabbits.

Reduction:

- In 2014, the AEC focused its attention on the sand rat breeding colony. After reviewing the number of animals used for experimental purposes and the health status of the animals, the AEC discontinued the approval to breed sand rats.
- The establishment continues to encourage researchers to harvest and share tissues in instances where animals have been humanely killed.

Refinement:

- For new procedures or high animal welfare impact procedures, the AEC requests the submission of a pilot study to be reviewed by the Committee prior to approval of the main study
- The AEC has continued to request conditions of approval to include the presence of either the Animal Welfare Officer or Animal Facility Manager (a Veterinarian) to oversee high impact or new scientific procedures.

Replacement

- In-vitro testing was undertaken during product development to assess the similarities of the product to the currently registered device.
- Dissolution studies were undertaken to ascertain that the disintegration of the tablet was quick enough to justify comparison to an oral suspension.
- Both in vitro systems and computer modelling were considered but it was deemed that these alternatives are not able to provide a complete picture of the ability of a drug to anaesthetise an animal. Ligand binding assays were also unable to provide accurate data concerning the anaesthetic ability of a drug.

Refinement

- The time points proposed in the initial application were refined. The last two animals remaining in the pen on any euthanasia day were humanely euthanased one directly after the other so as to avoid a lone remaining animal becoming distressed.
- The anaesthesia analysis protocol was performed in a quiet procedure room. Each animal was transported out of the room so that it was out of sight and sound to the other animals held in the housing room. Animals were handled calmly and with care throughout the procedure. They were restrained and injected as quickly as possible. The finest possible needle was used (31 G). Following injection, gauze was applied to the tail to staunch any bleeding. Whilst anaesthetised the animals had lacri-lube applied to their eyes to prevent drying and they were placed in a warmed cage. When recovering, mice were held in cages individually for at least 2 hours before returning to their cage mates. At the completion of the study, animals were rehomed through an animal welfare organisation, rather than being euthanised.
- A review of previous studies conducted using the same active ingredient was conducted to determine the minimum number of suitable blood collection time points needed to attain the parameters required by regulators. This study used the same time points as another study and the same dogs. This meant the data from this study could be directly compared to the reference product administered. Therefore, it was not necessary to conduct a crossover study, reducing the amount of individual dog handling and blood collection. Study personnel were given training in blood collection and handling techniques to reduce any pain or distress experienced by the animals during dosing and blood collection procedures.
- The animals were restrained in an appropriate manner and bled for harvesting plasma by qualified personnel. The plasma collected during each bleed is stored and utilised in future studies, as blank plasma is required. As such, the number of times an animal is bled is reduced.
- One test item was removed from the study, thus reducing the number of animals treated. The conduct of Day 0, communication with co-operators, and monitoring of sites has continually improved over the course of this study. This has ensured that Day 0 runs smoothly, all personnel are adequately trained and that co-operators and monitors are reporting any potential issues regarding animal welfare as soon as possible.

Reduction

- The number of animal was reduced from 122 to 56 after an extensive review of procedures, APVMA requirements and the available literature.
- Animal were given a 1 week recovery period and were re-used to examine higher dose effects. Animals were also re-used after a rest period to examine other formulations at a single dose. This meant fewer total animals needed to be used.
- When designing this study, consideration was given to previously conducted studies to determine the minimum number of animals required to achieve suitable power for statistical significance. The minimum number of animals required to achieve this aim (n=12) were used in this study.
- The number of animals used in the study was reduced from 12 to 8.
- With the removal of one of the test items, each subsequent investigator site had less animals

enrolled and treated.

A selection of the 3R's that have been implemented in 2014 are:

Replacement

- Video and images for demonstration of fish disease management.
- Generation of anatomical 3D models for the zebrafish to replace use of live animals.
- Use of archival footage from documentaries and tour operators available on the web for behavioural studies on foraging behaviours of leopard seals.

Reduction

- Continuous review of data obtained during experiments to refine our estimates of group variability and repeat power analysis to determine if sample size may be reduced in subsequent experiments.
- A number of researchers are utilising pilot studies to optimise animal numbers – often statistically significant results can be obtained with smaller numbers of animals.
- Data from previous studies are utilised to reduce the number of animals required.
- The establishment continues to encourage researchers to harvest and share tissues. In instances where animals have been humanely killed specimens are donated to the museum or other researchers.
- Sharing of tissues or storage of samples for re-use in future protocols where possible.
- Re-use of animals for research that would have been already in the laboratory for other research in order to reduce the number captured from the wild.
- Collection of samples such as hair, mouth/sternal gland/pouch swabs and blood from animals captured for other routine health checks minimising handling and use of wild animals.
- Blood samples collected from animals brought to the Animal Hospital by members of the public. In instances where a blood sample would normally be taken as part of standard prognosis and treatment procedures for wildlife.
- Re-use of animals from other previously approved projects where the animals are not allowed to be released back into wild and would otherwise be euthanased.
- Rehoming and re-use of 350 animals (lizards) with a long-term known pedigree from another tertiary Institution which would have otherwise been euthanased. These lizards have a long-term known pedigree and will provide researchers with access to both the parents and offspring for behavioural experiments. The level of background information provided is extremely rare and often takes years to obtain.

Refinement

- Use of Observational only applications.
- Longer periods of acclimation for wild caught animals in facilities post capture and prior to performing experimental trials thus providing animals with the opportunity to rehydrate and increase body conditioning prior to experiments being conducted.
- Non-invasive monitoring techniques such as use of cameras for identifying habitat use by animals in preference to traditional trapping methods this has minimised the need for animal handling.
- Increasing use of targeted remote infra-red cameras to replace/supplement trapping for wildlife surveys and monitoring.
- Utilisation of advanced technology which reduces size and weight of tracking devices.
- Utilisation of remotely operated Unmanned Aerial Vehicles (UAV's) mounted with automatic camera system for use in seabird and shorebird surveys. These techniques allow birds to be counted from a distance and altitude that do not cause flushing so that the likelihood of disturbance is greatly reduced.
- Individually housing wild caught animals collected from different sites to prevent negative interactions between animals from different locations/harems (Permit requirement).
- Improvements to housing and segregation of animals captured from the wild, reducing the

risk of introduction of potential pathogens to natural populations when animals are released back into the wild (respective government authorities permitting).
- Refinement of anaesthetic agents used and dosage rates reducing recovery times and the risk of complications such as respiratory depression for animals where surgical procedures are conducted.
- Upgrades to animal housing facilities: Upgrades to Animal House Facility - use of a BAS system (Building automation system). The BAS system will be used for monitoring temperature set-points and other variables such as humidity within the rooms. Alarm notifications will be improved. Installation of Ro water system to overcome issues with water quality and in particular issues with copper in the tap water.
- Donation/Rehoming of animals unable to be returned to the wild to suitable organisations such as Zoos, Wildlife and Conservation Parks.

- Researchers are encouraged to share tissue samples wherever possible. This is facilitated by the Facility staff members.
- Breeding programs are designed and maintained to produce stock to order only to reduce numbers and overproduction
- Genetically modified animals are bred for the desired genotype as far as possible to reduce numbers.
- Animals used for courses are shared between multiple participants to achieve the best learning outcome whilst reducing overall numbers of animals used.
- Training courses and induction programs refine techniques to ensure the most meaningful results are achieved with the minimum number of animals.

Many principal researchers now use cameras and audio recording devices where those techniques are appropriate; these refined procedures reduce the number of animals used.

- To reduce the number of animals a single blood sample was collected from animals in in a project which were previously used in other projects. This enabled new analysis to be performed and used in conjunction with previous data collected from these animals avoiding the need to collect multiple samples from new animals.
- Animals in a project were also enrolled in another project to reduce the total number of live animals required.
- Trained personnel only administered treatments on commercial farms to reduce adverse impacts on animals.

- Close monitoring of animals and development of monitoring checklists to identify adverse reactions in animals. The AEC will place conditions on projects at the approval stage to ensure that any pain or distress to animals is alleviated quickly in projects where it is impossible to eliminate this completely.
- Use of experienced veterinarians and other staff.
- Restraint time and dose rates kept to a minimum.
- Adoption of less stressful methodologies.
- Suitable housing provided and maintained including controlled environment facility.
- Use of adjuvants known not to produce adverse reactions.
- Procedures used routinely so that animals become accustomed.
- Procedures performed under anaesthesia or sedation when appropriate.
- Close scrutiny of the number of animals requested and Biometrician's comments reviewed to ensure numbers are adequate to obtain the desired statistical outcomes, to minimise the number of animals involved in trials and to ensure that trials do not have to be repeated unnecessarily.
- Reduction in number of animals used – researchers in a protocol have moved to PCR to reduce the number of animals used.
- Re-use of animals – researchers in protocols have transferred rabbits to other research institutes for possible future use. Goats used in a protocol have been re-used in another

protocol.
- Close scrutiny of the volume of blood collected.
- Use of the saphenous vein method as the standard technique for blood collection in rodents.
- A number of studies conducted on animals at the owner's property to minimise any possible stress.
- Similar studies have shared the same control animals.
- Environment enrichment has been introduced for pigs and rabbits.

Techniques to REDUCE number of animals used:

Training protocol endeavours to utilise animals that have completed their purpose in other protocols to REDUCE the total number of animals used.

Techniques to REFINE procedures:

Research for a protocol was divided into two stages. An initial pilot study to ensure the research was viable and to REFINE techniques prior to continuing onto the main body of research. This pilot study approach has been promoted by the AEC.

Biostatistician Advice to the AEC and Researchers

A biostatistician continued to support the AEC and researchers throughout 2014 and into 2015 as our Biostatistician and advisor. They provided invaluable advice and challenged investigators to statistically justify the number of animals proposed to be used and the validity of statistical data obtained from animal experimentation.

Along with the establishment's continued review of our Standard Operating Procedures, the main focus of the AEC in 2014 was the review of the Fauna Survey Standard Operating Procedures (SOPs) Manual and the assessment of 'high' risk projects (i.e. those not included in the SOPs). Due to the increase in fish deaths from the use of fyke netting in 2014, the SOPs review heavily focussed on improving the procedures to minimise adverse incidents and reduce by-catch of platypus, waterbirds and turtles. An external review conducted by the Victorian Department of Environment and Primary Industries on the use of fyke netting for fish, platypus and turtles also informed the improvement of the SOPs. The previous year's amendment to the SOPs for bait trapping adding additional mitigation measures for trap setting (in waters where low oxygen levels may occur) proved successful as there were no adverse incidents reported using bait traps for 2014.

In its decision making process, the Animal Ethics Committee does take into account the 3R's principle (3R's principle – Refine, Reduce and Replace) and will intervene in projects when necessary. Furthermore, the Committee maintains a website which provides detailed information and links to external websites and databases that promote alternatives to the use of animals in research and/or teaching. The 3 Rs are also discussed during the Animal Ethics workshops.

REPLACEMENT

Tissue Sharing:

- Samples collected under an ARA were properly stored and used years later for use in another project.
- Using control data across a number of related protocols.

In vitro technology:

- An in vitro thrombus formation testing system was devised to help reduce the number of animals on a protocol.
- Immortalised cell lines were used instead of animals

Other Alternatives:

- A Research Group was able to use pre- and postsurgical blood samples collected from human patients undergoing surgery instead of using blood samples from a rat model to validate a new technique.
- The use of captive animals in place of wildlife.

REFINEMENT

Monitoring:

- The AEC requests that monitoring record sheets are tailored to meet the requirements of individual protocols.
- The AEC requests that a minimum number of 2 personnel be listed for all protocol where monitoring of animals is required.

Enrichment:

- Wood blocks
- Seeds
- Straws
- Substrate maintenance
- Companionship provided by vasectomised animals

Training:

- Animal handling
- Injection techniques
- Anaesthesia
- Monitoring – anaesthetic and post-operative

Procedures:

- Multiple experimental procedures were applied during non-recovery experiments to increase data yield per animal recruited.
- Common procedures were standardised and endorsed as AEC SOPs
- On multiple occasions, the AEC sought clarification on the feasibility of reducing the number of repeat anaesthetics by incorporating more than one procedure per anaesthetic.

REDUCTION

Numbers:

- Animals that were scheduled for approved euthanasia were made available for tissue harvest, new technique training or post mortem technique training.
- At the conclusion of appropriate research protocols, some animals were retained for animal handling training.
- Researchers were encouraged to consult with statisticians to determine the minimum number of animals required for statistically valid and relevant results.

Replacement

Mouse lung **primary fibroblast cultures** were used to optimize FBLN-1C AO concentration in FBLN-1C inhibition experiments.

We have identified epithelial specific proteins and used **cell culture models** of epithelial healing to **replace** animal experiments for these proteins.

We have developed a complementary ***in vitro*** **experimental system** to investigate the relative importance of the pT286 and pT253 pathways in stroke damage. This experimental system involves the use of cultured neuroblastoma cell lines (derived from a nerve cell cancer). Using molecular engineering techniques we have introduced mutant forms of CaMKII into different cell groups in which the pT286 or pT253 “switches” have been permanently turned ON or OFF. We

have then treated these cells with a pharmacological agent that mimics the effects of stroke induced ischaemia and determined how many cells were no longer viable (were dead or dying) 24 hours after the pharmacological treatment. Results obtained in this system support our conclusion that the pT253 switch is the key regulator of cell death.

Refinement

A new balance with a **dynamic weighing feature** and a USB interface to a laptop was purchased. The use of this balance assisted in streamlining the weighing of individual mice thereby reducing stress on the mice.

Mice were exposed to a more **graded introduction** to the smoking protocol thereby minimising stress from smoke exposure.

The dose of **virus was optimised** to minimise potential adverse effects on animals.

A carotid occlusion model used recanalization as an outcome thereby **avoiding the need to induce stroke** in animals.

Small volumes of arterial blood were only taken **at key time points** in an experimental protocol.

The time period of behaviour testing was **reduced**.

Cumulative refinements resulted in less variability and very low mortality that enabled a reduction in sample size. Other measures such as training with **supplemental feeds** and pre-incisional **use of local anaesthetics** permitted greater survival of animals and minimised animal distress.

Advancements in **surgical techniques** led to shorter anaesthesia times and reduced surgical trauma.

A pulse oximeter appropriate for small animal use was purchased which allowed the surgical team to more **closely monitor** rats during surgery.

Small improvements to surgical procedures for kidney harvest and transplant greatly improved the quality of transplanting kidneys. These improvements are increasing the profusion time of donor kidneys prior to transplantation and this has also improved the quality of kidney harvest. The acquisition of more **appropriately sized vessel clamps** also improved transplant anastomosis quality.

The certification and use of the Animal Behavioural Laboratories **increased the capacity** for animals to be housed in **enriched cages**.

The **refinement of a surgical laparotomy technique** lessened the impact on animals by:

i. using **surgical scissors** instead of a scalpel to make a small 1-2 cm incision;
ii. pressing a **sterile cotton wool tip** onto an injection site for 60 seconds rather than 30 seconds to prevent the escape of cells into the peritoneum; and
iii. closing the abdominal cavity in **two layers** rather than a single layer.

Speeding up tissue preparation techniques enabled more viable tissue to be produced for experiments. This meant that more data per mouse could be generated and therefore less mice were required.

The use of **endoscopy identified perforations or obstructions** in the GI tract which would require euthanasia as a result therefore preventing undue suffering.

Clinical endoscopic scoring was found to be a far more accurate measure of disease severity. This allowed severely ill mice or those with the potential to reach critical illness to be identified prior to behavioural changes being exhibited or weight lost becoming apparent.

Reduction

Avenues of experimentation on animals were **initially verified in cell culture** and shown to be mechanistically relevant in an in vitro setting. The pathway was only investigated in vivo after the limit of in vitro analysis was reached and other assays suggested a mechanistically relevant pathway had been determined.

An experiment was **designed so that only one control group was needed** for both drug treatment groups. This significantly reduced the number of animals needed for the study.

Several different in vitro models (suspension cultures, patient blasts ex vivo, co-culturing with bone marrow stromal cells) were examined and used and the **effectiveness of a drug had been established in vitro**. The use of these models reduced the number of animals required.

The **re-use of male mice** from the breeding part of the protocol reduced the overall number of mice required.

Running experiments at the same time and sharing controls across experiments cut down on the number of mice required.

Controls and **experiments were run in parallel** where possible to minimise the number of animals required.

Increased sensitivity of molecular methods were used to increase the number of results from batches of tissues.

Sample size calculations for a project were **based on pilot data**.

Ongoing refinements to an existing stroke model reduced variability and thereby the number of animals required to produce a statistically/scientifically valid result.

The same male mice were mated to each new group of females, rather than using new males.

Numbers of animals were based on that required to achieve statistical significance based on an actual **variation found in previous studies**.

Experiments were planned in such a way that the **minimum number of animals were required** in order to obtain meaningful and significant data and statistically useful information.

Slides generated from **isolated tissues** were made available to other researchers.

Measuring **multiple physiological variables** within each animal reduced the sample size.

Improvements in data collection methods allowed more tissue to be harvested and investigated in each experiment thereby reducing the number of animals required.

Testing **two doses of a compound in a pilot experiment** minimised the wastage of animals that could be attributed to ineffective treatments being used in a larger experiment.

Researchers invited **other groups to utilise unused tissue**. For example, neurological and respiratory researchers were encouraged to utilise brains, spinal cord and lungs and these tissues were routinely shared.

All available lung and lymphoid tissue was collected for later analysis and other samples were made **available to interested research groups**.

The sharing of mice between groups interested in different aspects of the animals made it possible for **one mouse to be used for two different projects**.

The methodology for a program of research that is designed to minimise the use of animals and animal models. A substantial portion of this research has and will take place in **cell culture and**

in vitro model systems (i.e. analysis of individual cell signalling). All avenues of experimentation on animals had been initially verified in cell culture and shown to be mechanistically relevant in an in vitro setting. Only when the limit of in vitro analysis was reached and all assays point to a mechanistically relevant pathway, is that pathway investigated in in vivo.

The use of **interventional treatments** (dexamethasone/PHDi) employed and the conditions and time points based on **clinical indices of disease established from previous research** to ensure that the experimental protocol is efficiently designed.

Employing **disease scoring**, rather than set time points, reduced the number of animals required in an experimental group. The use of **clinical methods of evaluation**, such as body temperature and blood testing for immune status and gastrointestinal endoscopy and biopsy reduced animal numbers where traditionally these indices would be measured by endpoint euthanasia.

Verification of mechanisms ascertained from animal experiments carried out by **in vitro cell based experiments**. All remaining tissues from controls were of value to the research group and tissue was made **available to other researchers** from euthanized animals from all experiments.

A collaborative group encouraged researchers from other areas to investigate tissues for their research. In particular brains, spinal cord and lungs were available to researchers from neurological and respiratory groups and these **tissues were routinely shared**.

The use of mouse **tissue from other groups** meant that far fewer calretinin and parvalbumin transgenic mice used than was initially anticipated. In this instance, Oscillators or Spastic mice were not used because researchers were able to **reanalyse their data** in a different way thereby making the use of more of these mice unnecessary.

Epidymal sperm from rats euthanised during one research activity was **utilised by another group** of researchers thereby lowering the number of rats used. The male reproductive system **was also shared** and based on this arrangement the epididymal tract was collected and other tissue was made available.

The use of **endoscopy** facilitated reduction by:

1. Allowing the **clinical monitoring of disease** to confirm the level of disease which reduced "failed" models of disease or false negative treatments
2. Allowing the **tissue sampling in vivo**, and analysing inflammatory status without the need for a specific cull group.

The use of **control groups** for multiple **concurrent experiments**.

The **reuse of animals** supplied for a previous project rather than requesting new mice, in addition to **utilising unused animals** from one section of a project in another section before requesting additional animals.

Tissue from single animals being used for **three separate studies** (cardiovascular, metabolic, and behavioural) thereby reducing the number of animals required as one animal potentially replaces the need for three animals.

Several **control groups being run concurrently** with multiple interventions to minimise the number of mice.

- With the increased availability of computer simulations, the establishment is moving away from the traditional model of having students individually dissect an animal. The current model is for undergraduate students to access a computer/video demonstration, with a hands-on aspect of learning how to correctly handle an animal.

- The establishment also actively encourages researchers working together to develop projects that can be run in parallel, which uses different tissues of the same animals in order to reduce the overall number of animals.
- Researchers are also asked to provide power analysis to demonstrate an understanding of how to ensure that the minimal number of animal replicates is used.

Refinement:

- Use of new enrichment devices: glass marbles for mice and more wire rings for cage lids to enhance display of natural behaviours – play, exercise, territory marking.
- Provision of crinkle nest paper/more cardboard paper rolls for singly-housed males and animals showing signs of barbering.
- Use of white nesting paper for animals that had surgeries to visibly detect any blood stains as can be difficult to see with corn cob bedding material
- Using appropriate anaesthetics and analgesics for potentially painful procedures – introduction of use of other drugs like carprofen and meloxicam as analgesic options, medetomidine as injectable anaesthetic for rats, atipamezole for reversal of xylazine and medetomidine
- Ensure use of correct size surgical instruments for species under investigation – smaller incision, lesser wound clips, faster wound healing
- Introduction of Individually Ventilated Caging system for immunodeficient mouse strains

Reduction:

- Fewer breeder pairs can be set up for FRG immunodeficient mice due to improved housing, environment and health conditions
- Regular stock take by researchers to ensure animals being maintained are only what is needed
- Animal tissue sharing between research groups whenever possible
- Reduction of animals used for training purposes – use of animals that are due to be culled only
- Application of pilot studies for AEC projects where appropriate

Replacement:

Cell-based experiments whenever possible; use of alternatives to animal-based research

- We promote and encourage the use of tissue sharing throughout the facility users as well as external bodies looking for tissue sharing ability also.
- We meet with research groups routinely for colony management to ensure breeding is optimised for experimental or maintenance production only.
- By doing this we are contributing to the 3 Rs by minimising or eliminating the generation of unrequired animals through breeding strategies used.
- Score sheets for all monitoring during approved surgical procedures have been introduced to refine the process and appropriately identify and manage pain and distress in the animals.
- We have sourced a rich supply of free environmental enrichment for our animals allowing us to accommodate budget to further training resources for refinement of techniques in line with best practice in the industry. We have also been able to supply 5 external facilities with free enrichment.

- To improve animal welfare, the trial facility has undergone major renovations including: installation of a new, fully insulated roof; erection of a blacked-out curtain along the southern side of the shed, installation of free-range areas covered by shade clothes, improved lighting and fogging systems.
- Enrichment of pens with perches may improve bird leg strength and is encouraged for use in trials requesting use of layers and considered for broilers.
- An individual sample weighing for large birds has also been used to decrease stress on birds when handled at larger weights.

- Attempt to find backyard homes for all layers once experiment is complete (e.g. when egg production has ceased).
- Select injection procedures that are more tolerated by the animal (e.g. subcutaneous over intramuscular).

Replacement: The Committee continues to maintain a Biological Non-Human Tissue Database through which researchers are able to share excess tissue, thus replacing the use of live animals with the use of stored tissue. In addition, to make these tissues more widely available, the Committee has joined the Ethitex tissue sharing database which facilitates tissue sharing throughout Australia.

Refinement:

- The Committee continues to encourage researchers to undertake a pilot study if the impact of the proposed study interventions on animal health and well-being is unknown.
- Animal House veterinary managers review protocols with researchers in order to optimise anaesthesia protocols (including monitoring) and analgesia.
- Scoring systems for monitoring of experimental animals have been developed and refined, with the aim of minimising potential pain and distress that animals may experience as part of certain research related procedures.

Reduction: The Committee has minimised animal usage by the following techniques:

- Careful scrutiny of the numbers of animals requested to ensure that sufficient numbers are used to provide a statistically valid result, thus preventing the need for repeat experiments and use of additional animals.
- Approval of new techniques for embryo freezing rather than continuous breeding to maintain lines.
- Re-use of animals, where appropriate, after extended recovery interval
- Making surplus tissue available through a Biological Non-Human Tissue Database and seeking prior agreement from investigators to make surplus tissue available
- Consolidating breeding protocols to ensure no over-breeding which in turn reduces the need for culling
- Rederivation: Animal facilities optimise fostering process and thereby minimise the number of female mice used for fostering purposes.
- Training: Animal facilities use mice for training purposes that were identified with an undesired genotype (hence would have been euthanised regardless).
- Sharing: Where possible, mouse lines are shared between different research groups to avoid unnecessary breeding.

Where possible, staff will replace the use of live animals with video or synthetic / cadaver models, or by creating computer models. A project which involved filming of procedures using animals for teaching purposes was successfully undertaken in 2014.

Power analyses are frequently submitted as part of the application (sometimes at the request of the Animal Ethics Committee) which demonstrate how researchers and teachers calculate the most suitable numbers of animals required to give valid data.

Applications include justification by applicants for appropriate handling techniques where necessary, avoidance of pain and distress to the animals and how pain or distress will be alleviated if the animal shows signs of displaying either state.

Appendix I: 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 maintenance of the Animal Ethics Infolink website, 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	**5,249.70**
Travel and subsistence	**2,653.46**
Stores (including catering) and printing	**892.50**
Freight and postage	**1,040.52**
TOTAL	**9,836.18**

Appendix J: ARRP policies and guidelines

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

Policies

2. Payment of External Members of Animal Ethics Committees (revised 15/5/2009)

3. Procedures Prohibited under the NSW Prevention of Cruelty to Animals Act (revised 24/4/2009)

4. Non-Research Animals at Accredited Animal Research Establishments (revised 4/8/2010)

5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 24/1/2014)

5A. Accredited Animal Research Establishment Support for Animal Ethics Committees (revised 8/5/2014)

6. Differentiation between animal research and veterinary treatment (revised 8/5/2014)

8. Establishment of Protocols for Grievance Procedures (revised 16/12/14)

9. Criteria for Assessment of Animal Ethics Committee Membership (revised 16/12/14)

10. Emergency Procedures

11. Formal Agreements between Accredited Research Establishments sharing Animal Ethics Committees

12. Frequency of Animal Ethics Committee Meetings

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

Guidelines

1. Opportunistic Research on Free-Living Wildlife
2. Captive Wildlife
3. Individuals and Institutions Engaged in Collaborative Research
4. Use of Animals in Post-graduate Surgical Training
5. Collection of Voucher Specimens
6. Use of Pitfall Traps
7. The Use of Feral Animals in Research
8. Teaching Artificial Insemination and Pregnancy Testing in Cattle
9. Radio Tracking in Wildlife Research
10. Wildlife Surveys (revised 13/1/15)
11. Guidelines for Tick Serum Producers
12. Animal Research Model Application Form
13. Guidelines for the Production of Monoclonal Antibodies
14. Guidelines for the Care and Housing of Dogs in Scientific Institutions
15. Blood Collection
16. Supervision of Animal Supply by Animal Ethics Committees
17. Training Personnel
18. Guidelines for the Housing of Rabbits in Scientific Institutions
19. Teaching Cervical or Vaginal Artificial Insemination of Sheep
20. Guidelines for the Housing of Rats in Scientific Institutions
21. Guidelines for the Housing of Guinea Pigs in Scientific Institutions
22. Guidelines for the Housing of Mice in Scientific Institutions (April 2012)
23. Guidelines for the Housing of Sheep in Scientific Institutions
24. Consideration of high impact projects by Animal Ethics Committees (December 2015)

Appendix K: Standard conditions for Accreditation and Animal Supply Licence

The following are standard conditions that are placed on establishments seeking Accreditation as Animal Research Establishments and Licences as Animal Suppliers. Additional conditions are added on a case-by-case basis.

Accreditation

1. That any site inspection is satisfactory.

2. 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.

3. Rabbits should be housed in groups in pens. Rabbits may only be housed in cages with the express permission of the AEC on the basis of 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 (http://www.animalethics.org.au/policies-and-guidelines/animal-care))
(For establishments housing rabbits)

4. 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.
(For establishments housing chickens)

5. 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).
(For establishments housing dogs)

6. 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.

7. 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 .

8. 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).

9. 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)

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

Animal Supply Licence

1. That any site inspection is satisfactory.
2. 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.
3. 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.
4. 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.

5. 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*.