

Submission
No 251

**INQUIRY INTO USE OF PRIMATES AND OTHER ANIMALS
IN MEDICAL RESEARCH IN NEW SOUTH WALES**

Name: Ms Lisa Craig
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Partially
Confidential

Dear Honourable Members,

Please accept my submission and request to testify. I am a longer-term manager of animal research, with experience in Australia and overseas. I have serious concerns about the use of animals in research in Australia. Some of which have been indicated below. [REDACTED]

I wish to highlight that as a long-term animal care manager, my role has always been to oversee animal care and welfare, ensuring the implementation of the 3Rs, best practice standards, and regulatory compliance. This was of course, until coming to Australia, where I was told that my job was to “facilitate research.” I no longer had the responsibility or authority to ensure animals' appropriate care and welfare. [REDACTED]

[REDACTED] External oversight of animal care and welfare just does not exist in any impactful way. Mechanisms for complaints and investigations separate from the institution do not exist, and institutions have a significant conflict of interest in investigations of their facilities and personnel. These findings are not only a reputational risk but have serious financial implications.

It is long past time for Australia to have an effective and robust National Legislation that protects animals in research. One that is prescriptive, including animal welfare, animal care, animal housing, an adequate program of veterinary care that includes a qualified veterinarian with authority and responsibility for animal welfare, Ensure Ethics process and the proper review of 3Rs implementation, Ensure effective committee members including an animal care representative as a voting member, describes inspection standards and duties of the AEC, ensure the adequate funding and support of animal care to ensure the appropriate numbers of qualified and trained staff, and ensure transparency. The legislation must include incentive research and the development of alternatives to animals. Finally, the legislation needs an independent national oversight body for complaints and investigations of animal welfare and non-compliance issues.

Regards
Lisa Craig

Public submission

- a) Nature Purpose and effectiveness, including public health risks and benefits
 1. Despite the improvements and advances in alternatives to animal use, until these alternatives can mimic the complex physiology and responses of a whole organism, animals remain essential to the conduct of biomedical research
- b) Costs and extent of funding by Fed Gov and NSW
 2. While I cannot comment on the extent of funding, I can comment on the issues of appropriate support for Laboratory animal science (LAS), a discipline dedicated to the human care and management of animals in research in Australia
 3. Institutions run their animal programs as low priority services, meaning inadequate funding for the appropriate number and qualifications of the staff
 4. There are limited to no training programs in LAS in Australia. This includes having no appropriate training programs for veterinarians. Internationally LAS specialisations are a post-graduate undertaking, including significant education and funding. In addition, there are no specialist Fellows within the Management and Medicine of Laboratory Animals in Australia. Thus, there is no veterinary expertise available to support animals in research.
 5. There is no LAS training in higher education in Australia. As a result, we are not training staff with appropriate credentials, knowledge, or experience in managing animals in research to ensure proper oversight and management of animals in research.
 6. TAFE courses are geared only to entry-level cleaning staff and are all but gone. There are no TAFE courses in LAS in NSW.
 7. Infrastructure funds from grants received by the investigator using animals do not go to support the animal facilities, ensure staffing, training, or appropriate facilities and equipment.
- c) Availability, the effectiveness of funding for alternatives, and the ability of researchers to meet the 3RS
 1. There is no funding or support for the development of alternatives in Australia.
 2. There is nothing akin to the 3Rs-Centre of the Johns Hopkins Center for Alternative to Animal Testing in Australia
 3. Without adequate training and experienced staff, researchers are not getting support, training, or knowledge to ensure the application of the 3Rs.
 4. The Code does not include specifics of Ethics Committee functions or protocol review, including standards for inclusion of information related to the application of the 3Rs.
 5. A 2017 paper comparing the role of the Animal Welfare Officer (AWO) in AU to those in the UK indicate that AU AWOS are more junior, not involved in 3Rs communication or assurance, have little involvement in the training of researchers and staff, and do not believe the 3Rs receive appropriate attention in their institutions.¹
 6. Unlike in the US, EU, UK, and Canada, The Australia Code has no requirement for a veterinarian to be appointed to oversee the care, management, and welfare of animals. Overseas the veterinarian has primary responsibility and authority for animals and animal welfare in research. The Code leaves this to the primary investigator, despite the clear conflict of interest.

7. The Code requires that the institution only require access to veterinary advice, not veterinary care. While the public has an obligation to ensure veterinary care of animals, researchers using animals do not.

d) Ethical and animal welfare issues

1. Animal use in Australia is not supported by qualified, trained staff. Most animal care personnel in Australia do not have the appropriate training and education LAS to ensure proper procedure and care.
2. Breeding of animals for research, including commercially available animals, occurs at institutions across Australia, resulting in significant overproduction and culling of excess animals. This includes mice, rats, and guinea pigs
3. Researchers are not required to seek veterinary care for animals in research.
4. Australia lacks veterinarians with LAS training
5. Australian researchers using animals lack knowledge of animal physiology, genetics, appropriate animal care and management, and animal welfare practices.
6. Ethics committee members, even Cat A members, do not have appropriate training and education related to animal care or protocol review
7. There is no requirement for a representative of the animal care team included on the Ethics committee, either as an advisor or voting member.
8. There is no requirement for animal care staff to be supplied with, read, or understand what procedures and other approvals are included on ethics applications. This results in the unchecked ability of researchers to conduct unapproved procedures
9. There is no transparency in the approved protocol. In the US, ALL approved protocols must be made available and easily accessible to all.
10. I have personally witnessed a significant number of animal welfare issues. This includes the removal of toes and tail tipping of adult animals, animals not being given appropriate anaesthesia and analgesia, mass culling of animals as researchers are not happy with preliminary data from them, animals used in horrific inappropriate smoke inhalation studies, animal fasted for excessive periods of time, severe and significant overproduction of animals, None of which resulted in the suspension of a protocol or sufficient investigation.

e) Adequacy of current regulations

The current Code is ineffective and inadequate. Below are some examples, but this is in no way comprehensive

1. No requirement for an adequate program of veterinary care
2. No transparency
3. No standards for qualifications of the staff
4. No standards for 3Rs implementation
5. No standards for information to be included in ethics protocol, or evaluations of protocols
6. No standard for training and education of AEC
7. No standards for AEC procedures
8. No standards for inspection and evaluation of animal facilities
9. No standards for husbandry
10. No standards for cleaning and sanitation
11. No standards for adequate staffing of animal facilities
12. No standards to ensure the modern acceptable veterinary standards in surgery or other invasive procedures

13. The Code is not consistent with the OIE Terrestrial Animal Health Code requirements.

f) Overseas developments

1. Extensive training and education resources for Laboratory animal science and medicine professionalism, including post-graduate education and residency programs for veterinarians, and master's²⁻¹² level education for facility managers
2. Veterinarians are charged with responsibility and authority for animal welfare, not researchers
3. LAS qualifications are generally considered a postgraduate qualification
4. International harmonization of standards and practices in animal care and welfare in research
5. Profession education and training expectations of staff, not a trade level certification
6. Funding and support for alternatives and the 3Rs
7. Ensuring facilities are adequate and appropriate for animals

g) Any other issues

h) Please see below references for essential information about international standards, the need for professionals in LAS in animal care, and the need to include veterinarians with appropriate training and experience. Additionally, information is included about the Codes lack of robustness

Essential Bullet points with references

- In 2015, Australia world's fifth-highest user of animals in research¹³.
- World Organization for Animal Health (OIE) Terrestrial Code Animal Health Code, expectation of veterinary care in research by a veterinarian with the necessary expertise¹⁴.
- Australian legislation intended to protect animals in research lacks rigour^{2,3}.
- Australia's regulations do not require the appointment of a veterinarian in animal research^{2,3}.
- Australian laws lack specific indications of competence or training expectations^{2,3,15}.
- Animal welfare officers (AWOs) in Australia¹
 - junior roles compared to international counterparts.
 - Not involved in communicating animal welfare techniques or the 3Rs to scientists.
 - AWOs less likely to engage in staff training than their international counterparts.
 - AWOs in Australia do not have decision-making authority on Animal Ethics Committees.
- Animal research in Australia lacks transparency.²
- Overreliance on researchers to ensure the the 3Rs and animal welfare.
- Competency issues in animal care and procedures involving animals are also a risk to the reliability and reproducibility of research⁹.
- US Health Research Extension Act and the Animal Welfare Act of 1966 requires a multidisciplinary team, including veterinarians, to ensure regulatory responsibilities in the conduct of biomedical research¹⁶.

- Comparative medicine, or Laboratory Animal Science and Medicine (LASM), is a multidimensional discipline of science and veterinary medicine dedicated to humane animal experimentation ¹⁷.
- In 1951, the American Veterinary Medical Association (AVMA) recognised LASM as a speciality in veterinary medicine ¹⁸.
- LASM professionals have training in managing intrinsic and extrinsic variability in animal research. Controlling variability is essential to reproducibility and translatability in biomedical research ¹⁶.
- Reproducibility and translatability of research have become concerns to scientists and the public ¹⁹.
- LASM informs the selection of the animal models, replacement the 3Rs in experiments, determines animal care needs ensures animal welfare ¹⁷.
- The AVMA describes the job of veterinarians in research; to provide expertise in animal husbandry and welfare, disease control programs, serve on ethics committees, provide diagnostic services, advise on regulatory issues, and conduct research ²⁰.
- the veterinarian provides advice for all stages of research, including expertise in animal welfare, managing pain, reviewing research proposals, implementing the 3Rs, and training researchers and animal technicians ¹⁴.
- The importance of the veterinarian and other paraprofessionals in animal research, the wealth of roles, and the importance of expertise are recognised globally ¹⁴, but not in Australia ^{2,3}.
- the need to increase recruitment efforts, change the veterinary school curriculum, and increase funding for training programs, internships, and postgraduate placements ²¹.
- the EU, Directive 2010/63/EU established the roles of the veterinarian in ensuring health and welfare in biomedical research, and stipulating expectations of education and training ²².
- EU, 64 of 77 veterinary schools incorporate LASM in the veterinary curricula ²³. Postgraduate education in LASM is offered in approximately 52% of these schools ²³. France, Germany, the Czech Republic, Italy, and Sweden have specific training and education requirements ²³.
- Australia The Australian Code of Practice for the Care and Use of Animals for Experimental Procedures (the Code) does not require a veterinarian's appointment or include expectations of education and training in LASM ^{2,3}.
- In 2019, the medical technology and pharmaceutical sector ranked 8th as one of Australia's most valuable economic sectors, worth AUD 8.2 billion ²⁴.
- Spending on medical research was AUD 5 billion in 2017-18 ²⁵.
- According to the Association of Australian Medical Research Institutes, Australia has approximately 32,000 medical researchers, 50 pharmaceutical companies, 400 biotechnology companies, and 500 medical technology companies. ²⁴.
- There is no specific data on the number of veterinary professionals and paraprofessionals in LASM, however Australia is currently suffering a shortage in the veterinary and animal care sector. (veterinarians, veterinary technicians, animal attendants, animal trainers, and laboratory managers) ²⁶.
- According to the Australia and New Zealand College of Veterinary Scientists,
 - There are no veterinarians qualified at the Fellowship level (expertise) in Medicine and Management of Laboratory Animals in Australia or New Zealand.
- Ensuring an adequate supply of veterinarians and paraprofessionals into LASM is critical to animal welfare and quality research. Model selection, experimental design,

species-specific ethological needs, pain recognition and treatments, anaesthesia, and euthanasia are essential considerations in animal research^{11,17} for which veterinary professionals are qualified.

- Proper experimental design is critical to the translatability of research²⁷.
- Understanding how to control confounding factors, their impacts on animal physiology²⁸ how they influence research outcomes requires a competent animal care team. LASM personnel are vital to the quality of research¹⁷.
- Veterinary involvement ensures the application and adherence to contemporary best-practice veterinary standards²⁹.
- The inclusion of a knowledgeable animal care and use team has improved reliability and reproducibility in preclinical research and ensure animal welfare^{11,27 27,30}.
- The Code puts the chief investigator in charge of animal welfare.¹⁵,
- The US and the EU have legislated specific competencies and invested significantly in training and education in LASM, Australia has not.
- Veterinary and postgraduate training in LASM is not available in Australia.
- Internationally, expertise in LASM is regarded as a postgraduate qualification³¹⁻³³. Without the coursework available nationally, it can be presumed that there will be fewer qualified people available to support research in Australia.
- a well-qualified LASM team ensures that institutions meet regulatory requirements, research quality, the implementation of the 3Rs, animal welfare, transparency,
- Australia lags the western world in requiring expertise in veterinary medicine and animal care in animal research.
- These issues represent a risk to animal welfare
- Australia must address the gaps in regulatory requirements and ensure at least minimal alignment with the Terrestrial Code, if not harmonisation with standards in North America and the EU. Ultimately, these changes must also drive LASM into the higher education sector, including opportunities for LASM training for veterinarians. The evolution of LASM in Australia is crucial to animal welfare and quality reliable research

APPENDIX 1 BIBLIOGRAPHY

1. Chen, P.J. Animal welfare officers in Australian higher education: 3R application, work contexts, and risk perception. *Lab. Anim.* **51**, 636-646 (2017).
2. Timoshanko, A.C., Marston, H. & Lidbury, B.A. Australian regulation of animal use in science and education: A critical appraisal. *ILAR J* **57**, 324-332 (2016).
3. Whittaker, A. Animal research regulation in Australia – Does it pass the test of robustness? *GJAL* (2014).
4. Bayne, K. & Turner, P.V. Animal Welfare Standards and International Collaborations. *ILAR J* **60**, 86-94 (2019).
5. Bayne, K. & Anderson, L.C. Laws, Regulations, and Policies Affecting the Use of Laboratory Animals. in *Laboratory Animal Medicine* 23-42 (2015).
6. Bayne, K., *et al.* Harmonizing veterinary training and qualifications in laboratory animal medicine: a global perspective. *ILAR J* **52**, 393-403 (2011).
7. Zurlo, J., Bayne, K. & MacArthur Clark, J. Adequate veterinary care for animals in research: a comparison of guidelines from around the world. *ILAR J* **50**, 85-88 (2009).
8. Hedenqvist, P., *et al.* Toward Global Harmonization of Training and Certification of Specialists in Laboratory Animal Veterinary Medicine. *J Am Assoc Lab Anim Sci* **61**, 15-20 (2022).
9. Guillén, J. & Steckler, T. Good research practice: lessons from animal care and use. 367-382 (Springer International Publishing, 2019).
10. Craven, S. & Goh, A.C. Animal Laboratory Training: Current Status and How Essential Is It? in *Robotics in Genitourinary Surgery* 175-182 (Springer International Publishing, 2018).
11. Barbee, R.W. & Turner, P.V. Incorporating Laboratory Animal Science into responsible biomedical research. *ILAR J* **60**, 9-16 (2019).
12. Heintl, C., *et al.* Rethinking the incentive system in science: animal study registries: Preregistering experiments using animals could greatly improve transparency and reliability of biomedical studies and improve animal welfare. *EMBO Rep* **21**, e49709 (2020).
13. Taylor, K. & Alvarez, L.R. An estimate of the number of animals used for scientific purposes worldwide in 2015. *Altern Lab Anim* **47**, 196-213 (2019).
14. World Organization for Animal Health. Terrestrial Animal Health Code. (ed. World Organization for Animal Health) (2011).
15. National Health and Medical Research Council. Australian code for the care and use of animals for scientific purposes. (ed. Council, N.H.a.M.R.) (Australian Government, Canberra, 2013).
16. Macy, J. & Horvath, T.L. Comparative Medicine: An inclusive crossover discipline. *Yale J Biol Med* **90**, 493-498 (2017).
17. Forni, M. Laboratory animal science: a resource to improve the quality of science. *Vet Res Commun* **31 Suppl 1**, 43-47 (2007).
18. Quimby, F.W. Twenty-five years of progress in laboratory animal science. *Lab. Anim.* **28**, 158-171 (1994).
19. Mede, N.G., Schafer, M.S., Ziegler, R. & Weisskopf, M. The "replication crisis" in the public eye: Germans' awareness and perceptions of the (ir)reproducibility of scientific research. *Public Underst Sci* **30**, 91-102 (2021).

20. American Veterinary Medical Association. Veterinarians promote animal welfare through research [Internet]. Vol. 2021 (American Veterinary Medical Association, 2021).
21. Committee on Increasing Veterinary Involvement in Biomedical Research, N.R.C. *National need and priorities for veterinarians in biomedical research*, (The National Academies Press, Washington D.C., 2004).
22. The European Parliament and the Council of the European Union. Directive 2010/63/Eu of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. in *Official Journal of the European Union* (ed. Union, T.E.P.a.t.C.o.t.E.) 33-79 (2010).
23. Iatridou, D., Nagy, Z., De Briyne, N., Saunders, J. & Bravo, A. Mapping the teaching of Laboratory Animal Science and Medicine in the European Union and European Free Trade Area. *J. Vet. Med. Educ.* **45**, 556-566 (2018).
24. Association of Australian Medical Research Association Institutes. Health research in Australia. Vol. 2021 (2021).
25. Australian Institute of Health and Welfare. Australia's health snapshots 2020. (Australian Government, Canberra, 2020).
26. Department of Homeland Affairs. Skilled Occupations List. Vol. 2021 (Australian Government, Canberra, 2021).
27. Cheleuitte-Nieves, C. & Lipman, N.S. Improving replicability, reproducibility, And reliability in preclinical research: A shared responsibility. *ILAR J* **60**, 113-119 (2019).
28. Nevalainen, T. Animal husbandry and experimental design. *ILAR J* **55**, 392-398 (2014).
29. Workman, P., *et al.* Guidelines for the welfare and use of animals in cancer research. *Br. J. Cancer* **102**, 1555-1577 (2010).
30. Mohanan, S., *et al.* Evolving the Role of Discovery-focused Pathologists and Comparative Scientists in the Pharmaceutical Industry. *Toxicol Pathol* **47**, 121-128 (2019).
31. ACLAM Veterinary Curriculum Working Group. Recommendations for teaching Laboratory Animal Medicine to veterinary students in North America. (American Veterinary Medical Association, 2006).
32. Turner, P.V., *et al.* Roles of the International Council for Laboratory Animal Science (ICLAS) and International Association of Colleges of Laboratory Animal Medicine (IACLAM) in the global organization and support of 3Rs advances in Laboratory Animal Science. *J Am Assoc Lab Anim Sci* **54**, 174-180 (2015).
33. Whitcomb, T.L. & Wilson, R.P. Benefits and challenges of developing a customized rubric for curricular review of a residency program in Laboratory Animal Medicine. *J. Vet. Med. Educ.* **44**, 570-578 (2017).