Submission No 259

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

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Date Received: 13 April 2022

Legislative Council Portfolio Committee No. 2 – Health

Inquiry into the use of primates and other animals in medical research in New South Wales

I acknowledge the Gadigal People of the Eora Nation on whose land this Inquiry is being held, and pay respect to their Elders past, present and future. I also acknowledge the contribution of First Nations knowledges to science and medicine.

Thank you for the opportunity to make this submission which responds to Terms of Reference (a), (c), and (e).

(a) The nature, purpose and effectiveness of medical research being conducted on animals in New South Wales, and the potential public health risks and benefits posed by this research.

Institutions using animals in medical research in NSW

The University of Sydney Medical School and its affiliate institutes appear to be responsible for much of the medical research being conducted in New South Wales.[1] Some of this research uses animals. The affiliate institutes are the Anzac Research Institute, [2] the Centenary Institute,[3] the Children's Medical Research Unit, [4] the Heart Research Institute,[5] the Melanoma Institute Australia,[6] the Westmead Institute for Medical Research,[7] and the Woolcock Institute of Medical Research.[8] These affiliated institutes have research collaborations with other research partners nationally and internationally. Other universities and research centres in NSW also use animals in medical research.

Various forms of medical and scientific research are conducted on animals in New South Wales. Direct links to research publications can often be found on the websites of research

[1] See https://www.sydney.edu.au/medicine-health/our-research/sydney-medical-school.html.
[2] See https://anzac.edu.au/research/.
[3] See https://www.centenary.org.au/research/.
[4] See https://www.cmrijeansforgenes.org.au/research/research-teams.
[5] See https://www.hri.org.au/our-research.
[6] See https://melanoma.org.au/research/publications-and-papers/ .
[7] See https://www.westmeadinstitute.org.au/about/research-centres .
[8] See https://www.woolcock.org.au/research-overview .

institutes although the research publications of some groups may be harder to directly access. When this occurs, author searches on online medical research databases such as the US National Library of Medicine and National Health Institute's full text database can assist in discovering research in New South Wales in which animals have been used, and that has been published in Australian and international online medical journals.[9] Affiliations and international collaborations are also clearly signalled on research tools such as the Pubmed database hosted at the above central US site.[10] Researchers can also signal potential conflicts of interest including industry affiliations.

Numbers of animals used in research in NSW

Recent medical research in NSW has included a range of projects and studies using animals such as non-human primates (including baboons), mice, and cats. I will focus on these three species for the purposes of this submission. However, many more species of animals are used in research in NSW as revealed in the reports available on the Animal Ethics Infolink website provided by the Department of Primary Industries (DPI) and the Animal Research Review Panel (ARRP).[11] In 2020, the most recent reporting year available, 1,508,312 animals were used in research.[12] Excluding animals used in observation involving minor interference this number becomes 958,695.[13] The animals used include 30,814 amphibians, 393,127 aquatic animals, 441,729 birds, 161,886 domestic animals, 10,463 exotic feral animals, 66 exotic zoo animals, 424,170 laboratory animals, 31,164 native mammals, 217 primates, and 14,756 reptiles.[14]

Purposes of animal use in research in NSW

A breakdown of purposes of animal use in research in 2020 is given in the DPI and ARRP report.[15] 183,227 animals were used in human or animal biology research. 84,271 animals were used in human or animal health and welfare research. In addition, animals were used in other areas of research including 304,654 in stock breeding research; 9,899 in stock maintenance; 43,484 in education; 115,593 in animal management and production; 631,072 in environmental

[9] See https://www.ncbi.nlm.nih.gov/ ,
[10] Ibid.
[11] See https://www.animalethics.org.au/animal-use-statistics.
[12] See NSW Department of Primary Industries, December 2021, *NSW 2020 Animal use in Research Statistics*. Available as a PDF file at https://www.animalethics.org.au/animal-use-statistics, p 5.
[13] Ibid, p 9. Minor interference could include animals that were simply counted in environmental studies or were subject to non-invasive tests e.g., on their faeces.
[14] Ibid, p 5.
[15] Ibid.

study; 77,486 in production of biological products; 24,415 in diagnostic procedures; and 34,291 in regulatory product testing.[16]

Research procedures to which animals are subjected

The research procedures animals were subjected to in 2020 included: 549,697 observation involving minor interference; 111,511 animal unconscious without recovery; 362,254 minor conscious intervention (this can include trapping and euthanasia for collection of specimens); 18,112 minor surgery with recovery; 16,269 major surgery with recovery; 134,486 minor physiological challenge; 31,237 major physiological challenge; 10,926 death as an endpoint; 273,860 production of genetically modified animals. [17]

The most stressful or lethal procedures to which animals are subjected

Statistics relating to the number of animals used for human or animal biology research are further broken down into species and procedures in the report.[18] The most stressful or lethal procedures appear to be performed on laboratory animals such as mice and rats. Fish, poultry, and mice appear to have been subject to the most stressful or lethal procedures in research on human or animal health and welfare.[19] Guinea pigs and mice were most likely to be subject to procedures that had death as an endpoint which occurred mostly in regulatory product testing.[20]

A further breakdown of the categories shows that in research on human or animal biology, 12,201 animals were killed ("animal unconscious without recovery") and 14,497 were subjected to "major physiological challenge". 10,622 animals were subjected to "major surgery with recovery". It is not clear how many animals were euthanised within the category "minor conscious intervention."[21]

In research on human or animal health and welfare, 4,540 animals were killed ("animal unconscious without recovery") and 10,063 were subjected to "major physiological challenge". 5,347 were subjected to "major surgery with recovery". Again, it is not clear how many animals were euthanised within the category "minor conscious intervention."[22]

[16] Ibid, p 6.
[17] Ibid, p 7.
[18] Ibid, pp 15-16.
[19] Ibid, pp 17-18.
[20] Ibid, p 24.
[21] Ibid, p 10.
[22] Ibid, p 10.

Procedures on animals that should be immediately banned

The list of procedures carried out on animals in the annual DPI reports is disturbing. Procedures where animals may be killed clearly include "death as an endpoint", "animal unconscious without recovery" and "minor conscious intervention" whenever this latter procedure comprises trapping and euthanasia for collection of specimens. It is hard to comprehend how taking the life of a sentient being while conscious could be categorized as a minor conscious intervention and why it is placed in the same category as blood sampling. "Major surgery with recovery" and "major physiological challenge" are also of concern. "Animal Unconscious Without Recovery" is highly concerning as it includes vivisection followed by killing. The above procedures should all be prohibited in the Act.

Non-human primates - Baboons

Baboons have been regularly used to study pre-eclampsia in pregnant women. Funding for research using baboons in 2016 in which NSW researchers took part, came from an NHMRC Project Grant, an Australian Postgraduate Award, and the Howard Hughes Medical Institute (USA).[23]

The authors were affiliated with the following institutions: Medicine Faculty, Western Sydney University and Ingham Institute, Sydney; Medicine Faculty, University of New South Wales; Nephrology Department, Liverpool Hospital; Vascular Immunology Group, Heart Research Institute, Sydney; Nephrology Department, Melanoma Unit, and Obstetrics Department, Royal Prince Alfred Hospital, Sydney; Department of Surgery, University of Sydney; Anatomical Pathology Department and Vascular Surgery Department, Liverpool Hospital; Division of Nephrology, Massachusetts General Hospital, Boston; and Centre for Vascular Biology, Beth Israel Deaconess Medical Centre, Boston.

Earlier research on pre-eclampsia has included inducing the condition in pregnant baboons by the administration of low-dose Tumour Necrosis Factor-α for 2 weeks at mid-gestation.[24] One

[23] See Makris, A., Yeung, K. R., Lim, S. M., Sunderland, N., Heffernan, S., Thompson, J. F., Iliopoulos, J., Killingsworth, M. C., Yong, J., Xu, B., Ogle, R. F., Thadhani, R., Karumanchi, S. A., & Hennessy, A. (2016). Placental Growth Factor Reduces Blood Pressure in a Uteroplacental Ischemia Model of Preeclampsia in Nonhuman Primates. *Hypertension* (Dallas, Tex.: 1979), 67(6), 1263–1272. https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.116.07286

[24] See Sunderland, N. S., Thomson, S. E., Heffernan, S. J., Lim, S., Thompson, J., Ogle, R., McKenzie, P., Kirwan, P. J., Makris, A., & Hennessy, A. (2011). Tumor necrosis factor α induces a model of preeclampsia in pregnant baboons (Papio hamadryas). *Cytokine*, *56*(2), 192–199. https://doi.org/10.1016/j.cyto.2011.06.003

baby baboon died, and another baby baboon was orphaned when their mother died in this experiment.[25]

A 2021 review of international research on pre-eclampsia using animals also included reference to studies undertaken in NSW research facilities.

The authors acknowledged the limitations of translating pre-clinical animal studies to human clinical practice:

> (t)he presentation of preeclampsia in women is heterogenous with varying severity of maternal and fetal involvement at different stages of gestation. This is likely due to the complex interaction between pre-existing maternal health conditions, genetic susceptibility, the placenta as well as fetal susceptibility. Animal models may be able to replicate specific aspects of the pathophysiology but ultimately cannot predict the action of potential therapeutic agents in women. This limitation has been demonstrated both by varying responses to treatment in different animal models and by current attempts at the translation of preclinical studies to human trials where treatment efficacy has thus far been elusive (…).[26]

However, notwithstanding this acknowledgement of the limitations of using animal models, the review still concluded problematically that whole animal models still need to be used in pre-eclampsia research:

> Animal studies in hypertensive disorders of pregnancy have been vital to furthering the understanding of pathogenic pathways. The effect of various therapies on blood pressure in models of experimental preeclampsia needs to also be supported by evidence of improvement of feto-placental function or endothelial dysfunction but sadly, even when dramatic improvements in multiple facets are demonstrated, translation to clinical practice is still to be realised. This is not dissimilar to the success rates in other fields such as oncology where many potential therapeutic agents with strong evidence to support their efficacy in preclinical studies have failed in human studies. However, unlike other diseases, a disease of pregnancy cannot be studied without a whole animal model.[27]

The authors of the review were affiliated with the following institutions: Department of Renal Medicine, Blacktown Hospital; School of Medicine, Western Sydney University; Heart

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[25] See Maris Beck, "The monkey farm: Primates being bred for experiments," *The Age*, 25 November 2012, available at https://www.theage.com.au/national/victoria/the-monkey-farm-primates-being-bred-for-experiments-20121124-2a0gz.html (accessed 4 April 2022).

[26] Chau, K., Welsh, M., Makris, A., & Hennessy, A. (2021). Progress in preeclampsia: the contribution of animal models. *Journal of human hypertension*, 1–6. Advance online publication. https://doi.org/10.1038/s41371-021-00637-x.

[27] Ibid.

Research Institute, University of Sydney; Sydney Local Health District; South Western Sydney Clinical School, UNSW; Campbelltown Hospital, South Western Sydney Local Health District.

Mice

Mice have been used in research to determine how glucocorticoids work in rheumatoid arthritis,[28] how new combinations of therapies can target human melanoma,[29] and humanized FRG mice have been used as models for gene therapy studies.[30]

The use of humanized mouse models has complex ethical implications and has also occurred at the Illawarra Medical and Health Institute, Wollongong.[31]

The use of genetically modified mice to study the enhancement of Tristetraprolin (TTP) to reduce the effects of cigarette smoke induced experimental COPD was undertaken in collaboration by researchers affiliated with the following NSW institutions: Priority Research Centres for Healthy Lungs, Grow Up Well and Cancer Research, Innovation and Translation, Hunter Medical Research Institute, University of Newcastle; Woolcock Emphysema Centre, Woolcock Institute of Medical Research, University of Sydney; School of Chemistry, University of New South Wales; School of Biomedical Sciences and Pharmacy, Faculty of Health and Medicine, University of Newcastle; School of Life Sciences, Faculty of Science, University of Technology Sydney; Centenary Institute, Centre for Inflammation, University of Technology Sydney.[32]

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[28] See Hardy, R., Cooper, M.S. (2018) Unravelling how glucocorticoids work in rheumatoid arthritis. *Nature Reviews Rheumatology* 14, 566–567. https://doi.org/10.1038/s41584-018-0079-4. Affiliations of the authors are the Institute for Metabolism and Systems Research, University of Birmingham, Birmingham, UK and the ANZAC Research Institute, Concord Clinical School, University of Sydney, Sydney, New South Wales, Australia.

[29] See Emran, A. A., Tseng, H. Y., Gunatilake, D., Cook, S. J., Ahmed, F., Wang, S., Hersey, P., Gallagher, S. J., & Tiffen, J. C. (2021). A Combination of Epigenetic BET and CDK9 Inhibitors for Treatment of Human Melanoma. *The Journal of investigative dermatology*, 141(9), 2238–2249.e12. https://doi.org/10.1016/j.jid.2020.12.038

[30] See "More Information on Research Areas: Animal Models" at https://www.cmrijeansforgenes.org.au/research/research-teams/translational-vectorology (accessed 6/4/2022).

[31] See Sluyter, R., & Watson, D. (2020). Use of Humanized Mouse Models to Investigate the Roles of Purinergic Signaling in Inflammation and Immunity. *Frontiers in pharmacology*, 11, 596357. https://doi.org/10.3389/fphar.2020.596357

[32] Nair, P.M., Starkey, M.R., Haw, T.J., Liu, G., Collison, A.M., Mattes, J., Wark, P.A., Morris, J.C., Verrills, N.M., Clark, A.R., Ammit, A.J. and Hansbro, P.M. (2019), Enhancing tristetraprolin activity reduces the severity of cigarette smoke-induced experimental chronic obstructive pulmonary disease. *Clinical & Translational Immunology*, 8: e01084. https://doi.org/10.1002/cti2.1084

The Research funding for this project came from the Cancer Institute NSW (Cancer Institute NSW Fellowship), the Faculty of Health and Medicine, University of Newcastle (Gladys Brawn Fellowship), and the National Health and Medical Research Council.[33]

A recent list of potential science research projects at the University of Technology Sydney contains seventeen references to studies still using mice or unnamed animal models.[34]

Cats

In the past University of Sydney and University of Wollongong researchers carried out research in which anaesthetised cats held in stereotaxic frames were subjected to experiments on their eyes.[35] This what happened to the cats at the end of an experiment in 2000 as reported by the researchers:

> At the end of the recording session (lasting 2–6 days) the animals were deeply anaesthetized with an intravenous injection of 120 mg of sodium pentobarbitone and perfused transcardially (with descending aorta clamped) with 500 ml of warm (37°C) saline or Hartmann's solution followed by 1500 ml of a 4 % solution of paraformaldehyde in 0.1 M phosphate buffer (pH 7.4). The caudal halves of cerebral hemispheres were stereotaxically blocked and sectioned coronally at 50 µm on a freezing microtome, mounted on gelatinized slides, and counterstained with cresyl violet.[36]

The researchers had recorded that the "experimental procedures and husbandry follow the guidelines of the Australian *Code of Practice for the Care and Use of Animals for Scientific Purposes* and were approved by animal ethics committees at the University of Queensland, the University of Sydney and the Australian National University."[37]

In 2013, NSW and international researchers again performed procedures on the eyes of anaesthetised young adult cats during which they were subject to corneal epithelial wounding.[38] The researchers were affiliated with the following institutions: Vision CRC, Sydney; School of

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[33] Ibid.
[34] See UTS Graduate Research: Potential projects for future students in 2021 Research Session 2 https://www.uts.edu.au/sites/default/files/2021-04/Research%20projects%202021%20-%20science_2.pdf (accessed 7/4/2022).
[35] See Calford, M.B., Wang, C., Taglianetti, V., Waleszczyk, W.J., Burke, W. and Dreher, B. (2000), Plasticity in adult cat visual cortex (area 17) following circumscribed monocular lesions of all retinal layers. *The Journal of Physiology*, 524: 587-602. https://doi.org/10.1111/j.1469-7793.2000.t01-1-00587.x
[36] Ibid.
[37] Ibid.
[38] Petznick, A., Madigan, M. C., Garrett, Q., Sweeney, D. F., & Evans, M. D. (2013). Contributions of ocular surface components to matrix-metalloproteinases (MMP)-2 and MMP-9 in feline tears following corneal epithelial wounding. *PloS one*, *8*(8), e71948. https://doi.org/10.1371/journal.pone.0071948

Optometry and Vision Science, University of New South Wales; Save Sight Institute, University of Sydney; Brien Holden Vision Institute, Sydney; University of Western Sydney; CSIRO Materials Science and Engineering, Sydney and the Medical College of Georgia, USA.

The study recorded that one to three cats were killed at each predetermined timepoint of the study:

> One to three animals were sacrificed with an overdose of sodium pentobarbital (Virbac Australia Pty, Sydney, Australia) at each predetermined time point (prior to wounding; 8-, 16-, and 24-hours post-wounding, 48 hours, and wound closure; 7-, 14- and 28-days post-wounding). Ocular surface tissues, specifically the corneas, conjunctivas, lacrimal glands, and eyelids, were collected at each time point and fixed in 4% neutral buffered formalin, paraffin embedded and prepared for MMP-2 and MMP-9 expression (…).[39]

It is stated in the research paper that the studies "were conducted in accordance with the ARVO Statement for the Use of Animals in Ophthalmic and Vision Research and with approval from the Vision CRC and Brien Holden Vision Institute Animal Ethics Committee."[40] The research was supported by the Australian Federal Government through the Cooperative Research Centres Program (Vision CRC).[41] Vision CRC was funded by the Federal Government for twelve years from 2003 to 2015 during which time it received total funding of $59 million.[42]

This type of research using cats and then killing them is still occurring as documented by Humane Research Australia.[43] It continues although there has been strong community outrage about such experiments. It is highly concerning that Animal Ethics Committees are still approving such invasive and lethal research on animals. Invasive and lethal procedures on other animals including kittens, greyhounds and beagles, marmosets, macaques, baboons, primates, mice, rats, rabbits, wallabies, cephalopods, pigs, sheep, and day-old chicks, have been documented by Humane Research Australia and are available in case studies on their website.[44]

Preventing disease rather than using animals to find a cure

It is undeniable that medical research is needed to find ways to manage and cure diseases and conditions that affect children and adults. However, public funding would be better spent on

[39] Ibid.
[40] Ibid.
[41] See the company profile for Vision CRC at https://www.mtpconnect.org.au/Company?Action=Profile&Company_id=200
[42] See "Vision CRC Information" at https://rocketreach.co/vision-crc-profile_b4440e74faaa080b
[43] See https://www.humaneresearch.org.au/casestudies/cats/
[44] See https://www.humaneresearch.org.au/case-studies/

more public health education to prevent smoking rather than forcing tiny, humanized animals to smoke to study how to improve treatment of smoking-related COPD.

The issue of tobacco products still being legal, when they cause so much ill-health, suffering and death, alongside immense public health costs, also needs to be decisively and finally addressed by a total ban. To be forcing animals to smoke is absurd and cruel and disregards the true problem i.e., smoking.

Research that compares adverse pregnancy-related outcomes (including pre-eclampsia) to obesity severity in pregnant women, is an example of research that does not involve invasive tests on animals.[45] It also focuses on prevention rather than cure.

(c) The availability, effectiveness, and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 Rs of Replacement, Reduction and Refinement

There are many alternative approaches to animal research methods and technologies. These are listed in detail and at length in the latest *Animal Use Statistics Report 2020* found on the Animal Ethics Infolink website.[46] There are also strong arguments that it is time to go beyond the use of the 3Rs. I understand there may be submissions to this Inquiry which will give greater detail about the need for this.

Organisations that provide a resource base for researchers who wish to use alternatives approaches to the use of animals in medical research include the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART),[47] Johns Hopkins University Center for Alternatives to Animal Testing,[48] National Centre for the Replacement Refinement and Reduction of Animals in Research (UK-based but dedicated to helping the research community worldwide),[49] National Anti-Vivisection Society, Chicago,[50] Alternatives

[45] See Neal, K., Ullah, S., & Glastras, S. J. (2022). Obesity Class Impacts Adverse Maternal and Neonatal Outcomes Independent of Diabetes. *Frontiers in endocrinology*, *13*, 832678. https://doi.org/10.3389/fendo.2022.832678
[46] See *Animal Use Statistics Report 2020*, note 12 above, pp 34-62.
[47] See https://anzccart.org.nz/alternatives-to-animals/
[48] See https://caat.jhsph.edu/
[49] See https://www.nc3rs.org.uk/
[50] See https://navs.org/learn-more/alternatives-to-animals-in-research/

to Animal Testing in Australian Research,[51] and Medical Advances without Animals (MAWA).[52] Humane Research Australia has many more resources and centres listed on its website as well as information about funding.[53]

The principles of academic freedom

Adherence of institutions to the principles of academic freedom would indicate that there should be no barriers for medical researchers who wish to pursue alternative approaches to animal research methods and technologies.[54] The National Tertiary Education Industry Union (NTEU) takes a strong stance on protecting academic freedom and has been supported in this by the Federal Court in late 2021.[55]

A prospective PhD candidate in medicine or science who wants to avoid research using animals will also seek a supervisor whose research interests coincide with their own research priorities and interests. It should follow that funding applications for research using approaches alternative to animal use should be judged based on the merit of a research proposal and respect for the academic freedom of the researcher. Logically, there should be no barrier here, although others may have different views based on experience.

The principles of academic freedom are subject to the law. If a total ban on the use of animals in medical and scientific research was introduced by Parliament, there would be no conflict here.

Alternative approaches to animal research methods and technologies

Research is being conducted at the Heart Institute (affiliated to the University of Sydney Medical School) where microsystems are being developed to replicate blood vessel dynamics

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[51] See http://alternatives-to-animal-testing-in-australian-research.org/Alternative%20Methods

[52] See http://www.mawa-trust.org.au/ Their website is currently under development but contact details are available on the site for further information.

[53] See https://www.humaneresearch.org.au/for-researchers/

[54] See, for example, the University of Sydney's *Charter of Academic Freedom* which was revised and renamed in 2020 as the *Charter of Free Speech and Academic Freedom*, available as a PDF file via https://www.sydney.edu.au/news-opinion/news/2019/12/10/charter-of-freedom-of-speech-and-academic-freedom-to-be-adopted.html, (accessed 8/4/2022).

[55] See "Australia: Court upholds University of Sydney's collective agreement protecting academic freedom" available at https://www.ei-ie.org/en/item/25324:australia-court-upholds-university-of-sydneys-collective-agreement-protecting-academic-freedom (accessed 8/4/2022). See also Adrienne Stone, 'The Meaning of Academic Freedom: The Significance of *Ridd v James Cook University*' [2021] SydLawRw 10; (2021) 43(2) *Sydney Law Review* 241. Available online at http://classic.austlii.edu.au/au/journals/SydLawRw/2021/10.html

to potentially reduce the use of animals in pre-clinical testing of new therapies.[56] The new University of Sydney Nano Research Institute is also doing research in certain areas to replace the use of animals.[57]

A lay person with a concern that the rights of animals be respected may struggle to understand why animals are still being used when research shows many other alternatives are available. However, it is heartening to see that a growing cohort of medical researchers are actively exploring alternative approaches to animal research methods and technologies. At the same time, on reviewing the research, it is clear some researchers still actively advocate animal use in medical research and encourage postgraduate researchers to do likewise.

(e) The adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability

The regulatory regime regarding the use of animals in medical research in NSW includes legislation, regulations, national guidelines, animal ethics committees (AECs), and local health district animal welfare committees. The supply of animals for research is also regulated and overseen by the Department of Primary Industries. Some may argue that the regulatory regime is reasonably strong. However, it could also be argued that it is still inadequate to fully protect animals. Certain tests or types of testing are still permitted which should be prohibited by law. In fact, to fully protect animals it is clearly necessary to take decisive action to phase out and cease all use of animals in medical research.

A regime of transparency and accountability?

The *Animal Research Act 1985* (NSW) ("ARA") and the *Animal Research Regulation 2021* (NSW) ("ARR") govern the conditions under which animal research may be conducted. The object of the Act is to protect the welfare of animals used in all research (i.e., not only medical research) and there are legislative requirements that need to be met by researchers using animals and by suppliers of animals to research. Authorisations may only be granted for recognised research purposes. The Act was intended to set up a regime of transparency and accountability. If the Act is currently failing to do this, it needs to be improved rather than be

[56] See https://www.hri.org.au/our-research/cardiovascular-medical-devices/micro-system-to-replicate-blood-vessel-dynamics
[57] See https://www.sydney.edu.au/nano/industry-partners/themes/health-and-medicine.html

replaced by a general animal welfare statute with the regulatory regime for the use of animals in research being relegated to regulations and a licensing scheme, and the danger of the existing protections being weakened. The law must give clear guidance in a context where some researchers clearly still fail to acknowledge the sentience, rights, and bodily integrity of animals.

The Draize test, LD50 test and lethality tests – less transparency in future?

It is of strong concern that the current animal welfare law reform process may see less transparency and accountability regarding the use of animals in medical research. At present the ARA refers to types of tests performed on animals in laboratory research situations. These include the Draize test being "the animal research procedure involving the application of any material or substance to the eye of an animal for the purpose of determining the irritancy of that material or substance to the eye"[58] and the LD50 test – "the animal research procedure in which any material or substance is administered to animals for the purpose of determining the concentration or dose of the material or substance which will achieve any predetermined death rate."[59] The third test of strong concern the Act currently refers to are lethality tests, "meaning 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."[60]

However, the proposed new Animal Welfare Act ("AWA"), which is planned to replace the ARA, will contain no similar provisions. The excision of any reference to these tests in the proposed new AWA may effectively mean a greater level of secrecy about the existence of such tests. As the tests are extremely cruel, it is highly concerning that there will be an apparent additional layer of secrecy about their use. The use of the Draize test, the LD50 test and lethality tests should be banned in the Act.

Australian code for the care and use of animals for scientific purposes **("the Code")[61]**

The Code was created in 1969 and has been periodically revised by the Code reference group which includes representatives from the NHMRC, CSIRO, the Australian Research Council,

[58] *Animal Research Act 1985* (NSW) ("ARA"), s3.
[59] Ibid.
[60] ARA s56A.
[61] National Health and Medical Research Council (2013) *Australian code for the care and use of animals for scientific purposes*, 8th edition. Canberra: National Health and Medical Research Council. https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes

Universities Australia, relevant state and federal departments, the RSPCA, and Animals Australia. It is hard to understand how the Code's governing principles and ethical framework to guide decisions, when put into practice, still result in the approval of animal experimentation that is highly concerning.

Animal Ethics Committees (AECs)

The Code, Chapter 2.3, describes the responsibilities of the AECs. Animal research cannot be undertaken without the approval of the AEC. In the past there has been criticism of AECs for allowing certain research to be approved. In fact, in 2012, AECs were referred to as one of the reasons alternatives to animal use are not being utilized.[62] Ten years later it is not clear whether the situation is changing rapidly enough. More transparency is still needed. However, there is also currently strong support from within the universities for the work of AECs who have allegedly been aiming to achieve a balance between the priorities of research and the welfare of animals used in research and encouraging the use of the 3Rs.[63] At first glance it might seem that if members of the animal rights community were included in the AECs and the Animal Research Review Panel, alongside existing animal welfare members, this might assist in better balancing the AECs and improving the protection of animals used in research. However, it appears AECs may still be unable to protect animals while, in some instances, academic careers are being built on animal cruelty. Unfortunately, it also is doubtful that the opinions of animal rights members would carry any significant weight in a context where they could be essentially marginalised lay members of a committee. Animals will continue to suffer in medical research until their use in such research is clearly and unequivocally prohibited by the law.

A culture of non-disclosure?

Section 6 of the Code provides for independent external review of the operation of institutions. However, as far as it has been possible to establish, it appears the independent external review reports may not publicly available.

[62] See Maris Beck, op cit, note 24 above who refers to comments by Professor Anne Keogh.
[63] See reference to the role played by AECs in the submission by the University of New South Wales to the current Inquiry into Animal Welfare Policy in New South Wales at https://www.parliament.nsw.gov.au/lcdocs/submissions/77552/0105%20University%20of%20New%20South%20Wales,%20Professor%20Sven%20Rogge.pdf

Researchers are also known to hide behind commercial in-confidence reasons for limiting disclosure about tests done on animals prior to publishing their research.[64] This will always be an aspect of privately or part-privately funded research.

As referred to above, animal use statistics are published each year by the Department of Primary Industry NSW and the Animal Research Review Panel.[65] However, there is no indication about which institution uses the different procedures on animals. As documented earlier in this submission, it is necessary to look at medical and scientific research publications to see who is doing what to animals.

The escape of the baboons

The escape of three baboons at Royal Prince Alfred Hospital in Sydney in 2020 brought the breeding of animals for medical research again to public attention.[66] Investigation revealed they were part of a national baboon colony located at Wallacia, NSW, where they were reportedly bred for scientific purposes. It was also revealed that information about the colony, including the numbers bred, was not publicly available and information about four-yearly inspections of the facility was not published.[67] This demonstrated the secrecy that surrounds the breeding of animals for medical research. This secrecy needs to cease.

The Sydney Local Health District Animal Welfare Committee (SLHDAWC) was set up to provide ethical review, oversight and advice regarding research, teaching and other activities undertaken within facilities of the Sydney Local Health District (SLHD). These include RPAH Animal House, the Institute of Academic Surgery, RPA Surgical & Robotic Training Institute, ANZAC Research Institute – Molecular Physiology Unit, ANZAC Research Institute – Translational Research Facility, the Australian National Baboon Colony, and the following affiliated institutions: Heart Research Institute and Centenary Institute of Cancer Medicine and Cell Biology. Further information on the functioning of the SLHD AWC is available in their Terms of Reference and Operating Guidelines.[68]

[64] See Maris Beck op cit. note 24 above.
[65] See notes 11 and 12 above.
[66] Calla Wahlquist, "Sydney baboon escape: the questions that remain," *The Guardian*, 26 February 2020. Available at https://www.theguardian.com/science/2020/feb/26/sydney-baboon-escape-questions (accessed 3 April 2022).
[67] Ibid.
[68] See https://www.slhd.nsw.gov.au/rpa/research/content/pdf/awctor21-03.pdf

It may be possible to find further information about the RPAH Animal House and the Australian National Baboon Colony by contacting the SLHDAWC or even by contacting the relevant facilities directly to see if the members of the current committee of Inquiry can inspect the sites.

In conclusion: The costs to the animals

The costs to the animals of the interventions they experience need to be factored into any examination of the costs associated with animal research. Animals are not objects to be exploited without acknowledgement of the immense cost to them of being subjected to invasive and sometimes lethal experiments. Their lives and sentience have value even though research proposals may not account for this. To use a sentient being as an object of experimentation is a disregard of the inherent rights of that living, feeling being. It could be strongly argued that attenuating pain and suffering through use of medications and anaesthesia does not make the exploitation of animals any less immoral and does not lessen the harshness of the reality of what occurs in the laboratory. The performance of lethal experiments on an animal that no one would contemplate performing on a human being, disregards the sentience and intrinsic value of that animal and ignores the cost to that animal of losing their life. It is also highly concerning that certain species of animals are still being bred to be experimented on and killed when alternatives are clearly available. As stated previously in this submission the only way to ensure animals are not harmed or exploited in medical research is for a total ban on their use in this context.

Thank you for considering my views.

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