

Submission  
No 245

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

**Organisation:** Animal Defenders Office

**Date Received:** 11 April 2022

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# Animal Defenders Office

Using the law to protect animals

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The Chair  
Portfolio Committee No. 2 - Health  
Parliament House  
Macquarie Street  
Sydney NSW 2000

11 April 2022

By email: [PortfolioCommittee2@parliament.nsw.gov.au](mailto:PortfolioCommittee2@parliament.nsw.gov.au)

Dear Sir/Madam

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

Thank you for the opportunity to provide a submission to the Inquiry into the use of primates and other animals in medical research in New South Wales (“the Inquiry”) by the Portfolio Committee No. 2 – Health.

The Animal Defenders Office notes that the primary legislation relevant to this inquiry – the *Animal Research Act 1985* (NSW) – is currently the subject of review as part of the inquiry into animal welfare policy in New South Wales (“NSW”).<sup>1</sup> As the inquiry is ongoing, this submission is based on the current legislative and regulatory framework.

Our comments on the Inquiry’s terms of reference are set out below.

**About the Animal Defenders Office**

The Animal Defenders Office (“ADO”) is a not-for-profit community legal centre that specialises in animal law. The ADO provides pro bono animal law services to the community. The ADO is a member of Community Legal Centres NSW Inc., the peak body representing community legal centres in NSW.

Further information about the ADO can be found at [www.ado.org.au](http://www.ado.org.au).

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**General Comments**

Hobbes’ seventeenth-century description of ‘the life of man, solitary, poor, nasty, brutish and short’<sup>2</sup> could also describe the life of a laboratory animal in contemporary Australia. Animals used for invasive medical research are bred to be harmed and killed. Just under a million animals were bred and/or used for this kind of research in NSW in 2020.<sup>3</sup> Given the immense suffering inflicted by humans on animals used for medical research, the ADO supports phasing out the use of animals in medical research in favour of modern, more humane, and more reliable methods and technologies. The ADO submits that the NSW Government must prioritise and support the development of

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<sup>1</sup> <https://www.parliament.nsw.gov.au/committees/inquiries/Pages/inquiry-details.aspx?pk=2853#tab-termsofreference>.

<sup>2</sup> Thomas Hobbes 1651, *Leviathan*, Part 1, Chapter 13.

<sup>3</sup> NSW Department of Primary Industries (“DPI”), *NSW 2020 Animal Use in Research Statistics* [the most recent available at the time of writing this submission], p 9, <https://www.animaletics.org.au/animal-use-statistics>.

non-animal alternatives to animal research. The ADO also submits that the current regulatory regime fails to provide sufficient accountability and transparency to address community concerns about the welfare of the many hundreds of thousands of sentient animals used each year for invasive medical research in NSW.

**Term of reference (a): the nature, purpose and effectiveness of medical research being conducted on animals in NSW, and the potential public health risks and benefits posed by research.**

The primary goal of medical research conducted in NSW is to develop knowledge about human health and physiological processes.<sup>4</sup>

While animal experimentation may have constituted one of the main ways to achieve this goal in the past, this is no reason to continue to accept that the use of animals in biomedical research is still appropriate today. Nonhuman animals – even chimpanzees, who belong to the closest related living species to humans (aka *Homo sapiens*) – do not share the same physiological processes as humans. Indeed, not all human groups are good models for other human groups – a point that has only recently been recognised. For example, medical treatments that have been tested clinically only on men have been found to yield results that are inappropriate when applied to female patients.<sup>5</sup>

Moreover, the use of animals in medical research for humans is now at odds with contemporary attitudes in Australia. A survey conducted in 2018 by Humane Research Australia found that:

- 70% of respondents opposed the use of dogs in research.
- 63% of respondents opposed the use of monkeys in research.
- 45% of respondents believed that animals are necessary for the development of human medicine – a figure which has declined from 50% in 2013 and 59% in 2008.<sup>6</sup>

When it comes to assessing the effectiveness of animal experimentation in Australia, it must be pointed out that neither the ADO, nor the community in general, can do this unless steps are taken to improve transparency and public access to data. Given that significant numbers of animals are used in research in NSW,<sup>7</sup> and that research can be funded by the taxpaying public,<sup>8</sup> the ADO submits that information regarding the type of experiments and the outcomes must be made readily available and in non-technical language. The ADO also submits that it is the responsibility of bodies that fund or commission research using taxpayers' money, such as the National Health and Medical Research Council ("NHMRC") and state equivalents, to publish summaries of animal research projects that concluded in the reporting period. The summaries could be based on existing

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<sup>4</sup> National Health and Medical Research Council, *Australian code for the care and use of animals for scientific purposes*, 2013; updated 1 June 2021, 8th edition, 1.5(i), 1.6(i)-(ii).

<sup>5</sup> Irving Zucker, Brian J. Prendergast. 'Sex differences in pharmacokinetics predict adverse drug reactions in women', *Biology of Sex Differences*, 2020; 11 (1) DOI: 10.1186/s13293-020-00308-5

<sup>6</sup> <https://www.humaneresearch.org.au/achievements-2018/>.

<sup>7</sup> NSW DPI, *NSW 2020 Animal Use in Research Statistics*.

<sup>8</sup> The National Health and Medical Research Council ("NHMRC") funds animal research:

<https://www.nhmrc.gov.au/research-policy/ethics/animal-ethics/use-animals-nhmrc-funded-research>. The NHMRC became an independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act) on 1 July 2006.

information contained in end-of-project reports provided to animal experimentation ethics committees, and de-identified to maintain confidentiality.

The ADO's primary concern is to reduce and eventually eliminate the immense suffering of animals used for invasive medical research in Australia. Fortunately, this objective benefits not only animals, but also aligns with improving efficacy in human health research and embracing contemporary technological advancement. Given the downward trajectory of public support for the use of animals in research and the exponential upward trajectory of alternative technologies,<sup>9</sup> the ADO submits that the NSW Government must aim to phase out the use of animals in medical research within a specified timeframe.

**Term of reference (b): the costs associated with animal research, and the extent to which the New South Wales and Federal Government is commissioning and funding the importing, breeding and use of animals in medical research in New South Wales.**

The ADO notes the lack of readily available information about State funding for the importing, breeding and use of animals in medical research in NSW. In NSW, information on how much public money is granted to animal research projects is not collected.<sup>10</sup> This is a concern, as the public has a right to know and have access to information on how public funds are used to fund animal research.

The NHMRC provides some funding at the federal level.<sup>11</sup> It is not clear, however, how much funding is directed towards animal research projects or how much is spent on importing and breeding animals.

***The ADO recommends that a reporting framework be established in NSW to report on the amount of public money directed towards animal research, including importing and supplying animals, and the types of projects funded.***

**Term of reference (c): the availability, effectiveness and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 R's of Replacement, Reduction and Refinement.**

*Focussing on alternatives*

The first Governing Principle in the *Australian Code for the Care and Use of Animals for Scientific Purposes* ("the Code") advocates applying the principles of Replacement, Reduction and Refinement 'at all stages of animal care and use'.<sup>12</sup> This requirement in the Code is reflected in community attitudes, with 67% of respondents in the 2018 poll referred to earlier supporting the allocation of medical research grants to finding scientific alternatives to animal experiments.<sup>13</sup>

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<sup>9</sup> Medical Advances Without Animals, <http://www.mawa-trust.org.au/#>.

<sup>10</sup> Based on correspondence with the NSW DPI animal welfare department.

<sup>11</sup> <https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes/australian-code-care-and-use-animals-scientific-purposes-code>. 'NHMRC funding summary, 2020-21' in *NHMRC Annual Report 2020-21*, p11, <https://www.nhmrc.gov.au/file/17478/download?token=ROzbPXjP>.

<sup>12</sup> National Health and Medical Research Council, *Australian code for the care and use of animals for scientific purposes*, 2013; updated 1 June 2021, 8th edition, 1.1.

<sup>13</sup> <https://www.humanerresearch.org.au/achievements-2018/>.

Significant investigations into viable alternatives have already been conducted in Australia. For example, the Replace Animals in Australian Testing Project, led by researchers from the University of Wollongong in 2010, identified viable alternatives to the use of millions of animals used in experiments each year in Australia.<sup>14</sup> Technologies have only improved since then, and exponentially so. Alternative, non-animal techniques and methods include ‘organ-on-a-chip’ microdevices, as developed by researchers from Harvard;<sup>15</sup> human-derived tissue models; human blood derivatives; computer modelling (in silico modelling); and human volunteers.<sup>16</sup>

### *Funding alternatives*

In the ADO’s view, instead of remaining bound to the animal experimentation paradigm, we need to move forward and begin investing more in alternatives that better model *humans*, and the diversity that exists in this one species. There is a strong case to be made in favour of the economic and scientific benefits for developing alternatives.<sup>17</sup> With dedicated funding for alternatives that will increase and fast-track translation of medical research to human application, NSW has the potential to become a leader in scientific innovation. The ADO submits that committing and implementing funding for alternative approaches to using non-human animals for biomedical research should be a high priority for the NSW Government. The goal should be to invest in the development of alternative methods to the extent that they achieve cost-parity (or better) with animal models. This would allow researchers to run more trials, and thereby ensure that their results are reliable, accurate and humane.

This call for funding to develop and implement alternatives to using animals in biomedical research is not new. In the 1980s the Australian Senate Select Committee on Animal Welfare conducted an inquiry into animal experimentation.<sup>18</sup> In its report released in 1989, the Commonwealth committee recommended:

... that the Commonwealth Government establish a separate fund for research into the use of alternatives to animal experimentation and that grants be disbursed from this fund by a board composed of representatives of the scientific community, animal welfare organisations... and government authorities.<sup>19</sup>

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<sup>14</sup> Boyde, Melissa and Denise Russell, ‘The RAAT Project: Alternative to using animals in research’ (2010) <https://ro.uow.edu.au/cgi/viewcontent.cgi?article=2854&context=artspapers>. See also ‘Animal Experiments. Get educated.’, *Animal Liberation Queensland* (2002) <https://alq.org.au/animal-experiments>.

<sup>15</sup> Huh D, Matthews BD, Mammoto A, Montoya-Zavala M, Hsin HY, Ingber DE, ‘Reconstituting organ-level lung functions on a chip’, *Science*, 2010 Jun 25; 328(5986):1662-8. doi: 10.1126/science.1188302.

<sup>16</sup> Cheluvappa R, Scowen P, Eri R, ‘Ethics of animal research in human disease remediation, its institutional teaching; and alternatives to animal experimentation’, *Pharmacology Research & Perspectives*, 5( 4), 2017, e00332, <https://doi-org.virtual.anu.edu.au/10.1002/prp2.332>.

<sup>17</sup> See, for example, <https://www.humanerresearch.org.au/wp-content/uploads/2021/02/Final-business-case-Feb-2021.pdf>.

<sup>18</sup>

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/significant%20reports/animalwelfarect/animalexperimentation/index](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/significant%20reports/animalwelfarect/animalexperimentation/index).

<sup>19</sup> Parliament of the Commonwealth of Australia, *Animal Experimentation. Report by the Senate Select Committee on Animal Welfare*, 1989, p xv.

### *Legislating for alternatives*

The ADO submits that it should no longer be left to the discretion of researchers, institutions, and animal experimentation ethics committees to determine whether alternatives are developed and used. There must be legislative requirements that:

- a proportion of research projects authorised by a research establishment must relate to developing and validating alternatives,<sup>20</sup> and
- individuals applying for an animal research authority must include detailed particulars of their consideration of non-animal alternatives in their application.<sup>21</sup>

### *Personal experience – membership of AEECs*

ADO volunteers include animal-welfare category members of animal experimentation ethics committees (“AEECs”).<sup>22</sup> In their experience, the principles of refinement and reduction are mentioned occasionally by researchers, while replacement is almost never mentioned. It is not part of the culture of researchers to consider alternatives. At most, standard words about ‘monitoring the literature’ are used in protocol applications. This entrenched behaviour is what needs to change in animal research in NSW, and it will only change if pressure is exerted from outside the industry – that is, if mandated by legislation and funding conditions.

### *Dedicated 3Rs centre*

Currently there is no national or state specific centre or programs for the development of non-animal alternatives in Australia. Dedicated centres exist around the globe, including in the USA and Europe.<sup>23</sup> The NSW Government should consider committing its support to, and initiating a national process to implement, an Australian centre for developing and validating alternatives.<sup>24</sup> However, while a national approach in Australia is preferable, the ADO supports the creation of an interim state institution for the advancement of non-animal alternatives and technologies in NSW. At the very least, the NSW Government should allocate meaningful funding to programs and grants aimed at reducing the numbers of animals used in medical research. These measures would demonstrate NSW’s commitment to the principle of replacement and would help define a timeline for phasing out animal use in medical research.

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<sup>20</sup> This requirement could be inserted in section 25 ARA.

<sup>21</sup> These requirements could be inserted in sections 25A and 26A ARA.

<sup>22</sup> ‘Category C—a person with demonstrable commitment to, and established experience in, furthering the welfare of animals...’, the Code, clause 2.2.4(iii).

<sup>23</sup> NHMRC, *Information Paper: The implementation of the 3Rs in Australia*, 2019, chapter 5 ‘International 3Rs Centres’; and <https://kb.rspca.org.au/knowledge-base/what-are-the-3rs-in-animal-research/>.

<sup>24</sup> Media Release, Humane Research Australia, ‘Proposed EU phase out of animal experimentation is a wake up call for Australia’, 28 September 2021, <https://www.humaneresearch.org.au/proposed-eu-phase-out-of-animal-experimentation-is-a-wake-up-call-for-australia/>.

**The ADO recommends that:**

- **Detailed consideration of non-animal alternatives be a legislative requirement for the issue of animal research authorities relating to biomedical research.**
- **Research establishments be required to ensure that a proportion of authorised research projects relate to developing and validating alternatives.**
- **The NSW Government fund research into and development of non-animal alternatives in biomedical research.**
- **The NSW Government work with the other States, Territories, and the Commonwealth to establish a national centre for developing alternatives to animal use in biomedical research.**

**Term of reference (d): the ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research.**

*Ethical and animal welfare concerns*

The ADO is concerned about the significant animal welfare implications of medical research involving animals. Current categories of invasive animal research procedures include ‘major surgery with recovery’, ‘major physiological challenges’, and ‘death as an endpoint’ (ie where researchers do not intervene to kill the animal before certain levels of suffering are reached).<sup>25</sup> In 2020 in NSW more than 58,400 animals were reportedly used for these three procedures.<sup>26</sup> There are serious ethical concerns about using animals in research where they will not only suffer but have their lives terminated.

*Importing non-human primates into Australia for research purposes*

The importation of non-human primates into Australia for research purposes is a significant ethical and animal welfare issue. In 2015 a Bill to ban live imports of primates for research was introduced into the Australian Senate and led to a Senate Inquiry into the issue.<sup>27</sup> The report by the Committee of Inquiry found that between 2000 and 2015, the Australian Department of the Environment issued 370 import permits for live primates for research purposes, including pigtail macaques and owl monkeys.<sup>28</sup> The transit of animals such as primates from other countries to NSW has serious animal welfare and animal protection consequences, including death due to stress-induced illness and, if they are not bred in captivity, ongoing psychological harm due to the separation of primates from their family groups in their habitat.<sup>29</sup>

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<sup>25</sup> NSW DPI, *NSW 2020 Animal Use in Research Statistics*, Appendix B, pp 66-67.

<sup>26</sup> NSW DPI, *NSW 2020 Animal Use in Research Statistics*, 2.4 ‘Number of animals used over time by research procedure’, p 7. The table in 2.4 has a breakdown of the numbers for each category.

<sup>27</sup>

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Environment\\_and\\_Communications/EP\\_BC\\_Live\\_Primates\\_Bill](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Environment_and_Communications/EP_BC_Live_Primates_Bill).

<sup>28</sup> Environment and Communications Legislation Committee [Report](#), Commonwealth of Australia, 15 March 2016, par. 1.23.

<sup>29</sup> Sentient The Veterinary Institute for Animal Ethics and Barristers Animal Welfare Panel, *Submission No 56 to Senate Standing Committees on Environment and Communications, Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015* (2015) 1-2; Cruelty

### *Immediate prohibition of some research projects*

The ADO acknowledges that a gradual phasing-out of the use of animals for invasive medical research would be the most viable option for ending the use of animals for such research. There are, however, certain experiments currently performed in NSW which, in the ADO's view, are unethical and unnecessary<sup>30</sup> and should be banned immediately. These are:

- Forced inhalation research, where mice are exposed to cigarettes and other hazardous inhalants over lengthy periods of time;<sup>31</sup> and
- The forced swim test,<sup>32</sup> where animals are made to swim in a container of water until they eventually stop struggling – a procedure which has been formally decommissioned by leading global pharmaceutical companies such as Bayer, Johnson & Johnson, Pfizer, AstraZeneca, amongst others.<sup>33</sup>

As these procedures inflict considerable harm on the animals and for dubious benefits to humans, the ADO submits that these procedures must be legislatively banned in NSW.

### *Immediate prohibition of some research animals*

Further, while the ADO advocates for the protection of all species, it proposes that medical testing and research using primates, dogs and cats be phased out as soon as possible, as it arguably no longer accords with the majority view of the Australian public. The 2018 poll discussed earlier found that 70% of respondents opposed the use of dogs in research and 63% opposed the use of monkeys.<sup>34</sup>

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Free International, *Submission No 48 to Senate Standing Committees on Environment and Communications, Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015* (2015).

<sup>30</sup> F Sewell et al, 'Preclinical screening for antidepressant activity – shifting focus away from the Forced Swim Test to the use of translational biomarkers', *Regulatory Toxicology and Pharmacology*, vol. 125, October 2021, 105002, <https://www.sciencedirect.com/science/article/pii/S0273230021001434>

<sup>31</sup> N Anderson (2021) *Optimising inhalation research: Transitioning to human-relevant science*. <https://www.humanerresearch.org.au/wp-content/uploads/2021/11/Optimising-inhalation-research-transitioning-to-human-relevant-research.pdf>.

<sup>32</sup> National Centre for the Replacement Refinement & Reduction of Animals in Research (UK), 'The forced swim test is not a regulatory requirement for the development of new antidepressants', 29 July 2021: 'The rodent forced swim test is used to test the antidepressant potential of new drugs. It involves placing a rodent in a container of lukewarm water from which it attempts to escape. Failing to do so, the animal becomes immobile and is removed after a set time. The durations for which the animal is active and then immobile are recorded and used to indicate antidepressant activity.' <https://www.nc3rs.org.uk/news/forced-swim-test-not-regulatory-requirement-development-new-antidepressants>.

<sup>33</sup> Millard SJ, Lum JS, Fernandez F, Weston-Green K, Newell KA. *The effects of perinatal fluoxetine exposure on emotionality behaviours and cortical and hippocampal glutamatergic receptors in female Sprague-Dawley and Wistar-Kyoto rats*. *Prog Neuropsychopharmacol Biol Psychiatry*. 2021 Jun 8;108:110174. doi: 10.1016/j.pnpbb.2020.110174. Epub 2020 Nov 12. PMID: 33189859. See also People for the Ethical Treatment of Animals, 'Victories! PETA is ending near-drowning experiments on animals.' PETA.org. <https://www.peta.org/features/peta-ends-near-drowning-tests-small-animals>.

<sup>34</sup> <https://www.humanerresearch.org.au/achievements-2018/>. The ADO suggests that a similar response would be received regarding the use of cats.



The ADO supports the ban on using Great Apes for biomedical research in Australia.<sup>35</sup> The ADO submits that the ban should be extended to other primate species. All primates are sentient and cognitively complex animals, who share the same interests in avoiding harm. The guidelines pertaining to the use of non-human primates for scientific purposes in Australia (“the non-human primates guidelines”) refer to the Great Apes as ‘the closest species to human beings with the most advanced social and behavioural skills,’ and asserts that this status ‘raises even greater ethical concerns than that of other non-human primates.’<sup>36</sup> The ADO submits that how ‘close’ a species is to humans is ethically irrelevant when it comes to the fundamental interest of sentient beings in avoiding harm. Ironically, if anything, being ‘the closest species to human beings’ would make the Great Apes more suitable for biomedical research than other non-human primates.

#### *Meaning of ‘good welfare’*

To the extent that ‘good welfare’ is taken to mean the reduction or minimisation of suffering, the paradigm of ‘welfare’ in medical animal research needs to be fundamentally reconsidered. Ensuring good welfare does not end at sparing animals from ‘unnecessary’ suffering, providing them with sufficient food and water to keep them alive, or ensuring that their tiny cages are ‘enriched’. The vast majority of animals used in medical research, such as birds, mice, guinea pigs, and fishes, are complex, social beings. These animals, if free to live in a home with human companions or in the wild, would be engaging in a range of social relations with humans and/or other animals, employing their creativity and problem-solving skills to face challenges in their environment, and using their autonomy to make choices about the kinds of lives they want to live. It is highly questionable whether such important activities are possible – to a sufficient extent, or even at all – in the context of animals’ confinement in a research setting.

For these reasons, there are now calls for the adoption of the ‘Five Domains’ framework (Nutrition, Environment, Health, Behaviour, Mental state) for research animals, which places more emphasis on not only the physical welfare of animals, but also their mental wellbeing.<sup>37</sup> The ADO supports the adoption of the Five Domains framework for animals used in medical research until animals are replaced by non-animal alternatives. The additional requirements placed on researchers and research establishments under the framework and any associated costs would act as further disincentives to continue to use live animals.

#### ***The ADO recommends that:***

- ***The NSW Government prioritise funding for alternatives to using non-human animals for biomedical research.***
- ***Forced inhalation research and swim tests be prohibited in legislation.***
- ***The policy ban on using Great Apes for medical research be legislated and extended to all primates.***

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<sup>35</sup> National Health and Medical Research Council, *Principles and guidelines for the care and use of non-human primates for scientific purposes*, September 2016, Part A, pars 5-6.

<sup>36</sup> *Ibid*, par. 2.

<sup>37</sup> RSPCA Australia 2020, ‘What are the Five Domains and how do they differ from the Five Freedoms?’, *RSPCA Knowledgebase*, <https://kb.rspca.org.au/knowledge-base/what-are-the-five-domains-and-how-do-they-differ-from-the-five-freedoms/>.

- ***The ‘five-domains’ framework be adopted for research animals in Australia.***

**Term of reference (e): the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability.**

The use of animals for research and teaching purposes in NSW is governed by the *Animal Research Act 1985* (NSW) (“AR Act”). Public service employees who are also veterinary practitioners may be appointed as inspectors for the purposes of the AR Act (s49). The regulatory regime is informed by the Code which is incorporated into NSW legislation.<sup>38</sup>

The ADO’s general comments on the current regulatory framework<sup>39</sup> and those regarding transparency and accountability are set out below.

*Sentience*

- A major failing of the AR Act in its current form is that it refers only to promoting animal welfare in the context of research and does not acknowledge the sentience of animals. The failure to acknowledge animal sentience explicitly in the AR Act’s objects clause is out of step with contemporary understandings about animal protection in 21st century Australia.
- This is reflected in contemporary animal welfare legislation in other common law jurisdictions such as the UK, where the Animal Welfare (Sentience) Bill was introduced in the House of Lords in May 2021.<sup>40</sup>
- The sentience of animals is one of the core reasons why they are used for medical research. Acknowledging sentience in legislation that deals with research animals should be uncontroversial.
- NSW is lagging behind other Australian jurisdictions in its recognition of animal sentience. The Australian Capital Territory amended its *Animal Welfare Act* in 2019 to acknowledge animal sentience and the intrinsic value of animals in the objects clause of the Act (s 4A(1)). Victoria has committed to recognising animal sentience as part of modernising its animal welfare laws.<sup>41</sup> On 24 February 2022 a Private Members Bill was introduced in the NSW Legislative Council to amend the *Prevention of Cruelty to Animals Act 1979* (NSW) to recognise the sentience of animals and their intrinsic value.<sup>42</sup> The ADO strongly recommends that any regulatory framework covering animal research also acknowledge animal sentience and the intrinsic value of animals.

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<sup>38</sup> *Animal Research Regulation 2021* (NSW), regulation 4.

<sup>39</sup> The ADO acknowledges the ongoing reform of animal welfare legislation in NSW, as part of which the provisions of the AR Act may be incorporated into the proposed Animal Welfare Bill 2022 (NSW) and as yet unpublished regulations; <https://www.dpi.nsw.gov.au/animals-and-livestock/animal-welfare/animal-welfare-reform>.

<sup>40</sup> <https://bills.parliament.uk/bills/2867>. As at 24/03/2022 the Bill had been through both Houses of Parliament and was at the ‘consideration of amendments’ stage which occurs after the 3<sup>rd</sup> reading in the House of Commons. The Bill is scheduled to return to the House of Lords in April 2022 for consideration of Commons amendments.

<sup>41</sup> ‘Victorians In Favour Of New Animal Welfare Act’, The Hon Daniel Andrews, Premier of Victoria, Press Release, 29 April 2021, <https://www.premier.vic.gov.au/victorians-favour-new-animal-welfare-act>.

<sup>42</sup> Prevention of Cruelty to Animals Amendment (Animal Sentience) Bill 2022, introduced by Abigail Boyd MLC (NSW Greens), <https://www.parliament.nsw.gov.au/bills/Pages/bill-details.aspx?pk=3946>.

### *Animal Care and Ethics Committees*

- The membership of an Animal Experimentation Ethics Committee should include at least one (voting) member with demonstrated knowledge and commitment to replacing animal models.

### *Accreditation and Licensing*

- In order to improve transparency, NSW should maintain a public list of accredited animal research establishments.

### *Animal usage*

- There is very little transparency and accountability regarding the use of animals in medical research, which is extremely concerning given the serious welfare implications for the almost one million animals used in experiments last year in NSW.<sup>43</sup> The current framework relies too heavily on a system of 'enforced self-regulation' under the AR Act, with the result that most information about research on animals is kept out of the public eye.<sup>44</sup>
- The ADO again refers to the Senate Select Committee on Animal Welfare's 1989 report on its inquiry into animal experimentation.<sup>45</sup> The Committee recommended that:

The Commonwealth, State and Territory Governments publish annually accurate and comprehensive information on the extent and forms of animal experimentation, conducted within their respective jurisdictions.

- The ADO submits that animal research in NSW should be subject to more rigorous public disclosure requirements, including the disclosure of the numbers of animals used for biomedical research and the broad outcomes of the research projects (eg development of drug, drug moved to clinical trials on humans, number of peer-reviewed publications, etc).
- The ADO notes the draft 'Openness Agreement on Animal Research in Australia'.<sup>46</sup> The ADO supports this initiative but suggests that all research institutions should be required to report on all biomedical animal-use, including numbers used and wastage, and not just the 'good news stories'.

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<sup>43</sup> Boyde, Melissa and Denise Russell, 'The RAAT Project: Alternative to using animals in research' (2010) <https://ro.uow.edu.au/cgi/viewcontent.cgi?article=2854&context=artspapers>. See also 'Animal Experiments. Get educated.', *Animal Liberation Queensland* (Web Page, 2002) <<https://alg.org.au/animal-experiments>>.

<sup>44</sup> The animal research industry is required under the AR Act to self regulate: AR Act, section 2A(1); Monika Merkes and Rob Buttrose, 'The elusive ethics of animal ethics committees', 20 November 2012 <https://theconversation.com/the-elusive-ethics-of-animal-ethics-committees-10056>.

<sup>45</sup> [https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/significant%20reports/animalwelfare/ctt%E2%80%8Ce%E2%80%8C/animalexperimentation/index](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/significant%20reports/animalwelfare/ctt%E2%80%8Ce%E2%80%8C/animalexperimentation/index), p xv.

<sup>46</sup> <https://anzccart.adelaide.edu.au/openness-agreement-public-consultation>.

### *Complaints and review mechanisms*

- The complaints and administrative review mechanisms under the current framework are important accountability mechanisms. However, it would appear that these mechanisms are rarely if ever used.<sup>47</sup> From the ADO's experience, this is not for the want of trying.
  - The ADO recently represented members of the public who wished to challenge a decision by a researcher not to release certain animals who survived a research project, so that they could be rehomed at the end of the project. The individuals made a complaint to the Animal Research Review Panel ("ARRP") under the AR Act. The ARRP referred the complaint to the NSW Department of Primary Industries ("DPI").<sup>48</sup> The complaints process was lengthy due to slow responses from the relevant agencies and a refusal by the DPI to release certain critical information. Ultimately the individuals sought review of the relevant administrative decisions in the NSW Civil and Administrative Tribunal ("the Tribunal").<sup>49</sup> While the case involved an important issue of public policy (rehoming of laboratory animals at the end of their use for research), it was stymied at the outset by poor conduct by the DPI. This government agency, which is supposed to act as a model litigant, withheld crucial information from the complainants throughout the lengthy complaints process, and then relied on the applicants' failure to refer to the information (which was concealed from them) to persuade the Tribunal that it lacked jurisdiction. The DPI thus succeeded in avoiding having the matter heard by the Tribunal.
- The case study exemplifies the challenges faced by members of the public in holding decision-makers to account in an animal research context.
- Where complaints are made, there is limited information on outcomes such as whether the complaint was investigated, charges were laid, or prosecutions initiated.<sup>50</sup>

### *General reporting*

- In NSW, general information must be reported by Accredited Animal Research Establishments<sup>51</sup> (other than schools)<sup>52</sup> to the NSW DPI<sup>53</sup>. While reporting has been consistent since 2002,<sup>54</sup> the details which can be gleaned from this information are limited and do not enable the community to assess key aspects of the animal research industry such

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<sup>47</sup> NSW DPI, *Animal Research Review Panel Annual Report 2020-21*, 2.12 (p20): 'In the 2020-21 reporting period, no statutory complaints were made under the Act.'

[https://www.animaethics.org.au/data/assets/pdf\\_file/0006/1388121/Annual-Report-2020-21.pdf](https://www.animaethics.org.au/data/assets/pdf_file/0006/1388121/Annual-Report-2020-21.pdf).

<sup>48</sup> AR Act, s 12.

<sup>49</sup> Case number 2019/00396471.

<sup>50</sup> For example, the *Animal Research Review Panel Annual Report 2017-18*, 2.12 (p 13) merely states: 'In the 2017-18 reporting period one complaint was received';

[https://www.animaethics.org.au/data/assets/pdf\\_file/0011/1135658/animal-research-review-panel-annual-report-2017-18.pdf](https://www.animaethics.org.au/data/assets/pdf_file/0011/1135658/animal-research-review-panel-annual-report-2017-18.pdf).

<sup>51</sup> *Animal Research Act 1985* (NSW) ss 3, 18, 46-47 – in order to carry out research on animals, the establishment carrying out the research must be registered.

<sup>52</sup> *Animal Research Regulation 2021* (NSW) s 24.

<sup>53</sup> <https://www.animaethics.org.au/animal-use-statistics>.

<sup>54</sup> *Ibid*.

as the general types of research projects approved in a reporting period, the effectiveness of the research or of the implementation of the 3Rs, or the level of animal wastage.<sup>55</sup>

- For the purpose of transparency, comprehensive reporting is essential. Reporting should include the following:
  - Number of projects approved each year and any that were not approved.
  - Information on research that has succeeded in reaching objectives i.e., translating to human advancements and research that has failed.
  - Information on how the 3Rs are being implemented; for example, a database which collates projects which use alternative methods or develop alternative methods.
  - Information on how much funding animal research receives annually, and how much of that is funded publicly.
  - The outcomes of complaints made.

#### *Lethality and Draize Tests*

- Lethality tests (where animals are administered substances to determine at what dose death will be caused)<sup>56</sup> and the Draize eye test (where substances are forced into the eyes of animals to determine their harmfulness)<sup>57</sup> can still be carried out subject to approvals from ethics committees and reporting<sup>58</sup>.
- The ADO submits that, to improve transparency, and until these extremely harmful experiments are prohibited, information about approved lethality tests should be more comprehensive and published in plain English, to enable the general public to properly evaluate the tests.<sup>59</sup> Similarly, information about approved Draize tests should be included in the annual statistical reports.

#### *Forced Swim Test, Forced Inhalation Research*

- As discussed under Term of Reference (c), the ADO recommends that the use of forced swim tests and forced inhalation research be legislatively prohibited due to the significant harm inflicted on animals and dubious scientific outcome.<sup>60</sup>

#### *Fate of animals*

- The *NSW Animal Use in Research Statistics* reports now include information about the ‘fate’ of animals after their use in research ends.<sup>61</sup> Reporting on the fate of animals is mandatory only for domesticated dogs and cats used in research.<sup>62</sup> Reporting is voluntary for all other animal groups.<sup>63</sup> This is unacceptable from a transparency standpoint. Firstly, while the report does include information about other animal groups, this information is not sufficiently specific; animals are clumped into broad groupings such as “birds” and “exotic

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<sup>55</sup> <https://www.animalethics.org.au/three-rs>.

<sup>56</sup> *Animal Research Act 1985* (NSW) s 56A(4).

<sup>57</sup> *Animal Research Act 1985* (NSW) s 3 for definition.

<sup>58</sup> *Animal Research Act 1985* (NSW) ss 26 (3) and (4)(a) and (b), 56A.

<sup>59</sup> Basic information is currently reported in the annual *Animal Use in Research Statistics* reports eg *NSW 2020 Animal Use in Research Statistics*, Part 5, pp 29-33; <https://www.animalethics.org.au/animal-use-statistics>.

<sup>60</sup> <https://www.humanerresearch.org.au/case-studies/> - includes experiments in NSW.

<sup>61</sup> *NSW 2020 Animal Use in Research Statistics*, Part 4, pp 25-28.

<sup>62</sup> *Animal Research Regulation 2021* (NSW), clause 24(4).

<sup>63</sup> NSW DPI, *NSW 2020 Animal Use in Research Statistics*, Part 4, p 25.

feral mammals”, which encompass a broad range of animals. Furthermore, there is no ethical justification for requiring reporting on cats and dogs but not other species. The ADO submits that reporting on the fate of all animals should be mandatory.

### *Rehoming*

- NSW is to be commended for introducing the voluntary Research Animal Rehoming Guidelines.<sup>64</sup> The ADO submits that they should be incorporated in legislation and made mandatory, and that animal welfare legislation (the AR Act or any future animal welfare law) should give legal effect to clause 3.4.2 (‘Rehousing’) in the Code.
- The ADO is aware of two charities that currently operate in Australia: Liberty Foundation Australia and Beagle Freedom Australia.<sup>65</sup> The ADO submits that these and other organisations should be assisted with government funding to help coordinate rehoming of surviving research animals once they are no longer used or kept for research purposes.

### *Inspectors*

- Animal research facilities are not accessible to the public, which means that any breaches of the Code and relevant legislation can only be reported by employees, animal experimentation ethics committees or inspecting officers. Powers of inspectors are broad, without the need of a warrant.<sup>66</sup> However, due to lack of information about inspections, it is difficult to determine whether inspectors exercise their powers of entry without prior announcement to conduct pro-active inspections.
- The ADO notes that inspectors must be public service employees who are also veterinary practitioners.<sup>67</sup> The ADO suggests that this may unnecessarily restrict the pool of potential individuals who may be appointed as inspectors for the purposes of enforcing the relevant legislation.

### *Animals and projects not covered by legislation*

- The ADO submits that hatching projects should be prohibited under the animal research regulatory framework. Hatching projects are acknowledged around the world as having serious animal welfare concerns.<sup>68</sup> If hatching projects are not proscribed under the animal research regulatory framework, then they should at least be subject to the standard regulatory requirements under animal research laws (that is, they should not be exempted from these requirements).

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<sup>64</sup> [https://www.animaethics.org.au/data/assets/pdf\\_file/0005/1275251/Research-Animal-Rehoming-Guidelines.pdf](https://www.animaethics.org.au/data/assets/pdf_file/0005/1275251/Research-Animal-Rehoming-Guidelines.pdf).

<sup>65</sup> <https://www.libertyfoundation.org.au/>; <https://www.beaglefreedomaustralia.org/>.

<sup>66</sup> *Animal Research Act 1985* (NSW) s 50 in general and specifically s 50(3).

<sup>67</sup> *Animal Research Act 1985* (NSW) s 49.

<sup>68</sup> See RSPCA Australia: <https://kb.rspca.org.au/knowledge-base/what-are-the-animal-welfare-issues-with-chick-hatching-in-schools/>; Animal Kind (UK): <http://animalkind.org.uk/wp-content/uploads/2019/10/AA-Hatching-Worksheet.pdf>; United Poultry Concerns (USA): <https://www.upc-online.org/hatching/>.

*The ADO recommends that:*

- *The regulatory framework covering animal research also acknowledge animal sentience and the intrinsic value of animals.*
- *Membership of an Animal Experimentation Ethics Committee should include at least one member with demonstrated knowledge of and commitment to replacing animal models.*
- *Animal research in NSW should be subject to more rigorous public disclosure and reporting requirements.*
- *The Research Animal Rehoming Guidelines should be incorporated into legislation.*
- *Reporting on the fate of all animals should be mandatory.*
- *Rehoming charities should receive (more) government funding.*
- *Hatching projects should not be exempt from animal research requirements and should ultimately be prohibited.*

**Term of reference (f): overseas developments regarding the regulation and use of animals in medical research.**

Jurisdictions around the world have taken significant steps to phase out the use of animals in medical research and prioritise non-animal alternatives.

#### **European Union**

- In September 2021 the European Parliament voted to accelerate the transition to innovation **without the use of animals** in research, regulatory testing and education, affirming that ‘European citizens have consistently demonstrated support for an end to the use of animals for scientific purposes’.<sup>69</sup> The EU Parliament resolved to achieve its goal by, inter alia:<sup>70</sup>

...establishing a high-level inter-service taskforce ... to work with the Member States and relevant stakeholders to draw up an EU-wide action plan, with the aim of driving the active phase-out by reducing, refining and **replacing** procedures on live animals for scientific and regulatory purposes, as soon as scientifically possible and without lowering the level of protection for human health and the environment, while **accelerating the development of the alternative animal-free methods, technologies and instruments necessary for change**; stresses that a clear and ambitious timeline and list of milestones should be set out to incentivise progress;...

#### **UK**

- The National Centre for the Replacement Refinement and Reduction of Animals in Research (“NC3Rs”) is an independent UK-based scientific organisation dedicated to the 3Rs, originally set

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<sup>69</sup> European Parliament, ‘European Parliament resolution of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education’ (2021) par. H. [https://www.europarl.europa.eu/doceo/document/TA-9-2021-0387\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2021-0387_EN.html)

<sup>70</sup> Ibid, par. 1, emphasis added.

up in 2004 in response to the House of Lords Select Committee report on Animals in Scientific Procedures, which recommended establishing a national centre to help advance the 3Rs.<sup>71</sup>

### **Netherlands**

- Previous and current governments of the Netherlands have committed to being largely free of animal testing by 2025 or within the near future.<sup>72</sup>

### **USA**

- The proposed *FDA Modernization Act of 2021* was introduced into the Senate on 10 July 2021 and would allow:<sup>73</sup>

...an applicant for market approval for a new drug **to use methods other than animal testing** to establish the drug's safety and effectiveness. Under this bill, these alternative methods may include cell-based assays, organ chips and microphysiological systems, sophisticated computer modeling, and other human biology-based test methods.

- The Centre for Contemporary Sciences was established in 2020 in the US with the goal of:<sup>74</sup>  
...pioneering a paradigm shift towards innovative, evidence-based research methods that are based on human biology... and that replace animal testing.

### **Australasia**

- In New Zealand, the *Animal Welfare Act 1999* prohibits any research, testing or teaching involving the use of a non-human hominid (defined as a gorilla, chimpanzee, bonobo, or orangutan) unless approved by the Director-General.<sup>75</sup>

The ADO hopes that NSW can join these international jurisdictions in implementing real and innovative measures to improve human health through human-specific medical research, in light of one attribute that is truly shared between humans and other animals – the capacity to suffer.

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These submissions were prepared with assistance from the following volunteer ADO officers:

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Thank you for taking these submissions into consideration.

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<sup>71</sup> <https://www.nc3rs.org.uk/3rs-public>.

<sup>72</sup> <https://www.maastrichtuniversity.nl/will-netherlands-ever-be-free-animal-testing>.

<sup>73</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/2952?s=1&r=3> (emphasis added).

<sup>74</sup> <https://contemporarysciences.org/#about-us>.

<sup>75</sup> *Animal Welfare Act 1999* (NZ), s 85(1),  
<https://www.legislation.govt.nz/act/public/1999/0142/latest/DLM49664.html>.