Submission No 257

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

Name: Ms Sel Burek

Date Received: 4 April 2022

The Director

Portfolio Committee No.2—Health

Parliament House

Macquarie Street

Sydney NSW 2000

By email: PortfolioCommittee2@parliament.nsw.gov.au

Dear Committee Members

Submission to the NSW Legislative Council Portfolio Committee No. 2 - Health inquire into and report on the use of primates and other animals in medical research in New South Wales.

INTRODUCTION

The inquiry into the use of primates and other animals in medical research in New South Wales is a highly important inquiry and I am grateful for the opportunity to make a submission.

Millions of vulnerable animals are used in medical experiments each year in Australia, yet little is known about the animal research industry. Concerningly, the industry is largely self-regulated and there is limited knowledge about the fate of the animals used and killed in medical research annually. There is also limited knowledge about the approval processes for proposals, the types of experiments animals are subjected to each year and how or whether the principles of Replacement, Reduction, and Refinement are being implemented.

The objective of the legislative framework in NSW is to protect animals used in research and regulate the industry. However, it cannot fulfill its assigned purpose of protecting animals because it sanctions cruel practices and essentially acts as a shield for the approval process for animal research projects. To achieve genuine protection of animals, the legislative framework would have to commit to ending the exploitation of animals in research[1]. Thus, at present, a realistic goal of the regulatory framework is to improve animal welfare by reducing the use of animals used in research and improving the wellbeing of animals trapped in the research industry. To achieve this, the legislation would have to provide for husbandry practices which are integral to animal welfare, such as environmental enrichment, exercise and access to the outdoors, and enact a compulsory rehoming program. The legislative framework

[1] Katrina Sharman, Opening the Laboratory Door: National and International Legal Responsibilities for the Use of Animals in Scientific Research - An Australian Perspective, 2006.

would also have to be updated to incorporate the principles of Replacement, Reduction and Refinement, provide for proper scrutiny of animal research proposals, and mechanisms for independent assessments of the outcome of research and systematic reviews of animal research.

While to fulfil its aim of regulating the industry the NSW legislative framework must provide for transparency and independent oversight of animal research. Comprehensive reporting, independent memberships on animal ethics committees and the Animal Research Review Panel, and unannounced audits would need to be introduced to achieve this end.

Morally the use of animals in research cannot be justified, due to inherent and unresolvable welfare issues, and the availability of alternatives. Research involving the use of animals is defended based on claims of providing 'life-saving' advances for humans or more vague assertions of being very beneficial or important. These claims require interrogation to determine if they are in fact evidence based. Particularly as there is compelling scientific evidence[2] that these claims are overblown and that countless animals are needlessly used in research. And while science is paramount in the interrogation of these claims, the legislative process also has an imperative role to play.

In addition, NSW is the only state with a separate legislative framework for animals in research. This approach should be preserved, and the relevant legislative framework should not be subsumed into one animal welfare act (which is currently being updated).

SUMMARY

My submissions will focus on providing recommendations to achieve transparency and accountability within the research industry, reduce the numbers of animals exploited and meaningfully improve the wellbeing of animals used in medical research each year.

The following core factors are essential to updating the legislative framework so that it might achieve the objective of improving animal welfare and regulation of animal research:

- Transparency in the form of comprehensive reporting.
- Independent oversight of the research industry, such as impartial membership on animal ethics committees and the Animal Research Review Panel, and unannounced audits.
- Incorporation of the principles of Replacement, Reduction and Refinement and enshrining the development of alternatives in legislation.
- Independent assessment of research outcomes and systematic reviews of animal research.
- Funding programs dedicated to developing and validating alternatives.

[2] https://www.humaneresearch.org.au/hra-resources/key-research-articles/.

- Animal welfare standards which mandate exercise of animals and access to the outdoors.
- A mandated rehoming program.

(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;

Background

In New South Wales in 2019, over one and a half million animals were used in research[3], with over ten million used nationally[4]. Animals used include primates[5], mice, rats, guinea pigs, rabbits, dogs, cats, sheep, cows, pigs, and fish[6].

Animals are used in various tests that can be broadly grouped into the following categories: drug/toxicity testing, models for diseases and production of biological products (including xenotransplantation). There are serious ethical concerns about using animals in research where they are confined to labs, where they suffer and where they have their lives terminated. Experiments where animals are subjected to major physiological challenges or surgeries, lethality tests, and Draize eye tests are permitted under the legislative framework and carried out each year in NSW and across the nation.

When viewing the statistics, important categories are 'laboratory mammals', 'primates' and 'fish', as these are the animals who are primarily experimented on and then killed. The figures show that there has been a large increase in the use of animals in the 'laboratory mammals' category since 2010[7]. While categories such as 'native mammals' are usually observational studies, not studies where animals are experimented on and killed.

Animal welfare concerns are compounded by the fact that there is compelling scientific evidence that challenges the validity of using animals in research[8]. There are serious questions about animal research being translatable to humans and resulting in beneficial outcomes[9]. For example, 95 per cent of drugs tested on animals fail in clinical trials[10]. This raises potential public health risks due to the concerns

[3] NSW 2019 Animal Use in Research Statistics – most current statistics available.
[4] https://www.humaneresearch.org.au/statistics-2018-animal-use-in-research-and-teaching-australia/.
[5] https://www.nhmrc.gov.au/about-us/resources/use-non-human-primates-scientific-purposes.
[6] NSW 2019 Animal Use in Research Statistics.
[7] NSW 2019 Animal Use in Research Statistics, pg. 6, 2. General Charts.
[8] https://www.humaneresearch.org.au/hra-resources/key-research-articles/.
[9] Pandora Pound and Michael B Bracken, Is animal research sufficiently evidence based to be a corner stone of biomedical research? 2014.
[10] Thomas Hartung, Food for Thought Look Back in Anger – What Clinical Studies Tell Us About Preclinical Work, 2013.

associated with the validity of animal research to humans, and possible lost opportunities as insufficient resources are dedicated to developing and implementing alternatives to animal experimentation.

Absence of Information

In NSW, general information must be reported by Accredited Animal Research Establishments[11] (other than schools)[12] to the NSW Department of Primary Industries ('NSW DPI')[13]. And while reporting has been consistent since 2002[14], the reporting requirements are low, and only limited information can be gleaned from what is currently reported. As stated: '*The aim of collecting these statistics is to give some indication of the level of 'invasiveness' of the procedures on the animals and to provide data on the use of animals in research and teaching*'[15]. This sets too low a threshold, and the information submitted does not allow for determinations to be made about the effectiveness of research, the precise experiments animals are subjected to or the level of suffering they are exposed to and who carries out this research. No information is provided on the implementation of the essential principles of Replacement, Reduction and Refinement.

Thus, at present, it is difficult to form a view of the nature, purpose and, in particular the effectiveness of medical research conducted in NSW, due to an absence of transparency and proper comprehensive reporting.

Recommendations

The effectiveness and the public health risks associated with medical research on animals will only be able to be measured once there is comprehensive reporting. This would necessarily include statistics on research which has reached its objectives, and which has failed i.e., not translated to humans or failed for other reasons. This is important as animal trials that have failed are not usually published and this effects results when doing systematic reviews of the efficacy of animal research for humans.

Information should also be collected on how and where the principles of Replacement, Reduction and Refinement are implemented and barriers to their implementation. Further recommendations on annual reporting discussed below. Lastly, regular retrospective assessments of animal research and its validity to humans in NSW should become part of the reporting scheme.

[11] *Animal Research Act 1985* (NSW) ss 3, 18, 46-47.
[12] *Animal Research Regulation 2021* (NSW) s 24.
[13] https://www.animalethics.org.au/animal-use-statistics.
[14] Ibid.
[15] Ibid.

Over three decades ago, a Commonwealth inquiry into animal experimentation resulted in two important recommendations[16], which continue to remain relevant and are essential for improving animal welfare in research. The recommendations were: that states and territories annually publish comprehensive information on animal experimentation, and that the Commonwealth establish a separate fund for research into the use of alternatives to animal experiments. Although this was a Commonwealth inquiry, both these recommendations are applicable at state level, and they are integral to creating transparency and improving the welfare of animals.

(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;

Hundreds of millions of dollars are spent on animal research across Australia each year[17], with the National Health and Medical Research Council being a major grant funder at the federal level[18]. However, at present it cannot be determined how much funding is directed towards animal research projects, how much is spent on importing and breeding and how much is going towards alternatives to using animals in experimentation. These details are not collated and published. Similarly, in NSW, no information on how much money is granted to animal research projects is available as this information is not collected[19]. Details and transparency as to where funds are going is essential, particularly where public money is being used.

Recommendations

A system to track and collect information on how much money is used in research involving animals should be introduced in NSW. Information on how much public money is directed towards animal research, including importing and supply of animals, and the types of projects funded should then be made available to the public. This should also include how much funding is diverted to projects which use alternatives to animals in research.

16 https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/significant%20reports/animalwelfarectte/animalexperimentation/index.

17 Australian Government Science Research and Innovation Budget Tables 2018-2019.

18 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.

19 Based on correspondence with the NSW DPI animal welfare department.

Imperatively, there needs to be a separate fund dedicated to the implementation and development of alternatives to animal experimentation.

(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;

Based on the developments in many overseas countries and regions, there is a growing availability of alternatives to using animal models in medical research, including centres which are entirely dedicated to developing alternatives. However, Australia appears to be trailing behind, with barriers such as funding and education/training[20] identified as primary impediments to progress.

Beyond identifying barriers, making accurate determinations on the current availability and effectiveness of alternative approaches to animal research in NSW is not possible as specific information related to alternatives is not available because it is not collated or published in the annual reports. Similarly, as discussed above, there is no specific information on funding for research which utilises alternatives to animal research, or how much money is granted towards the development of alternatives to animal experimentation.

Under the legislative framework, the present reporting scheme is general, and research establishments are not required to provide specific information on projects using alternatives to animal research. Further, the legislative framework offers only minimal guidance as to how the 3 Rs are to be met. The *Australian code for the care and use of animals for scientific purposes* (2013) ('the Code') and the *Principles and guidelines for the care and use of non-human primates for scientific purposes (2016)* only provide guidelines for the principles of Replacement, Reduction and Refinement and some criteria for how these principles might be applied in practice. While in NSW, the principles of Replacement, Reduction and Refinement are not defined or included in the NSW legislative framework for animals in research.

Unfortunately, based on the statistics of animal use, there does not appear to have been any significant reduction in animals used in research in the last decade, rather the use of animals in laboratories has increased[21].

[20] Information Paper-The Implementation of the 3Rs in Australia (2019) NHMRC; Animal Ethics Committee education and training resources survey (2020) ARRP, https://www.animalethics.org.au/__data/assets/pdf_file/0008/1321388/AEC-survey-summary.pdf.

[21] NSW 2019 Animal Use in Research Statistics, pg. 6.

Recommendations

To assess the availability and effectiveness of alternatives to animal experimentation, the reporting scheme needs to be expanded to include reporting of projects which apply alternatives to animal experimentation. Funding bodies would also have to be compelled to collect and provide figures for how much money is directed towards alternatives each year. While to improve the availability and effectiveness of alternatives, a fund would need to be dedicated to expanding new technologies which do not use animals in research and for regular training of researchers and members on animal ethics committees and the Animal Research Review Panel. Further, many similar jurisdictions, such as Canada, the US and the EU have all set up centres which are dedicated to validating alternatives to animal testing. Funding, including funding training and education, is integral to creating a cultural shift towards new technologies and innovation.

Importantly, the principles of Replacement, Reduction and Refinement need to be enshrined in the *Animal Research Act 1985* (NSW), and the development of alternatives to animal research.

Researchers would have to demonstrate how they are meeting these principles before approval for research proposals could be granted. This would entail including a comprehensive definition of the three R's and criteria that must be satisfied in order for researchers to demonstrate that they are meeting those principles. At present there are examples of criteria found in the Code but no mandated provisions. Examples of specific criteria (taken from the Code) that researchers would have to satisfy could include clear descriptions of the steps taken to consider and apply the 3 Rs and the number of animals required and the justification for this number[22]. The Code also outlines that before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined[23]. The Code provides examples of replacement techniques, consideration of which should be mandated and regularly updated as technology advances[24]. Further criteria could include steps taken to ensure there is no 'doubling up' i.e., that research projects are not simply repeating studies that have already been carried out. And systematic reviews which demonstrate the translatability of the particular research area to humans. Information sharing between research establishments should be facilitated to reduce the repeating of research.

[22] *Australian code for the care and use of animals for scientific purposes* (2013) cl 2.7.4.
[23] Ibid 1.19.
[24] Ibid 1.19

The approval process must also ensure that proposals do not preclude the same level of scrutiny because they appear at first instance not to have alternatives, for example in circumstances where a project seeks to refine an animal model.

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

There are myriad ethical and animal welfare issues surrounding the use of animals in medical research, including breeding facilities and transportation of animals. Animals are sentient, capable of both physical and psychological suffering, and they are forcibly used in research which often causes great stress and suffering. Animals are used in lethality tests, Draize eye tests, and other tests involving major surgeries and 'major physiological challenge', which subjects animals to extreme suffering. Further, even if animals used in experimentation do not die, they are usually euthanised when they are no longer needed as there are no rehoming programs.

There are serious ethical concerns about using sentient beings in research that exposes them to confinement and harm, and then death when they are no longer of use. Further, there have been continued reports of highly concerning experiments that inflict grave suffering on animals, and experiments where the objective are dubious.

Lastly, there is no rehoming program to at least give some of the animals subjected to research a chance at life. Animals used in research spend their entire lives inside laboratories in cages, and either die as part of the experiment or are discarded when they are no longer of use. This is an indictment of how little value is assigned to the lives of animals used in research.

Welfare Standards Under the Regulatory Framework

The understanding of what constitutes good animal welfare has evolved beyond the Five Freedoms, which are archaic, developed approximately 60 years ago in the context of intensive farming practices. Good welfare encompasses far more than just the provision of food, water, and shelter. Contemporary animal welfare science is more aligned with the Five Domains Model[25] and A Life Worth Living[26], which provides for not just an avoidance of negative impacts on animals but provides for positive impacts, a major example being the ability to live a natural life which necessitates the freedom to move, engage in natural behaviours and have meaningful access to the natural environment.

[25] https://www.four-paws.org.au/campaigns-topics/topics/science-and-research/the-animal-welfare-concept.

[26] David J. Mellor, Updating Animal Welfare Thinking: Moving beyond the "Five Freedoms" towards "A Life Worth Living"; ACT Animal Welfare & Management Strategy 2017-2022.

It is difficult, and in the case of some species not possible, to meaningfully meet animal welfare standards within the animal research field. Further, the regulatory framework offers general guidelines which cannot attain the objective of good animal welfare. The Code outlines basic provisions, while the *Animal Research Act 1985* (NSW) and the *Prevention of Cruelty to Animals Act 1979* (NSW) contain only general provisions about supplying food, water and shelter, with laboratory animals exempt from having to be exercised[27].

The Code does contain a fairly comprehensive definition of 'wellbeing', however, the basic guidelines provided cannot meet the aim of this definition. Specific standards for animal husbandry in research facilities would have to be set, including mandating environmental enrichment, exercise, and access to the outdoors. The Code for primates mandates access to outdoors, but there are broad exemptions[28].

A wide range of animals are used for research in NSW, from mice and rats to cats, dogs and primates. Whilst most research uses mice and rats, their sentience and ability to suffer means their welfare must be treated as equally important as other animals. The welfare requirements of animals such as cats, dogs, and primates are more complex due to longer lifespans, much greater space requirements for exercise, housing, and to meet behavioural needs. Laboratory environments cannot meet those needs and those animals should cease being used in research.

Recommendations

At a minimum, any research where animals are exposed to pain, or 'major physiological challenge' should be prohibited. Lethality tests and Draize eye test should be prohibited.

Any research causing pain and distress (apart from low levels of stress and pain in observational studies, where animals might be fitted with tags, and which benefit wild animals) should be prohibited. Animals with more complex welfare needs and greater space and exercise requirements should be prohibited from use in laboratory research, this would include cats, dogs, primates, farmed animals and wild animals.

A rehoming program should be mandated under the legislative framework, with researchers having to demonstrate that they can meet the requirements of such a program.

[27] *Prevention of Cruelty to Animals Act 1979* (NSW) ss 8-9.
[28] *Principles and guidelines for the care and use of non-human primates for scientific purposes* 2016, Part B.

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

Legislative Framework

In NSW animal research is regulated by the *Animal Research Act 1985* (NSW) and the *Animal Research Regulation 2021* (NSW). Nationally, animal research is governed by the *Australian code for the care and use of animals for scientific purposes* (2013).

The current regulatory framework is not adequate for ensuring transparency and accountability, or genuine wellbeing of animals used in research.

The regulatory framework must be updated to improve welfare standards for animals and reduce the numbers of animals exploited. But there are significant limitations as to what can be achieved in terms of genuine protection of animals. Whilst animals continue to be used in research, their welfare will be compromised. At present, the legislative framework can ensure comprehensive reporting and proper implementation and funding of alternatives to animals in research. To reach the objective of animal protection, there would have to be a commitment to a phase-out of the use of animals in research.

NATIONALLY

Australian code for the care and use of animals for scientific purposes

The National Health and Medical Research Council's (NHMRC) *Australian code for the care and use of animals for scientific purposes* ('the Code') is the national code governing animal research. The Code must be incorporated into state and territory legislation to have effect[29]. Compliance with the Code is a prerequisite for receipt of NHMRC funding[30] through which the Federal government grants hundreds of millions of dollars each year towards research[31]. Compliance is also required with documents such as *Principles and guidelines for the care and use of non-human primates for scientific purposes*. However, both the Code and other documents only outline general guidelines for how animals are to be used and cared for within research and cannot ensure genuine animal welfare in practice. Further, there is no mechanism to independently assess the outcome of research nor does the NHMRC take responsibility for ensuring the Code is followed. Responsibility falls to the institutions conducting animal research[32].

[29] *Animal Research Act 1985* (NSW) s 4.
[30] 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.
[31] https://www.nhmrc.gov.au/funding/data-research/research-funding-statistics-and-data - general, does not state how much goes towards animal research.
[32] *Australian code for the care and use of animals for scientific purposes* (2013) cl 2.1.1.

And while ethics committees must be established under the Code[33] only two independent members need to be appointed[34]. Anaesthesia must be used for procedures that are likely to cause pain[35] but there are a number of exemptions[36], such as for lethality tests[37], which are in the category 'death as an endpoint'[38]. Over 15 thousand animals were used in these kinds of tests in 2019 (similar for other years)[39]. The Code states these should be avoided unless essential, yet high numbers of these projects are still approved each year.

Enforcement of even the minimum standards the Code sets is problematic due to the research industry being primarily self-regulated. Facilities are not accessible to the public and there are no unannounced audits, which means that any breaches of the Code and relevant legislation can only be reported by researchers and committees, which are primarily composed of people from the research industry.

The Code also sets very broad standards for the approval process[40], which essentially can capture any research project, thus providing little scrutiny in practice. There is also no criteria for how these principles or standards are to be implemented, which leaves it up to the discretion of researchers and animal ethics committees, and proposals which cause significant pain and distress are routinely permitted.

It is important for NSW legislation to be updated to create an independent approval process, stringent criteria to provide for proper scrutiny of research projects, and improve welfare for animals, discussed in detail below.

[33] Ibid ss 2.1.3, 2.2, 2.3.
[34] Ibid s 2.2.4.
[35] Ibid s 2.4.18 (x).
[36] For example, 2.7.4, 3.1.19, 3.1.28. Generally, section 3.1 contains several exemptions.
[37] *Animal Research Act 1985* (NSW) s 56A (4) for definition.
[38] NSW 2019 Animal Use in Research Statistics, 7. Appendix – Guide to the categories of reporting, Column D.
[39] NSW 2019 Animal Use in Research Statistics pg. 7.
[40] *Australian code for the care and use of animals for scientific purposes* (2013) e.g., cl 1.3, 1.6.

NEW SOUTH WALES REGULATORY FRAMEWORK

Transparency

In NSW, in order to carry out animal research, a facility must be accredited[41] and researchers must obtain an authorisation to carry out research on animals [42]. However, there is no publicly available information on which institutions are Accredited Animal Research Establishments in NSW.

General information must be reported by Accredited Animal Research Establishments (other than schools)[43] to the NSW Department of Primary Industries ('NSW DPI')[44]. However, the requirements for reporting are low – only basic information on numbers of animals used and types of research they are used in need to be provided. Expanding the reporting scheme to create a comprehensive reporting regime is essential to create transparency.

Independence

Under the accreditation and animal-supply licensing scheme, Accredited Animal Research Establishments and suppliers of animals, must establish an animal ethics committee[45]. The committee makes recommendations concerning the granting of approval for research[46], and carries out supervision of research[47]. However, the composition of committees is primarily comprised of research industry members[48].

In NSW there is also an Animal Research Review Panel (the Panel), which is constituted by the *Animal Research Act 1985* (NSW)[49]. The functions of the Panel include investigative functions (including overseeing the implementation of the Code), inspections and producing annual reports[50]. Similarly, as with animal ethics committees, the Panel is largely comprised of people from the industry. Therefore, there is no independence in the approval process for proposals.

---

[41] *Animal Research Act 1985* (NSW) ss 25-25C, 46.
[42] Ibid ss 18, 47.
[43] *Animal Research Act 1985* (NSW) ss 3, 18, 46-47; *Animal Research Regulation 2021* (NSW) s 15.
[44] *Animal Research Regulations 2021* (NSW) s 24.
[45] *Animal Research Act 1985* (NSW) ss 13, 40.
[46] Ibid ss 14, 25.
[47] Ibid s 14.
[48] Ibid s 13 (5); *Animal Research Regulation 2021* (NSW) s 21.
[49] *Animal Research Act 1985* (NSW) s 6 (1).
[50] Ibid ss 9 -11.

It is unknown how many research projects are denied by ethics committees. Non-profits with a focus on this area have highlighted seriously concerning research projects, with significant animal welfare concerns, being approved[51].

Lastly, there is no requirement for animal ethics committees or the Panel to do any follow up on research outcomes and there is no independent assessment of research outcomes.

Due to the concealed nature of research projects, the approval process, and lack of assessment of outcomes, there is no accountability to the public or any accountability for the lives of the animals used in research.

Inspectors

Powers of inspectors appear to be broad[52]. However, due to lack of information on inspections, it is difficult to determine how inspectors exercise these powers and whether they perform inspections without prior announcement. There is no available information on how many inspections are carried out each year or how many complaints are made.

Convictions

Convictions for offences under anti-cruelty statutes or legislation governing animals in research are usually only considered relevant if they took place in the last 3 years[53]. Convictions under anti-cruelty statutes be considered relevant irrespective of when they took place, and they should preclude researchers from engaging in animal research.

At present, there is no available information on whether charges have been laid or if any prosecutions have taken place of researchers or a research establishment.

Lethality Tests and Draize Eye Tests

Lethality tests (where animals are administered substances to determine at what dose death will be caused)[54] and Draize eye test (where substances are forced into the eyes of animals to determine their harmfulness)[55] can still be carried out subject to approvals from ethics committees and reporting[56]. This

[51] https://www.humaneresearch.org.au/case-studies/ - includes experiments in NSW.
[52] *Animal Research Act 1985* (NSW) s 50.
[53] Ibid s 17.
[54] Ibid s 56A(4) for definition.
[55] Ibid s 3 for definition.
[56] Ibid ss 26 (3) and (4)(a)(b), 56A.

is particularly concerning, as under the Code, there are exemptions for providing pain relief in lethality tests.

Lethality tests and Draize eye tests must be prohibited. Any experiments causing pain or distress should be prohibited and any exemptions allowing for pain relief not to be administered should be removed.

Supplying Animals for Research

Suppliers of animals for the purposes of research must be licensed[57], however certain animals are exempt from licensing requirements such as farmed animals[58], including deer[59], and commercially hatched fish[60]. And animals used in schools are exempt animals[61]. All animals should be covered by the licensing scheme irrespective of their species or use in schools.

Animals and Projects Exempt from Coverage

School hatching projects should at the very least be covered by the legislation, to offer some degree of protection for animals. A better alternative would be if they were banned due to the multiple animal welfare concerns, such as inappropriate care and handling resulting in injury and death[62].

Animal Welfare

The Code only provides for general guidelines for animal husbandry in research facilities. Precise standards mandating environmental enrichment, exercise, and access to the outdoors, with specific standards for each species is required. Any research causing pain, distress or death as an endpoint should be prohibited.

Lastly, there is no rehoming program for animals; rehoming is voluntary, and no information is provided in annual reports as to whether this is even implemented.

---

[57] Ibid s 37, 48.
[58] Ibid s 3 (e.g., cattle, horses, sheep, goats, pigs and poultry), s 3; *Animal Research Regulation 2021* (NSW) sch 3 (e.g., deer).
[59] *Animal Research Regulation 2021* (NSW) Sch 3 s 6.
[60] Ibid s 7.
[61] Ibid s 8.
[62] https://kb.rspca.org.au/knowledge-base/what-are-the-animal-welfare-issues-with-chick-hatching-in-schools/#:~:text=A%20chick%20hatching%20program%20is,substrate%2Fbedding%20for%20the%20chicks.

Replacement, Reduction and Refinement

At present the principles of Replacement, Reduction and Refinement are not enshrined in the legislative framework. They are mentioned as a general guide within the Codes but are absent in NSW legislation. Resultantly, there are no criteria for researchers to satisfy to prove that they are meeting these principles. There is no information collected on how, if at all, these principles are being applied. There is no separate fund dedicated to implementing and developing alternatives to exploiting animals in research. Australia trails behind most developed countries and regions, where both funds and centres have been set up to develop alternatives.

Recommendations

For the purpose of transparency and to begin to make determinations about the effectiveness of research, comprehensive reporting is essential.

- Reporting should include the following:
    - Number of projects approved each year and any that were not granted approval.
    - Information on research that has succeeded in reaching objectives i.e., leading to human advancements and research that has failed.
    - Information on how the 3 Rs are being implemented, such as projects which are using or developing alternatives.
    - Information on how much funding animal research receives annually, and how much of that is funded publicly.
    - Number of complaints made and their outcomes.
    - Number of inspections/site visits made each year.
    - Schools should no longer be exempt from reporting.
    - Animals, if any, that were rehomed (including details as to whether they were euthanised simply because there was no rehoming program).
    - Numbers of animals bred each year, irrespective of whether they are used in research.
    - This information should be included each year in the annual reports and statistics released by the Panel.

Change to the Composition of Animal Ethics Committees and the Animal Research Review Panel

A change to the membership requirements of ethics committees and the Panel are essential to create independence. Currently only 2 independent members need to be appointed within ethics committees (this is the minimum specified by the Code) and only 2 people (out of 12) on the Panel represent the interests of animals, with no provisions about members being independent.

Animal ethic committees need to be independent of the research establishment for which they carry out approvals and committees need an increase in members concerned with animal welfare. Similarly, the Panel must consist of members who are independent of the research industry and must appoint a greater number of members who represent the interests of the animals.

Proper Scrutiny of Research Proposals

The legislative framework must provide for greater scrutiny of projects before they are approved. Researchers need to precisely articulate and provide evidence for how their research will translate to humans and what benefits it will confer.

Specific criteria should be introduced into the legislative framework, which detail provisions that projects must meet before they can be granted approval. This has been detailed above in recommendations for meeting the principles of Replacement, Reduction and Refinement.

NSW legislation should be tightened to create clearer thresholds which researchers must meet. The Code has a number of broad and sometimes contradictory clauses for what standards proposals have to meet to gain approval but there are no stipulated criteria for how researchers are to demonstrate that they satisfy these clauses. The Code provides no information for how the balancing exercise of sacrificing animal wellbeing for the sake of potential benefits to humans is to be carried out.
As discussed above, NSW should introduce criteria which researchers must satisfy for approval and to demonstrate they are meeting the principles of Replacement, Reduction and Refinement. This should include a requirement that researchers provide evidence that they will apply randomisation and blind outcome assessment in their research. These are considered fundamental to minimising bias in clinical trials, the absence of which has shown skewed results in favour of animal research as translatable to humans[63]. And regular retrospective assessments of animal research in NSW should be undertaken.

Rehoming Program

A rehoming program must be implemented, and researchers should have to demonstrate their ability to comply with the rehoming program when applying to animal ethics committees.

[63] Jennifer A. Hirst et al, The Need for Randomization in Animal Trials: An Overview of Systematic Reviews, 2014.