

**Submission
No 247**

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

Organisation: Animal Liberation


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INQUIRY

INQUIRY INTO THE USE OF PRIMATES AND OTHER ANIMALS IN MEDICAL RESEARCH IN NSW

AN ANIMAL LIBERATION SUBMISSION
TO PORTFOLIO COMMITTEE NO. 2



We don't have a duty to **speak** for the animals;
we have an obligation to be **heard** for the animals.- Matt Ball

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ABOUT ANIMAL LIBERATION

Animal Liberation has worked to permanently improve the lives of all animals for over four decades. We are proud to be Australia's longest serving animal rights organisation. During this time, we have accumulated considerable experience and knowledge relating to issues of animal welfare and animal protection in this country. We have witnessed the growing popular sentiment towards the welfare of animals, combined with a diminishing level of public confidence in current attempts, legislative or otherwise, to protect animals from egregious, undue, or unnecessary harm. Our mission is to permanently improve the lives of all animals through education, action, and outreach.

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Acknowledgement of country

We acknowledge the Traditional Owners of country throughout Australia.

We acknowledge that this document was prepared on land stolen from and never ceded by the Gadigal People.

We pay our respects to their Elders, past, present and emerging

27 April 2022

Portfolio Committee No. 2 - Health

Parliament of New South Wales

Via email: portfoliocommittee2@parliament.nsw.gov.au

ATT: Portfolio Committee No. 2 Members

We present this submission on behalf of Animal Liberation.

Animal Liberation appreciates the opportunity to lodge a formal submission to the Portfolio Committee No. 2 – Health Inquiry into the use of primates and other animals in medical research in New South Wales.

Though Animal Liberation strongly opposes all animal experimentation and medical research which includes the use of animals, we are aware that terminating its practice is currently improbable and is not an objective of the Committee. We note that this is in spite of sound scientific evidence demonstrating the serious limitations and adverse outcomes of animal experimentation. For example, an estimated 90% of all drugs considered safe and effective in preclinical research, of which animal testing is currently mandatory, fail to make it to human clinical use (Van Norman 2019a).

In our consideration of the Inquiry's Terms of Reference ('TOR'), Animal Liberation has prepared a series of practical recommendations that are informed by sound contemporary science, and contemporary public expectations. We believe that these recommendations will be of value to the Committee and may be used as a model for transitioning from animal-based medical research to methods based on human biology. We will demonstrate the wide range of benefits such a transition will generate.

While we are aware that the current inquiry is specific to NSW, we will also demonstrate that a national approach is urgently required.

We request that it be noted from the outset that the following submission is not intended to provide an exhaustive commentary or assessment in response to the issues contained within the TOR provided by the Committee. Rather, our submission is intended to provide a general examination and responses to select areas of key concern.

As such, the absence of discussion, consideration or analyses of any particular aspect or component must not be read as or considered to be indicative of consent or acceptance. For the purposes of this submission, Animal Liberation's focus covers aspects that we believe warrant critical attention and response.

Kind regards,

Alex Vince
Campaign director

&

Lisa J Ryan
Regional campaign manager

LIST OF ABBREVIATIONS

AEC	Animal Ethics Committee
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research and Teaching
APO	Animal protection organisation
EU	European Union
HRA	Humane Research Australia
IOAW	Independent Office of Animal Welfare
NHMRC	National Health and Medical Research Council
HSUS	Humane Society of the United States
OIE	World Organisation for Animal Health
SSCAW	Senate Select Committee on Animal Welfare
The Code	Australian Code for the Care and Use of Animals for Scientific Purposes
TOR	Terms of Reference

SECTION ONE

INTRODUCTION

SECTION ONE

INTRODUCTION

The progressive changes in relation to the treatment of other-than-human animals, observed internationally since the 1970s (Rollin 1989; Rollin 2002; Rollin 2005; Wise 2005; Wise 2006; DeGrazia and Beauchamp 2019), include diverse areas ranging from industrial farmed animal production (Singer 1975), the promotion of plant-based diets, attitudes towards companion animals (Katcher and Beck 1983) and farmed animals (Le Neindre et al. 2009; Futureye 2018; McGreevy et al. 2019), and the use of animals for entertainment and their use in medical experimentation (Singer 2001). The latter is also gaining increasing prominence in scientific disciplines (Greek 2004; Gluck 2019; Ram 2019; Van Norman 2019b), where a dichotomy of approaches and perspectives can be observed: from those that reject the use of animals in medical experimentation to those that assume that animal testing cannot be interrupted, suspended or discontinued (Giles 2006; Greek and Kramer 2019; Mamzer et al. 2021).

An “animal experiment” can be generally defined as an intervention which causes suffering, harm, and distress to an animal for scientific purposes (Ferrari 2019). Given that suffering “lies at the heart of morality”, it is unsurprising that animal experimentation has become one of contemporary societies enduring ethical issues (Thomas 2005). Moreover, the breeding of animals for scientific purposes - which has become unavoidable because it ensures the standardisation and scientific consistency of results - must also be considered an ethical issue (Ferrari 2008).¹ Such animals are often born with specific characteristics biologically suited to scientific experiments (Linzey and Linzey 2015). The extent of animal use for these purposes, the purported advantages to the public, and the fact that most biomedical research is government-funded, also make this a public policy issue (Whittaker 2014).

While the study of animal behaviour has a long history that dates back over 2000 years, laboratory research became increasingly common in the twentieth century (Klopfer 1993; Fernandes and Pedroso 2017; Pollo and Vitale 2020). It is frequently justified on the basis of a consequentialist calculus that invokes harm-benefit analysis wherein the harms of an action should be weighed against the expected benefits, with any action that may inflict harm only ethically justifiable if it can be positively associated with a greater benefit (Perry 2007; Gutfreund 2020).² Such a framework is often formalised with explicit statements in regulations and guidelines that require researchers to justify their intended use of animals based on benefits to either humans, other animals or the environment (Brønstad et al. 2016; Khoo 2018). This has become the core ethical principle that underpins regulation and policy relating to animal experimentation (Knight 2012).

Questions exist, however, regarding how it can be practically applied in the context of ethical decisions. Animal research seldom falls within clear rubrics of harms and benefits (Gutfreund 2020). While the benefits may be demonstrated indirectly by incorporating or building upon existing knowledge from several projects, the costs (harms) are directly inflicted on animals during single research

¹ The fact that breeding is not classified as an “animal experiment” in itself impacts the public perception of the suffering and the number of animals used for research (Ferrari 2019).

² Similar approaches have been taken in other animal welfare contexts under a utilitarian approach (Singer 1989; Singer 1990; Gutfreund 2020). These were largely informed by the utilitarian philosophy of Jeremy Bentham, who maintained that “it is the greatest happiness of the greatest number that is the measure of right and wrong” (Griffin et al. 2014).

projects (Knight 2012).³ Such an approach can provide opportunity for interpretation (Mann and Prentice 2004; Bout et al. 2014; Würbel 2017; Leland et al. 2019).⁴ Moreover, although some research may be directed at producing benefits for animal species or the environment, most is intended for human benefit (Knight 2011a). As such, how to practically decide and regulate decisions about instances when harms exceed the benefits - or vice versa - is not a trivial or minor concern.

In Australia, the use of animals by science and educational institutions is regulated at the national and state or territory levels.⁵ Although differences exist in the regulation of animals used for scientific and educational purposes in the 6 states and 2 territories of Australia, the core features are consistent. First, in all Australian jurisdictions, the use of animals in science or education requires authorisation or a license (Cao 2015; Sharman 2006). Second, every jurisdiction in Australia also requires the establishment of an animal ethics committee ('AEC') to review applications for the use of animals in science or education (Sharman 2006; Russell 2012; Cao 2015). Third, the substantive content of the regulation is effectively national due to the legislative incorporation of the Code in each jurisdiction (Knight 2013). Finally, each state and territory has rules regarding the inspection of research facilities and proscribes sanctions for breaching the legislation (Sharman 2006).

When three baboons escaped from the Royal Prince Alfred Hospital ('RPA') in February 2021 (Convery 2020), there was heightened public awareness that primates are being used, which led to an increase in the incidence of public objections (Anon. 2020; Clun 2020; Marston 2020; Penberthy 2020; Sanda 2020; Wahlquist 2020; Wray 2020). In attempting to recapture the baboons, police locked down roads until they were caught two hours later (Butler 2020; Swain 2020). It was later revealed that the baboons were from a colony in Wallacia and were "purpose-bred for medical research" (Nguyen 2020). A senior adviser at the facility maintained that baboons had been used in "important biomedical research" for at least three decades and that research had been used to study "priority" medical issues, including diabetes, kidney disease and complications arising from pregnancy (Nguyen 2020). Subsequent media reports explained that the baboons are "used for studies on subjects including diet, exercise and electric shock" (Clun 2020). One suggested that they "must have known what was coming" (Woods 2020), implying that the experiments that they are subjected to are something to be avoided.

Finally, we note that a Commonwealth inquiry into animal experimentation was conducted in 1989. The final report published by the Senate Select Committee on Animal Welfare ('SSCAW') contained a number of key recommendations. These included that: (1) the Commonwealth, State and Territory Governments annually publish accurate and comprehensive data on the scope and forms of animal experimentation performed within their jurisdictions and; (2) the Commonwealth establish a distinct fund for research into the use of alternatives to animal

3 The term 'cost' is inaccurate as it expresses associations with an economic or financial price and should be replaced by 'harm' to make it clear that it is the negative impact for the animals that is of primary relevance in the ethical evaluation of animal experimentation (Voipio et al. 2004; Kalman et al. 2010; Brønstad et al. 2016). On this basis, the term "harm" will be used throughout the submission (unless contained within a quotation).

4 Merkes and Buttrose (2019) provide a detailed description and account of the method used to calculate harms and benefits in the UK. Similar guides exist in Australia, though they are less comprehensive. The Home Office guide, for example, views the process as ultimately subjective and is therefore value-laden. Furthermore, the public cannot view the harm-benefit analyses of the UK's Animals in Science Regulation Unit or the Australian AEC, further eroding transparency (Merkes and Buttrose 2019).

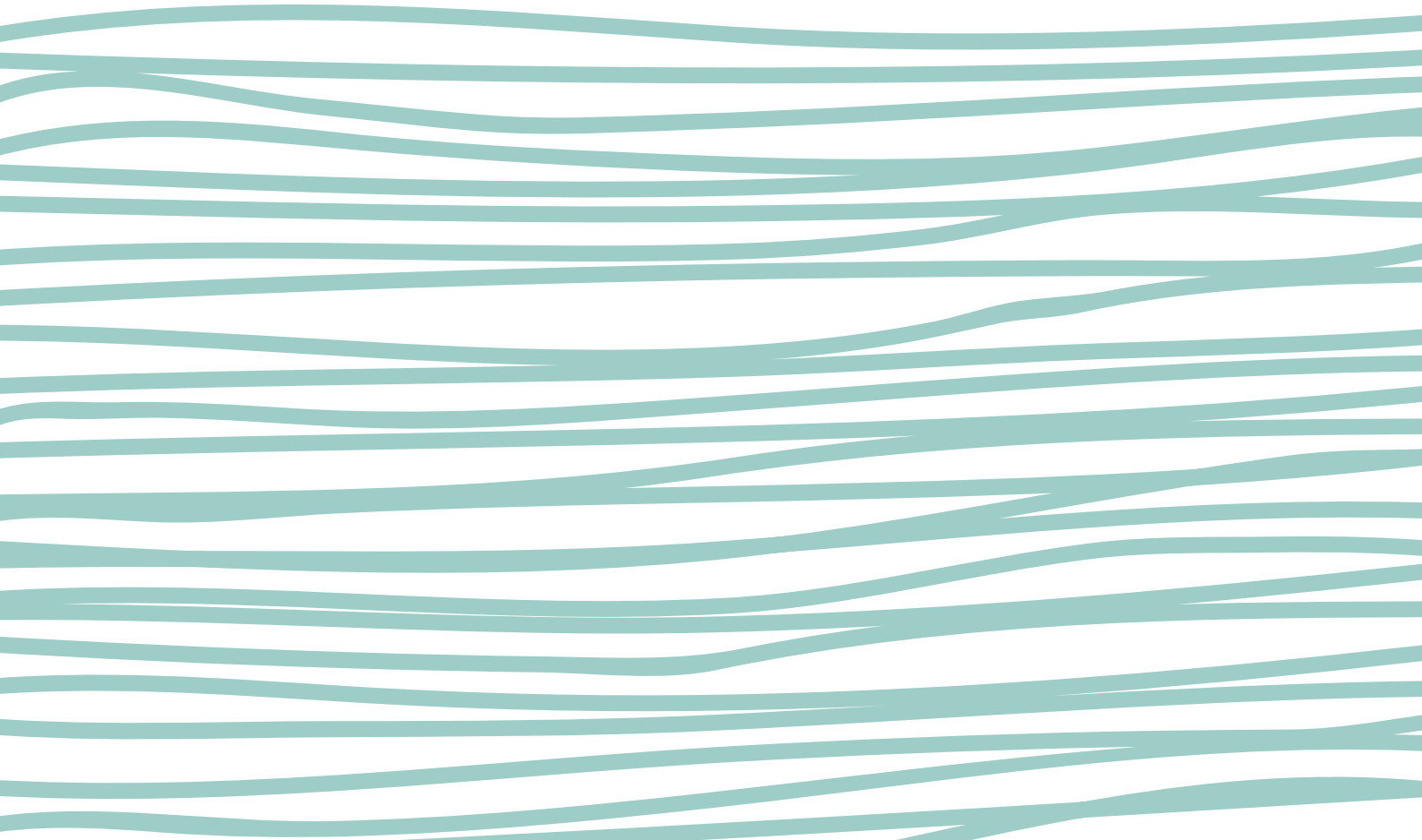
5 This framework is due to the division of legislative power under the Australian Constitution (1900). Prior to Federation, Australia was composed of distinct colonies that legislated in accordance with their separate geographical and social challenges. There was little contemplation of harmonisation or affiliation between the colonies (Timoshanko et al. 2016). This lack of cooperation was one of the driving influences in federating the colonies and in the following constitutional conventions made between 1891 and 1898 it was decided that the states and territories would preserve legislative responsibilities not explicitly administered by the Commonwealth (Harrison 2005). With the notable exception of fisheries, animal welfare is one such area. Thus, the use of animals for scientific purposes is primarily regulated through state and territory legislation (Sharman 2006). Such regulation generally exists in the animal protection legislation and the accompanying regulations (Cao 2015).

experiments (Commonwealth of Australia 1989). Over three decades later, however, these recommendations have not been implemented. Animal Liberation believes that this demonstrates the relatively low priority afforded to developing and implementing replacements to animal use in medical research in Australia. We note, furthermore, that Australia is one of the highest users of animals in research globally (Taylor and Alvarez 2019). NSW typically reports the usage of more than two million animals per year for this purpose.

In sum, we will show that humans have long debated the ethics of animal testing. Similarly, we will show that despite the fact that some countries have banned animal testing for cosmetics, animals are still used for a range of purposes, including the testing of safety products, makeup, chemicals, and medicine. If we are to take the moral status of animals seriously, even if this does not extend to the granting of rights to animals, this should trigger a comprehensive revision or the total elimination of many of the current animal experimentation practices (Galgut 2015). Ultimately, our submission will demonstrate that current regulations governing animal experimentation are not aligned with the moral consideration warranted by scientific advances in the understanding of animal abilities and characteristics (Knight 2011a).

SECTION TWO

RESPONSE TO TERMS



SECTION TWO

RESPONSE TO TERMS

TERM 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

“To kill an error is as good a service as, and sometimes even better than, the establishing of a new truth or fact” - Charles Darwin (1879)

The “effectiveness of medical research” is a critical component of this Term as research using animals is frequently framed as a “necessary evil” (Joffe et al. 2014; Mackenzie 2018). However, few would oppose the ethical argument that “if cruelty to animals is not wrong, then nothing is wrong” (Hansen and Kosberg 2019). In principle, such acts are not only morally unacceptable but illegal. Despite this, animals are commonly used in medical research without sufficient explanation of whether this research has generated commensurate benefits for human patients (Ram 2019).

By choice, precedent, or regulatory directive, animal research uses millions of animals and dozens of species every year for basic and applied life science research, and to test drugs, chemicals, and other consumer products (Keen 2019).⁶ While NSW publishes annual reports and statistics that provide some detail on the use of animals in research, the efficacy of the research outlined in these documents is unclear. Throughout the years, many have asserted that animal research has provided only poor contributions to medical progress (Fadali 1996; Shapiro 1998; Bailey 2008; Greek and Greek 2003). For example, the actual contribution of animal experimentation to several significant diseases is controversial and contested (Bliss 1982; Fadali 1996; Dowdle et al. 2003; Illman 2008; Carvalho et al. 2019).⁷

That animal studies are poor predictors of human reactions is not new (Bracken 2008).⁸ Pharmacologists, for instance, have long appreciated, understood and acknowledged the complications inherent in the extrapolation of data from animals to humans (Brodie 1962; Lasagna 1964; Van Norman 2019b). Epistemological problems in translating results from animal experiments into human clinical benefits have been acknowledged for some time (Johnson and Smajdor 2019). Several issues have been identified, including differences in physiology and metabolism (LaFollette and Shanks 1996), poorly practised or

⁶ “Basic” research refers to the investigation of biological phenomena using animal models and “applied” research refers to drug research and development (‘R&D’), toxicity and safety testing (Keen 2019).

⁷ Consider the poliomyelitis vaccine, for example. Poliomyelitis is a viral disease that gained epidemic proportions in 1916. Some contemporary accounts maintain that it was experiments conducted on mice and monkeys that allowed scientists to develop a vaccine (Illman 2008). Moreover, as both vaccines were initially grown in monkey kidney tissue (Dowdle et al. 2003), this reinforced the perception of the role played by animal experiments in its development (Illman 2008). Others, however, claim that animal experiments delayed the vaccine’s development (Fadali 1996). Rhesus monkeys, which were the widely-used animal model for poliomyelitis, actually misled scientists to believe that the virus was transmitted via the respiratory rather than the digestive route (Bailey 2008), as earlier research on humans had suggested (Fadali 1996). This error informed to a fallacious clinical trial in 1937 that exposed children to olfactory damage (Parish 1968). Furthermore, the first poliomyelitis vaccines which were grown on monkey kidney cells were responsible for exposing millions of citizens to “simian virus 40”, found in rare human cancers (Pennisi 1997).

⁸ A thousand years ago, Ibn Sina maintained that studies should be focused on humans rather than animals and Alexander Pope’s proclamation that “the proper study of mankind is man [sic]” are both well known and widely cited (Gold 1952).

inappropriately evaluated experiments (Pound et al. 2004; Perel et al. 2007) and animal stress due to the environmental factors identified elsewhere in this submission (Akhtar et al. 2008; Baldwin et al. 2006; Burwell and Baldwin 2006; Herrmann 2019; Jayne and See 2019). These insights inform the low success rate of translating animal experiments to beneficial human treatment (Van der Worp et al. 2010; Schulz et al. 2016).

Animal Liberation maintains that a majority of this research uses animals to fulfil scientific curiosity and support hypotheses that are solely applicable to animals and merely generate more research, funding and publications. For example, research published by the University of New South Wales ('UNSW') detailed experiments in which rats were fed a diet of various fast-food items, including pies and dim sims, to analyse connections with obesity (Martire et al. 2013). Human data has already demonstrated the connection between such a diet and obesity (Zhao et al. 2017).

The benefits or advantages to human health or wellbeing derived from animal experimentation are often exaggerated. For example, of 20 clinical reviews only two (2) involving animal models were found to have greatly contributed towards the development of human clinical intervention (Knight 2007). Similarly, another study found that only one-third of highly cited animal studies translated into successful human research and eventual clinical use (Hackam and Redelmeier 2006). One study found that less than 10% of "highly promising" scientific findings become routinely used within two decades (Contopoulos-Ioannidis et al. 2003). More recently, a review considered 27 examples of animal research that were highly publicised and declared "breakthroughs" for human health. Each study was reviewed over two decades later to determine whether any genuine human benefit had occurred, with results indicating that only one of these studies had produced a genuine benefit to humans (Bailey and Balls 2020). These concerns led the Editor-in-Chief of the British Medical Journal ('BMJ') to state that "funds might be better directed towards clinical rather than basic research, where there is a clearer return on investment in terms of effects on patient care" (Godlee 2014).

Moreover, experimentation subjects animals to unnecessary suffering and places human clinical trial participants at potential risk (Vogt et al. 2016; Ionnidis 2017). Given that the concept of "unnecessary suffering" has been a key tenet of animal protection legislation in NSW since the passing of An Act for the More Effectual Prevention of Cruelty to Animals in 1850 (White 2016) and remains central to the state's current primary animal protection framework under the *Prevention of Cruelty to Animals Act 1979* ('POCTAA') (Arbon and Duncalfe 2014), such a failure appears considerable.⁹ As there is increasing worldwide awareness of the limited translation of animal research to human patients (Pound et al. 2004), it is reasonable to assume that these issues occur in NSW.

While Animal Liberation acknowledges that medical research is critical to advancing human health, we strongly believe that there must be a system wherein the methods applied are subject to meticulous, independent, transparent and routine examination. On the basis of poor translation to human treatment and the suffering experimentation causes, the severity of a condition should not be used to legitimise the use of animals. We note, for example, decades of animal-based research that has cost billions of dollars yet failed to provide cures for human patients (Keen 2019). It is reasonable to believe that such funds could or should have been better expended on alternatives (Pound and Bracken 2014).

⁹ Considerable concerns exist regarding the definition of cruelty under legislation being couched in such language as "unnecessary", "unjustifiable", and "unreasonable" because such terms are ambiguous and become problematic when the question of what actually constitutes "unnecessary", "unreasonable", or "unjustifiable" suffering arises. If the welfare of an animal is balanced against perceived human needs, an act can often be justified and deemed necessary (Arbon and Duncalfe 2014). For further information, see Animal Liberation (2022).

The scientific questions involved in the appraisal of the validity of using animals in medical experimentation is complex, and experienced scientists should be at the forefront of the study of these issues, professionals and stakeholders in other fields can also offer substantial contributions (DeGrazia and Beauchamp 2019).

Animal Liberation firmly believes that transparent and routine examination of these matters, including via opportunities for the general public to register concerns, is of critical importance in the development of a robust and holistic understanding of the core issues. According to a widespread perception observed in the literature on the ethics of animal research, an increasingly gaping disconnect separates (1) an animal-research community devoted to the scientific value and moral acceptability of laboratory animal research and (2) a growing animal protection community that prioritises the protection of animals' interests (Rudacille 2000; Ibrahim 2006; DeGrazia and Beauchamp 2019).

While the historical developments that influenced this perception are well understood, it is lamentable and potentially dangerous insofar as it suggests an antagonistic or adversarial disparity between two deeply competing perspectives (Frank 2002). It is reasonable to believe that this discourages or conceals acknowledgement or realisation of common ground. It can, moreover, promote a view of the ethics inherent in animal research as a political battlefield of vying ideologies (Thomas 2005). Indeed, as our response to Term C provided below will show, the authors of the 3R's noted that "it has sometimes seemed that there is an irreconcilable conflict between the claims of science and medicine and those of humanity in our treatment of lower animals" (Russell and Burch 1959).

Finally, It should not be left to animal charities or animal protection organisations ('APOs') to fund non-animal experimentation and medical research. For example, organisations like PETA have continued to work closely with government agencies, industry, and educational institutions to push for humane, effective non-animal tests (Ibrahim 2006). These efforts include directly funding the development and validation of these tests (PETA 2022).¹⁰ Other international APOs, such as Animal Research UK, have similarly endeavoured to develop funding and grants to "award research funding to cutting-edge scientists that develop human methods and non-animal technologies to study human disease". It is intended that such research funding will be "awarded to scientists in universities, hospitals and research organisations all over the UK following a rigorous and independent peer-reviewed selection procedure" (Animal Free Research UK 2021). The former chair of the International QSAR Foundation board explained that "the science sponsored by such APOs is "critical to the elimination of animal use" (PSCI n.d.).

It is Animal Liberation's view that reasonable representatives of both communities (i.e., the animal research and animal protection) should be able to acknowledge and concur on a single central moral norm that is inherent to animal research ethics: sentient animals have an inviolable moral status and are not merely tools of research (DeGrazia and Beauchamp 2019).

¹⁰ "To date, PETA entities worldwide have contributed millions of dollars toward the development and implementation of non-animal test methods and other alternatives to animal use" (PETA 2022).

TERM 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

Public attention to and interest in the ethics of using animals in biomedical and behavioural research has increased over the past four (4) decades (DeGrazia and Beauchamp 2019). Such interest derives from diverse motivations (Clemence and Leaman 2016), including an interests in monitoring: (1) transparency and how public funds are expended; (2) monitoring the welfare of animals used in experiments and; (3) understanding what scientific research consists of and its broader implications for society (Mamzer et al. 2021). When combined, these interests result in circumstances where animal experimentation is becoming a critical social issue with rising interest among non-professionals and stakeholders outside the industry (Hobson-West 2010).

Most people know very little about animal research (Merkes and Buttrose 2019). Many people who live in countries where animal experiments take place are unaware of the number and kind of animals used, the procedures they undergo, or the pain and suffering involved (Hadley 2012). Though many are divided over the validity of animal research (Funk and Rainie 2015; Jones 2017), many are unaware of the fact that using animals as models for human research is widely regarded as ineffective (Merkes and Buttrose 2019). For example, a poll commissioned by Humane Research Australia ('HRA') in 2013 found that 43% of Australians were unaware that animals are used in experimental research (HRA 2016). This is partially due to the limited detail provided by research institutes, including what procedures are conducted in animals, their stated purpose, and their funding source.

Despite this general lack of awareness, previous sections of this submission have demonstrated that the public is interested in these details. Though public funds finance most animal research, the public is often unaware of the impact this has on animals (Merkes and Buttrose 2019). However, because people enjoy the advantages of animal research when they utilise pharmaceuticals or undergo surgical procedures, critics have maintained that "it seems reasonable to inform them of the costs to animals for which their consumer choices are to some extent causally responsible" (Hadley 2012). Australia, unlike many other countries, does not keep a national record of animal use (Merkes and Buttrose 2019).

The public should have easy access to a contemporary document detailing what animal research involves, the variety of species used and killed, for what purpose, the results and how research is funded. Since proposals to use animals must be approved by an AEC, funding institutes can obtain records and release this information. The public's demand for transparency, outlined above, can be met by publishing this information and allowing independent monitoring. Similarly, expenditure on the development of non-animal models or methods should be recorded and made publicly available.

TERM 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

Earlier sections of this submission detailed the emergence of the principle of humane treatment of animals in contemporary Western society in the late eighteenth century (Smith and Boyd 1991; Webster 1994). Fundamentally, humane treatment required minimising the pain and fear inflicted on animals regardless of their intended use of purpose. In 1831, guidelines and principles intended to ensure the humane treatment of animals used in experimentation were first proposed (Smith and Boyd 1991). In some aspects, the 3Rs represented an extension of these earlier principles (Houde and Dumas 2011).

The principles or directives of reduction, refinement and replacement, known as 'the 3Rs', were introduced by Russell and Burch in 1959 to eliminate "inhumanity" towards other-than-human animals (Russell and Burch 1959; Ibrahim 2006; DeGrazia and Beauchamp 2019).¹¹ The authors of the 3Rs proposed the following: "suppose, for a particular purpose, we cannot use replacing techniques. Suppose it is agreed that we shall be using every device of theory and practice to reduce to a minimum the number of animals we have to employ. It is at this point that refinement starts and its object is simply to reduce to an absolute minimum the amount of distress imposed on those animals that are still used" (Russell and Burch 1959). Briefly, the principles are as follows: (1) reduce refers to improvements that minimise the absolute number of animals used in research; (2) refine refers to improvements that minimise the suffering of animals who are used in research and; (3) replace refers to the use of non-animal alternatives instead of animals (Ibrahim 2006).

The authors of the 3Rs were guided by and followed a utilitarian approach to animal ethics. A utilitarian approach pursues a reduction in the amount of suffering and an increase in the amount of pleasure, for all affected parties (Schuppli et al. 2004). Under a utilitarian approach, an action is considered correct when the balance of good versus bad consequences outranks those of any identifiable alternative. Russell and Burch intended to reduce the suffering of animals used in experimentation by minimising the sum total of distress, including pain and fear, by using the 3Rs as "convenient rules of thumb" (Schuppli et al. 2004).

Since the 1990s, the 3Rs have gradually gained endorsement within the animal research community and have been recognised by a growing number of international organisations (Council of Europe 1986; OIE 2018). Though the principles were largely overlooked for a decade and thereby remained academically obscure (Festing 1995), they were increasingly identified as relevant to the controversies surrounding animal experimentation that arose during the 1960s and 1970s (Rudacille 2000; Ibrahim 2006).¹² Today, the 3Rs are universally-accepted and are ingrained in legislation, policy and regulatory activities around the world (Zurlo et al. 1996; Brennan 1997; Herrmann et al. 2009; Olsson et al. 2012; Guillén 2013; Griffin et al. 2014; Bayne et al. 2015).¹³ This growing body of

¹¹ The term "inhumanity" was used to demonstrate the harmful conditions animals are subject to and the procedures that cause adverse mental states (Herrmann 2019).

¹² It should also be noted that the 3Rs were published at a time in which ethical concerns relating to animal experimentation were at an all time low (Loew 1996).

¹³ Directive 2010/63/EU on the protection of animals used for scientific purposes came into effect in 2013 and requires all EU members to implement the 3Rs comprehensively.

agreements, regulations and guidelines relating to the use of animals in research emphasises that such use is not a given that is summarily granted by society to the research community (Brønstad et al. 2016).

Beyond government regulations and various codes, the principles have been accorded something akin to canonical or authoritative status for animal research ethics in many contexts (DeGrazia and Beauchamp 2019). They have been widely supported by many large animal protection organisations ('APOs') (Ibrahim 2006).¹⁴ Some have since concluded that they represent "a common language and a vehicle for identifying common goals" held by both the research community and animal protection advocates (Rudacille 2000). There is strong evidence suggesting that as technology evolves and better methods become available, the apparent necessity of animal experiments becomes of less relevance (Carvalho et al. 2019). For example, vaccines that were historically developed using animal tissues are increasingly being developed utilising human strains (Plotkin 2017).

However, the principles neglect a number of crucial aspects of animal welfare and some essential considerations relating to the human benefits that are often used to justify animal research (Ibrahim 2006). Regarding animal welfare, the 3Rs address this core value solely in the context of "humane experimental technique"; that is, animal welfare is only considered insofar as they are used in scientific research procedures (Russell and Burch 1959). Although the attention to this particular context is noteworthy and honourable, the limited focus overlooks other significant aspects of the animal's welfare beyond their use in scientific procedures (Schluppi et al. 2004). These include issues relating to transport, housing, feeding, and companionship (DeGrazia and Beauchamp 2019). The authors note, however, that such aspects were largely omitted on the basis that they should be sufficiently addressed elsewhere (Russell and Burch 1959). Similarly, they were not devised to apply to new or emerging areas of research that have the prospect of escalating the use of animals (Schuppli et al. 2004; Ibrahim 2006).

In contrast, Animal Liberation maintains that animal welfare principles must address *all morally relevant aspects* of an animal's life. Moreover, there are several reasons the 3Rs fail to meaningfully regulate animal experimentation. For example, the 3Rs do not provide a mechanism for challenging a researcher's proposed purpose in carrying out an experiment that will use animals (Ibrahim 2006). Instead, the 3Rs are designed to accept rather than challenge the proposed purpose, whatever researchers may claim it to be, and simply ask whether the use of animals could be rendered less frequent (reduction), less painful (refinement) or substituted (replacement). Suppose that in a given experiment many animals are required, pain relief cannot be provided, and an alternative cannot be used. Further, suppose that the necessity or utility of the experiment is questionable. If the 3R's are intended to prevent unnecessary animal suffering, should they not allow an avenue via which it is possible to prevent such an experiment from receiving approval and subsequently taking place? Damningly, the 3R's "stop short of making such an allowance" (Ibrahim 2006). Critically, this is not an academic exercise.

We have noted that the incorporation of the 3Rs into legislation has been compelled by increasing societal concerns regarding the treatment of animals (Pew Research Centre 2015; Clemence and Leaman 2016; ECI 2016; Jones 2017; Pew Research Centre 2018). As such, it is reasonable to expect progressive changes toward the replacement of animals with non-animal models (Herrmann

¹⁴ The Humane Society of the United States ('HSUS'), for example, has given a "Russell and Burch Award" to scientists who have "made an outstanding contribution" in advancing the 3Rs (Rudacille 2000). Similarly, in the United States PETA - regarded by some as the "perceived archnemesis of the research community" - have attended meetings on alternatives to testing alongside representatives of companies whose practices involve animal experimentation (Ibrahim 2006).

2019). Despite this, the total number of animals used worldwide has increased since the 2000s (European Commission 2013; Taylor et al. 2008; Taylor and Rego 2016). In part, this may be simply explained as another component of an animal welfare system that in other realms, such as agriculture and entertainment, claims to value animal welfare and high ethical standards, yet in its practical and legal application routinely fails to do so (Black et al. 2022). Rather than replacement, it appears that refinement is receiving the most attention (Daneshian et al. 2015). For example, a survey conducted with participants of laboratory animal science training courses in four (4) European countries found that refinement was seen as more feasible and more pressing than replacement and reduction of animal use (Franco et al. 2018).

In Australia, they were adopted by the National Health and Medical Research Council ('NHMRC') in 1984, to underpin the Australian Code for the Care and Use of Animals for Scientific Purposes ('the Code') and are considered a cornerstone of Australia's regulation of the use of animals for scientific or educational purposes (Timoshanko et al. 2016). Despite these advancements, however, it can be argued that Australia has made relatively little progress in replacing animals in research. Australia has, for example, been cited as the fourth highest user of animals in research despite a proportionately low population (Taylor et al. 2008). Other approaches, such as that taken in the European Union ('EU') are considered more comprehensive because it explicitly promotes a strong transition away from animal experimentation under its goal for the "full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible" (European Parliament 2010). Further, the EU Directive stipulates that replacement should be prioritised, followed by reduction and then refinement (ibid). After the 3Rs were introduced, replacement was considered prior to reduction with refinement considered last (Curzer et al. 2016; Lee et al. 2020). As such, this generally corresponds with the intent of the original authors, who maintained that "refinement is never enough and we should always seek further for reduction and if possible replacement" (Russell and Burch 1959).

When the 3Rs were developed, they functioned as a practical means to bring discipline to the ethics of animal experimentation (Schuppli et al. 2004). Others have since proposed the addition of 'Refusal' as a "fourth R" to be used when gains are unjustified and the cost of harm to animals cannot be clarified (Lee et al. 2020). Critically, the 3Rs are undoubtedly an animal welfare concept insofar as it professes to regard the exploitation of other-than-human animals as morally legitimate, yet subject to some limitations that are determined and applied by the scientific community may nevertheless continue to undergo experimentation (Francione 1996; Ibrahim 2006).

It is evident that there are alternatives to the ongoing use of animals in experimentation. There are a range of novel methods and technologies that can feasibly replace the use of live animals in research, testing, education and training contexts, including: (1) in-vitro methods performed with microorganisms, tissues, whole cells or parts of cells in test tubes, Petri dishes, etc.); (2) in-silico or computer-based methods; (3) studies with human volunteers and; (4) simulated or virtual reality-based techniques. It is similarly evident that such alternatives offer advantages that extend beyond the elimination of harm inflicted on animals. There are significant scientific and financial benefits that could be accrued by adopting non-animal research methods.

Despite this, and recommendations made over three (3) decades ago by the Senate Select Committee on Animal Welfare ('SSCAW') to establish a separate funding stream for alternatives to animal experimentation (Commonwealth of Australia 1989), Australian researchers are currently dependent on limited international funding for such research (HRA 2021). This causes significant

obstacles and implications for animal welfare. In 2019, the NHMRC published a paper that advised that a “lack of appropriate scientific or technological innovation” and insufficient fundings as representing “the primary barrier[s] to the implementation of the 3Rs” (NHMRC 2019).

TERM D: the ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research

Previous responses to the Terms above have provided an insight into Animal Liberation's position on the ethical and animal welfare issues inherent in the use of animals in medical research. Fundamentally, this relates to the ethics of using individual sentient animals and inflicting suffering or harms that are of no benefit to themselves and, in many cases, the humans such research is ostensibly carried out to advantage.

In the 1970s, Professor Peter Singer maintained that the suffering of more-than-human animals should not be afforded less consideration than the suffering of humans and that the majority of animal research should therefore end (Singer 1989; Singer 1990). A rights-based framework, based on the belief that animals have inherent value as individual living creatures, informs calls for the total abolition of all animal research (Regan 1987).¹⁵ Since that time, opinion polls have demonstrated that the proportion of adults who believe medical research that using other animals is unacceptable has been increasing since 2002 (Wadman 2017). While clinicians and the public often consider it self-evident that animal research has contributed to clinical knowledge of benefit to humanity, this is largely based on anecdotal evidence or untenable claims (Pound et al. 2004). Despite this, the alleged benefits of animal research remain the primary argument proffered by scientists who use animals (Bennett and Ringach 2016), even though the public and other academics increasingly regard these claims as unconvincing (Slicer 1991; Hursthouse 2006; Francione 2007; Marks 2013). As we have shown, a key issue is that the calculation of ethical harms to animals and the benefits of animal research are inherently imprecise if they are even possible at all (Singer 1989; Galgut 2015; Khoo 2018).

Most scientific experimentation and testing on animals takes place behind closed doors (Black et al. 2022). Every year, millions of animals are used in various types of scientific research around the world. While a comprehensive estimate for this figure is 115.3 million animals, Australia ranks highly both in terms of absolute laboratory animal usage figures and per capita use, being ranked fourth largest in the world in 2005 (Taylor et al. 2008). Most of this research involves evident harms, either as a direct result of experimentation or due to the conditions under which the animals are kept (Johnson and Smajdor 2019).¹⁶ Other harms include lack of access to conspecifics, inadequate stimulation, or the intrusion of light and noise (NHMRC 2013).

As with other animal welfare issues, the surrounding debate is polarised, and involves complex cultural, social and personal beliefs (Rose and Grant 2009; Whittaker 2014; Degeling and Johnson 2015; Futureye 2018). Opponents of animal research either assign less weight to the benefits and greater weight to the harms (Francione 2007) or criticise researchers for having the opposite bias (Galgut 2015). There is strong evidence, however, that many people have empathy for animals. One recent study found that when asked to choose between empathising with a human stranger or an animal, participants were more inclined towards empathising with another human (Anon. 2022). A second series of studies, however, found that when offered a choice between empathising with a human

¹⁵ As rights-based frameworks have struggled to gain formal acceptance, as courts have struggled with the idea of granting rights to animals (Cupp 2018), few animal ethics systems have formally adopted its guiding principle (i.e., that animals have inherent value as individual living creatures) (Regan 1987; Knoo 2018).

¹⁶ The captive conditions in which animals used in research, testing, and education spend their lives is very different from their natural environment (Herrmann 2019). This makes their behaviour different from free-living animals (Jayne and See 2019).

and an animal people were more inclined to empathise with an animal than a human (Cameron et al. 2022; Fitzner 2022).¹⁷ The lead author of the study concluded that while people may see human interests as competing with those of other animals and that this may cause them to prefer empathising with fellow humans, if there is no basis for believing interests are competing and the circumstances require a decision to either empathise with an animal or a human, people opt to empathise with animals (Anon. 2022; Cameron et al. 2022). As there is strong evidence indicating that experimentation on animals does not translate into meaningful improvements or benefits to humans, this has profound implications for animal experimentation.

17 While empathy may feel automatic (Bloom 2016; Ferguson et al. 2020), it is an active process (Jamison 2014) that is considered essential in guiding and motivating prosocial behaviour (Batson 2011; Dickert et al. 2011; Erlandsson et al. 2015). The researchers explain that empathy is a process of “thinking about another living being’s suffering and experiences as if they were their own” (Anon. 2022). Others have similarly described empathy as the act of “putting oneself in the potential victim’s shoes” (Thomas 2005). While this study compared empathetic reactions to a koala (Cameron et al. 2022), the case of a silverback gorilla named Harambe who was killed by zookeepers in 2016 indicate such a response extends to primates (Cameron et al. 2017).

TERM E: the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability

Transparency concerns the communication of meaningful information, including data or details of decision-making processes, in a forthcoming and sincere manner with the purpose of informing, facilitating understanding and meeting obligations of accountability (Yeates and Reed 2015). Studies have shown that transparent communications during a crisis lead to higher levels of public trust (Auger 2014). As such, providing publicly available details about animal experimentation practices can add legitimacy to such research by increasing public trust (Ormandy et al. 2019). Citizens could thereby benefit from greater transparency (Merkes and Buttrose 2019).

Community engagement, particularly in the governance of controversial research, is now widely accepted as a critical component of the public governance of science (Gaskell et al. 2003; Burgess and Tansey 2008). Good governance, therefore, is another reason for transparency in animal research (Merkes and Buttrose 2019). One of the key themes in scientific governance is uniting transparency and public trust (McLeod and Hobson-West 2015). As such, it can be argued that “more transparency will increase public confidence in the appropriate conduct and regulation of animal research and therefore help to maintain public acceptance” (Varga et al. 2010). For example, the Basel Declaration, signed on 29 November 2010 by a group of 80 biomedical scientists, committed to “promote the dialogue concerning animal welfare in research by transparent and fact-based communications to the public” (Ormandy et al. 2019). Similarly, attendees passed the Montreal Declaration at the 8th World Congress on Alternatives and Animal Use in the Life Sciences, calling for an “increase in the transparency of the translation of animal-based research” in 2011 (Leenaars et al. 2012).

In 2014, the UK Government began a consultation process on discarding a section of its law on animal experimentation “in the interest of openness” (Merkes and Buttrose 2014). Public consultation found public support for openness and interest in a wide range of key information (Ipsos MORI 2013). Information of interest includes details about animal use, including organisations that use animals, numbers and percentages of animal species used, the severity of procedures used, how animals are killed, and whether there are non-animal alternatives (Merkes and Buttrose 2019).¹⁸ Critically, respondents to the aforementioned public consultation asserted the animal research sector “should subject itself to external scrutiny by those who have an interest in the animals’ welfare, rather than by those who have a vested financial or scientific interest in the research being carried out” (Ipsos MORI 2013). A subsequent poll found that 42% of respondents perceived organisations that use animals for research as “secretive” (Clemence and Leaman 2016).

We note that a draft Australian Openness Agreement on Animals Research, prepared by a working group convened by the Australian and New Zealand Council for the Care of Animals in Research and Teaching (‘ANZCCART’), is currently open for consultation (ANZCCART 2022a). Such an agreement is a voluntary pledge signed by organisations intending to demonstrate commitment to greater transparency in their use of animals (ANZCCART 2022b). Though this engenders some optimism, it is not binding and voluntary. Significantly, it

¹⁸ Other key areas of concern include information about genetically altered animals, outcomes for animals, alternatives to animal use and reports on finalised projects from an animal welfare perspective (Merkes and Buttrose 2019).

contains no duty or obligation for regulators to report performance. As such, it is unlikely to provide the level of public confidence we have described and discussed in this section.

TERM F: overseas developments regarding the regulation and use of animals in medical research

Though relevant details pertaining to international developments and approaches to the regulation of animals in biomedical research have been provided in applicable sections of our responses to previous TORs, the following section will briefly outline those not otherwise discussed.

Internationally, government-funded initiatives are increasingly appreciating and responding to the need for the development and corroboration of non-animal methods of research. Some have invested substantial sums and others have codified its urgency in law. For example, South Korea has proposed federal legislation that would prioritise funding for human-based approaches in biomedical research (Anon. 2019). Similarly, the UK's Animals in Scientific Procedures Act 2012 revision has codified the concept as a legal requirement.¹⁹ Critically, the latter contains a provision stating that “the Secretary of State must support the development and validation of alternative strategies”.

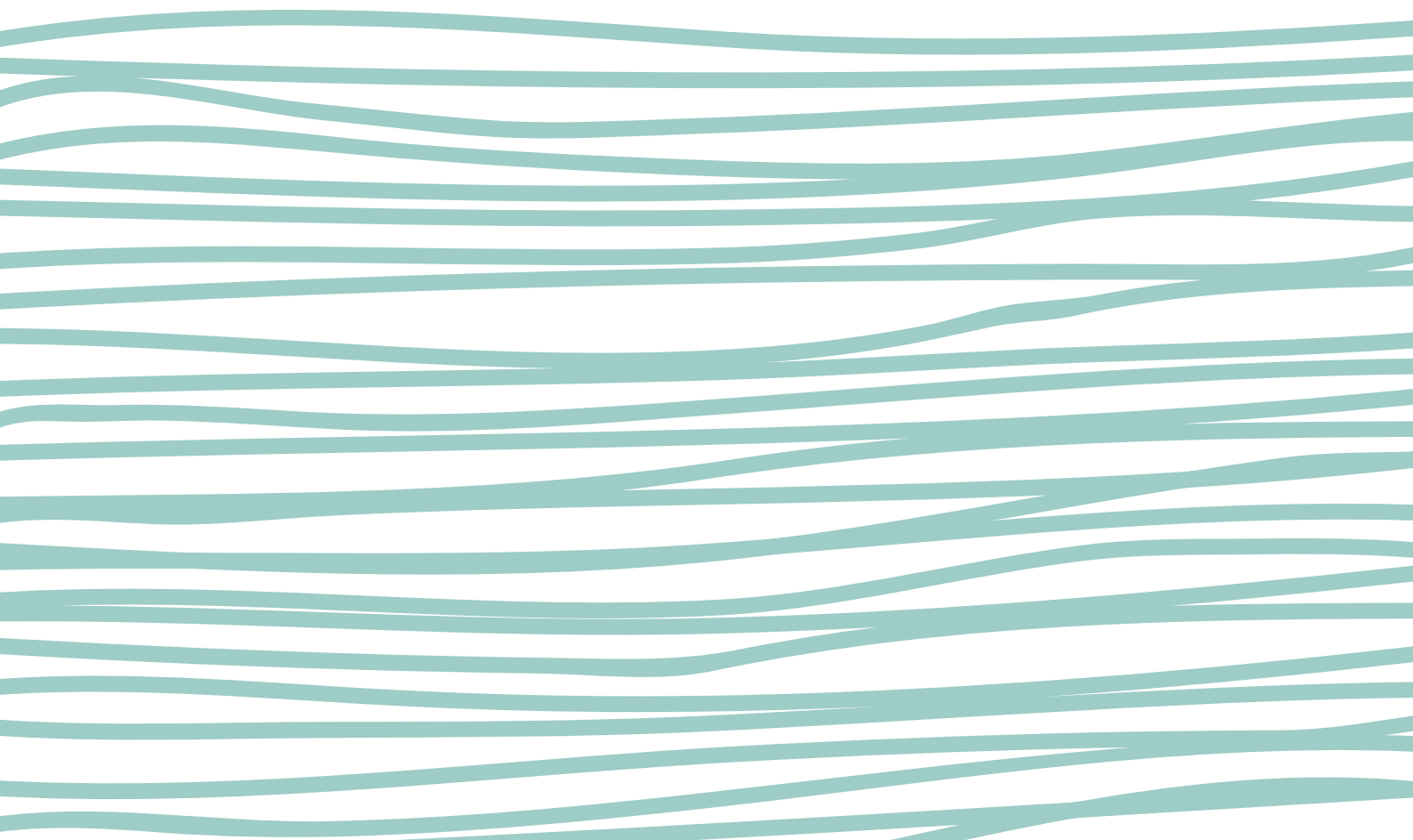
Other governments have announced policies to phase out particular methodologies. As we have demonstrated in earlier sections of this submission, the European Union ('EU') has established a number of initiatives and approaches that surpass those in place elsewhere. Other nations, however, have increasingly developed similar policies, tools and mechanisms. For example, the Dutch Government has announced plans to phase out the use of toxicology tests by 2025 for a wide range of purposes, including chemicals, food, pesticides, veterinary medicines, and vaccines (Anon. 2017). In the United States, the Food and Drug Administration Modernisation Act has been introduced to conclude mandates that require experimental drugs to be tested on animals prior to humans in clinical trials (Gatenholm 2021; Oshin 2021). The American Environmental Protection Agency ('EPA') has also announced that it will stop conducting or funding studies on mammals by 2035 (Grimm 2019). As it applies to transparency, the United States Department of Agriculture ('USDA') provide a publicly available tool with which citizens can access information on people licenced or registered under the Animal Welfare Act, details obtained during inspections, enforcement actions and annual reports (USDA 2020).

Additionally, a growing number of Centres for the Validation of Alternative Methods ('CVAMs') have been established worldwide. These include Brazil, Canada, the United States, Netherlands, Japan, the United Kingdom, Korea and Germany.

¹⁹ See the Animals in Scientific Procedures Act 2012 here: www.gov.uk/government/publications/animals-scientific-procedures-act-1986-amendment-regulations.

SECTION THREE

RECOMMENDATIONS



SECTION THREE

RECOMMENDATIONS

R1. THE NSW GOVERNMENT SHOULD ESTABLISH A REGISTER OF ALL PUBLICLY FUNDED ANIMAL RESEARCH PROJECTS

A recent report published by the United Nations Secretary-General's High-Level Panel on Access to Medicines called for governments' to require "the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register" (UN 2016). There is a belief that the current lack of transparency in clinical trials undermines clinicians', researchers', and patients' ability to make informed decisions about treatments (Merkes and Buttrose 2019). Animal research is, we believe, no different.

Throughout this submission, we have demonstrated that the use of animals in research is insufficiently transparent. Australian governments, animal experimenters, and their institutions provide far less information to the public about animal research than other jurisdictions, such as the EU (Merkes and Buttrose 2019). To rectify this, we recommend that pre-existing information be made publicly available. An important responsibility of AECs is monitoring the care and use of animals. According to the Code, the timing and frequency of inspections are at the discretion of AECs. Though such inspections may also be undertaken by the state government, reports about facility inspections are not made publicly available.

As such, the provision of information and data should include AEC meeting records, AEC annual reports, licensed institutions' annual reports to the NSW Government, and institutions' reports of AEC external reviews. We note that the latter, according to the Code, are to be undertaken at least every four (4) years (NHMRC 2013). Animal Liberation also contends that where a company or organisation derives a public or financial/business benefit from either public or privately funded animal experimentation and research, the relevant details should also be made publicly accessible and available to ensure full consumer awareness and transparency.²⁰ Such a register should also include data detailing the total numbers of animals who are bred for but not used for medical research, and may be killed.

We recommend that ethics reporting be guided by the principles of transparency (i.e., the reporting of sufficient detail to allow the public or other interested parties to assess and duplicate the research ethics methods used) and proportionality (i.e., the provision of details at a sufficient level that is commensurate to the ethical intricacy and risk to animals used) (Anderson et al. 2013). Data and full protocols of research projects using animals must be publicly available to minimise publication biases, as well as to improve accountability to the public, the quality of research, and the effectiveness and safety of new drugs and treatments (Ionnidis 2012; Merkes and Buttrose 2019). Finally, upon the conclusion of the research, we need to know what the research has contributed, and how the research has been balanced with the suffering of the animals (Knight 2011b; Lund et al. 2012; Lund et al. 2014).

²⁰ See the Animals in Scientific Procedures Act 2012 here: www.gov.uk/government/publications/animals-scientific-procedures-act-1986-amendment-regulations.

Public reporting should include transparent results involving adverse drug responses, clinical trial failures and any/all adverse incidents. Coinciding with annual reporting, the NSW Government should commission and publish an independent report evaluating the impact of animal-based research in NSW. Finally, the NSW Government should include a public register that details the specific ‘breeding’ origins of all animals used in animal experimentation and medical research.

R2. THE NSW GOVERNMENT SHOULD INVESTIGATE AND CONSIDER INCORPORATING ADDITIONAL ELEMENTS INTO THE 3Rs

Given the challenges and concerns we have outlined in relation to the 3Rs, we recommend the NSW Government investigate additional elements that motivate more progressive and holistic approaches to the ethical regulation of animal experimentation. We have noted, for example, that some have proposed the addition of ‘Refusal’ as a “fourth R” to be used when gains are unjustified and the cost of harm to animals cannot be clarified (Lee et al. 2020).

Other considerations should include:

- 1) relevancy - of proposals to use animals in experimentation);
- 2) recognition - of failing models whose funding should be terminated);
- 3) redirection - of funding to alternatives to animal experimentation or human-predictive methods);
- 4) re-education - of scientists in alternative research methodologies) and;
- 5) redesigning (of curricula to develop awareness and expertise in alternatives to animal use).

R3. THE NSW GOVERNMENT SHOULD REQUIRE ETHICAL REPRODUCIBILITY

We have demonstrated that public attitudes to animal research are evolving. While some believe that humans have no right to subject sentient animals to painful or lethal procedures (Merkes and Buttrose 2014), others maintain that animal models fail to predict human responses (Pound et al. 2014). For example, despite the deeply rooted belief that animal experiments accurately predict human toxicity (Fomchenko and Holland 2006; Gad 2007; Huff et al. 2008), assessments of the translation of animal research to human trials raises significant concerns (Van Norman 2019b). An analysis of over 2,000 drugs concluded that “results from tests on animals (specifically rat, mouse and rabbit models) are highly inconsistent predictors of toxic responses in humans, and are little better than what would result merely by chance - or tossing a coin - in providing a basis to decide whether a compound should proceed to testing in humans” (Bailey et al. 2014). Similar results have been found for primates and canines (Bailey et al. 2015). Ultimately, only about 12% of pharmaceuticals ever pass preclinical testing and enter clinical trials (Van Norman 2019b). Overall, approximately 89% of novel

drugs fail human clinical trials and approximately half of those fail due to unanticipated human toxicity (Van Norman 2019a).²¹

Ethical reproducibility mandates reporting the basic features of study design that relate to the distinct ethical challenges of a project. We propose the NSW Government consider the following procedures for reporting:

- 1) Report strategies used to avoid or replace the use of animals that has the potential to cause harm or suffering;
- 2) Report improvements to procedures that minimise actual or potential pain, suffering, distress, or lasting harm;
- 3) Report methods that minimise animal use and allow researchers to obtain equivalent information from fewer or no animals.

We recommend that a statistics compilation platform or publication be established that systematically reports on the degree to which the 3Rs are being implemented (Bain and Debono 2013). Given that the 3Rs are prominent in the Code, and AECs already require some information about the implementation of the 3Rs, such a collection process would contribute to accountability and transparency of animal research (Merkes and Buttrose 2019). Furthermore, it would provide benchmark data on how animal use is evolving over time. At present, sparse information is provided about the living conditions of animals in laboratories, such as enrichment, opportunities to express species-specific behaviours, and whether individual animals are kept in isolation from other animals (Merkes and Buttrose 2019). This is of increasing interest to the Australian public and could be supplied on a dedicated website or webpage of an existing website, as some research institutions in the EU do.

Transparency is paramount to scientific methods and ethical conduct. It is reasonable to believe that authentic transparency will facilitate greater scrutiny of animal research projects (O'Sullivan 2006; Hadley 2012) and that this will, in turn, generate greater reductions and replacements of animals in research (Merkes and Buttrose 2019).

R4. | OTHER RECOMMENDATIONS

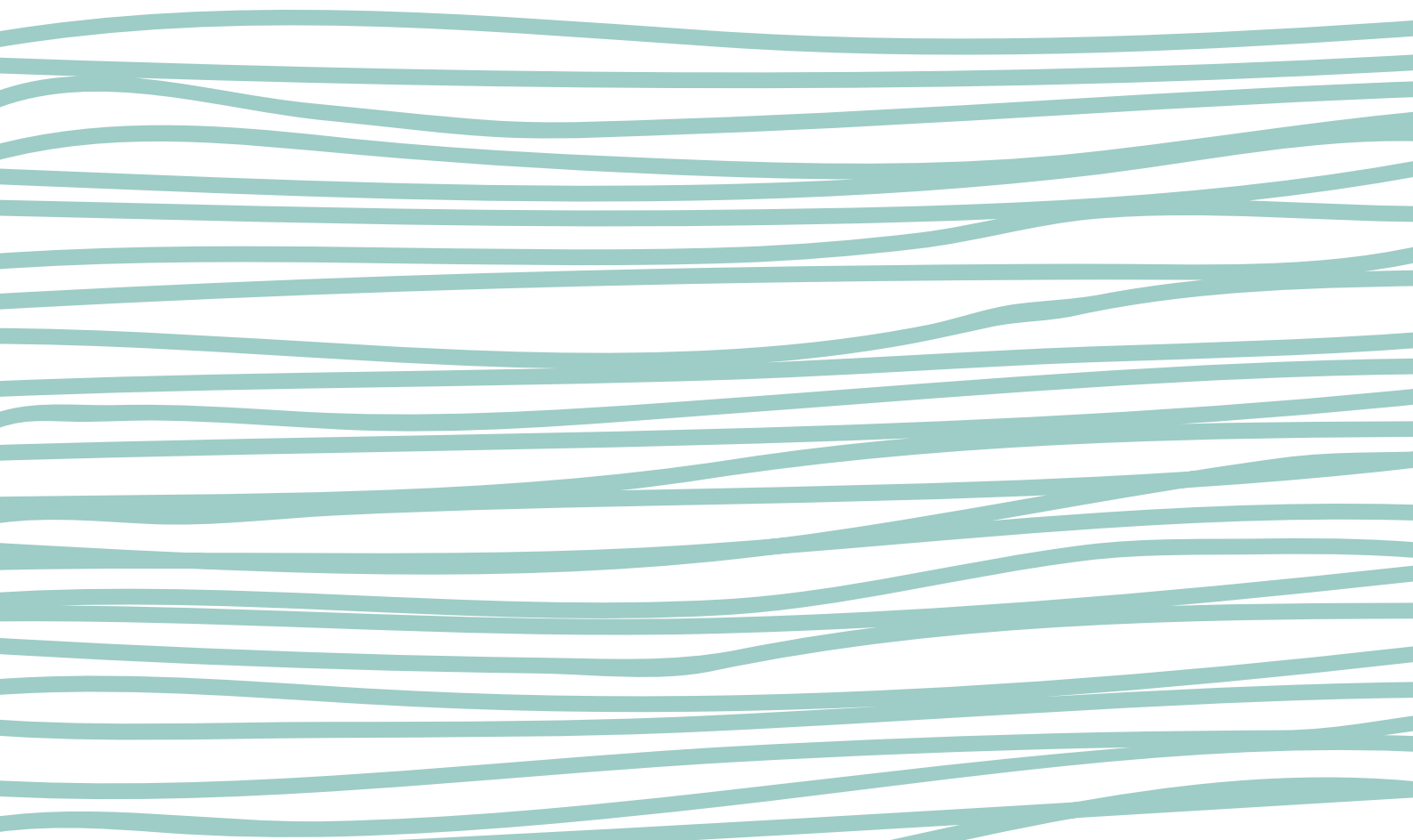
- 1) The NSW Government should be prioritise and advance the concept of 'RightToRelease' to ensure better outcomes for animals through meaningful standards rather than guidelines;
- 2) The NSW Government should introduce a mandatory retirement age of 5 to 6 years of age for animals, and specifically dogs and cats, used in experimentation and research;
- 3) The NSW Government should improve oversight involving the use of animals in secondary schools, undergraduate and postgraduate studies;
- 4) The NSW Government should ensure licence holders are held publicly accountable including incidents involving breaches to animal welfare legislation;

²¹ Reviews have found that of 93 post-marketing serious adverse outcomes, only 19% were identified in preclinical animal studies (van Meer et al. 2012)

- 5) The NSW Government should introduce mandatory CCTV in all facilities undertaking animal experimentation and medical or other research;
- 6) As developed by the EU, the NSW Government should commit to and develop an action plan including realistic targets to transition away from the use of animals in experimentation and research;
- 7) The NSW Government should establish an Independent Office of Animal Welfare ('IOAW') incorporating oversight for a national body for animal ethics reviews and;
- 8) The NSW Government should invest in progressive non-animal experimentation and medical research through adequate funding including recognition and rewarding for non-animal experimentation and research

SECTION FOUR

SUMMARY AND CONCLUSION



SECTION FIVE

SUMMARY AND CONCLUSION

Each year, substantial amounts of time and resources are devoted to and expended on developing tools and techniques to treat or cure human illness. Rarely do these interventions attain commercialisation without having first been tested on animals (Greek and Kramer 2019). Meanwhile, millions of animals are routinely subjected to painful procedures and prolonged suffering ranging from physical mutilation to drug addiction (Keen 2019; Kenehan 2019). While the intention of regulations that require the use of animals is to ostensibly to ensure that only safe and effective treatment is applied to patients, we have shown that there are serious practical and ethical concerns concerning this standard practice.

Though research and testing that causes significant harm to animals is a widely accepted in many industries (Kenehan 2019), we have demonstrated and predicted increasing declines in public support. Few people would argue with the ethical conclusion that cruelty to animals is wrong. This is amply supported by the fact that it is, at least conceptually, not only wrong but illegal. Yet, as we have shown, the intentional infliction of pain and suffering upon animals that meets such definitions of cruelty - under both common parlance and legislation - is routinely countenanced when it is performed under license or otherwise excused (Hansen and Kosberg 2019).

We have challenged the imprecise premise that because some animal experimentation may lead to improvements in human treatment, it is acceptable. Indeed, we have shown that as the vast majority of such experiments fail to reach a stage in which they are applied to humans, this argument necessarily fails this test. The suffering all experiments cause is almost always both cruel and unnecessary on this basis alone.

In sum, if we take the moral status of animals as seriously as our laws, policies and regulations suggest, the only reasonable, rational and appropriate conclusion is to undertake either a comprehensive revision of the existing framework or embrace the total elimination of animal experimentation.

Animal Liberation appreciates the opportunity to provide this submission and expects the Committee to consider its contents thoroughly and transparently.

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