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for all creatures great & small

RSPCA AUSTRALIA AND RSPCA NSW

RESPONSE TO SUPPLEMENTARY QUESTIONS

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

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1. **The Committee received evidence from an animal care technician that she witnessed *"mass culling of animals as researchers are not happy with preliminary data from them".* Does that concern you, both from an animal welfare perspective and a transparency perspective? What kind of additional oversight and/or regulation do you think is necessary to address this kind of conduct?**

The breeding of animals and subsequent culling of large numbers that are perhaps 'surplus' to requirements or do not meet the needs of research is a concerning part of the use of animals in medical research. As per RSPCA Policy;

> *Policy 4.3 RSPCA Australia is opposed to animals being bred in excess, in order to meet fluctuating demands for particular characteristics, or to be continuously bred to maintain specific lines, leading to unnecessary wastage of animals' lives. Researchers and breeders must work together to improve their forward planning to prevent overbreeding.*

The RSPCA advocates for reporting of all research results including negative results to improve transparency in the medical research space.

Before culling of animals is to be undertaken, the potential humane reuse of the animals or repurposing for other projects should be considered to determine if they can be utilised for other research purposes within a strict ethical framework as outlined by Australian code for the care and use of animals for scientific purposes (the Code).

At the institution level, individual ethics committees should be empowered to ensure that annual reporting includes culling that is not foreseen in the approved ethics protocol. Such reports should be subject to review by the animal ethics committee and lead to a review of the project, as permitted under the Code, and assessment of any future risk to animal welfare and potential further excess breeding or poorly managed use of animals. Where such risks are identified, there must be a requirement to develop plans to mitigate such risks. Noting that the current Code *does* require annual reporting of numbers and some project details – the level of specificity of these reports is left to the individual animal ethics committee and there can be significant variation in the level of detail provided by the researchers and justifications for animal use are not necessarily included.

As per our submission, the RSPCA is supportive of pre-registration of animal-based experiments that requires researchers to commit to statistical modelling prior to beginning research and report on results. An example of this can be found here:
https://www.animalstudyregistry.org/asr_web/index.action

Whilst the RSPCA acknowledges that reporting alone does not fix animal welfare issues it can lead to greater transparency and identification of common failures/issues in animal breeding and management practices that require review and action.

Whilst not all experimental results can be expected to prove the hypothesis, appropriate study design and peer review can assist in ensuring studies are appropriately justified. As per our submission, the RSPCA supports the need for all research projects to be peer reviewed, including those funded outside the standard peer review process that accompanies government funded research (e.g. philanthropic funding may not require peer review).

2. **One of your recommendations is that *"All animal-based research should be conducted and published in accordance with the ARRIVE 2.0 Guidelines or a similar standard of reporting to ensure transparency and reproducibility of findings."* Can you please explain what the ARRIVE Guidelines are, and why you think they are important?**

The ARRIVE 2.0 Guidelines provide a checklist which ensures consistent and transparent reporting of the parameters around which animal based research has been conducted. Version 2.0 of the Guidelines includes a summarised list of the 'essential ten' - the most important parameters to report on and record with regards to animal based research which are;

1. Study design
2. Sample size
3. Inclusion and exclusion criteria
4. Randomisation
5. Blinding (to ensure those assessing the data cannot be bias in their conclusions, I.e. the researcher should not know which set of data comes from which group of animals).
6. Outcome measures
7. Statistical methods
8. Experimental animal details (e.g. species, strain, substrain, sex, age, developmental stage, weight)
9. Experimental procedures
10. Results

Whilst these 10 parameters may seem obvious to include, it is often the case that not all this detail is reported in journal articles[1]. As a result of this inquiry, the panel could recommend a change to the Animal Research Act regulations to make it a requirement for researchers to provide these minimum parameters at the planning stage of a research program, for instance in the animal ethics application stage. This would necessitate researchers to consider each of these key parameters prior to beginning their research and, as a result, ensure that appropriate study design practices are implemented to improve the robustness of any results received. It also allows for improved reproducibility of results which would improve public confidence in the use of animals for medical research.

Consistent with RSPCA policy, using the ARRIVE 2.0 Guidelines would help ensure that any use of animals for research is scientifically robust. By empowering animal ethics committees to base part of their assessment on the ability for the research to meet these guidelines would improve consistency, transparency, and accountability to ensure research is conducted with appropriate planning and consideration of the factors that can affect translatability and reproducibility of any results attained.

Reducing the use of animals in research is a fundamental approach to limiting the extent of suffering caused by animal research. Experiments that are poorly designed risk exposing animals to welfare compromise for no benefit to research.