DOES HEALTH EFFECTIVELY MONITOR, MEASURE AND EVALUATE MRFF's PERFORMANCE?

Humane Research Australia (HRA) makes the following submission. In doing so, we note that one of the important aspects of the MRFF is to build stronger relationships between researchers, healthcare professionals, government and the community and we are grateful for this opportunity to raise matters which we submit are pertinent to effectively monitoring, measuring and evaluating MRFF's performance.

HRA recognises itself as a stakeholder as an advocacy group promoting the use of reliable and human-relevant non-animal alternative methods of medical research to ensure better human health outcomes. By 'alternative', HRA is referring to the many in-vitro, in-silico methods available, as detailed in the report 'Better Ways to Do Research' (1).

HRA holds that the Department of Health, through the MRFF's distribution of funds, supports research to predict human clinical outcomes and this prediction needs to be monitored and evaluated. Yet much research is based on animal models which do not provide predictability or enable measurable outcomes for humans. The differences in physiology, metabolism and numerous other differences between human and non-human animals makes outcomes extremely unpredictable. According to the U.S. Food and Drug Administration, despite a huge research effort and expense, development of new treatments has slowed, as preclinical success has not followed through into clinical trials (2). Latest figures have revealed a 95% failure rate of clinical trials following 'successful' animal trials (3). Drugs for Alzheimer's disease, for instance, have a 99.6% failure rate (4). Not only does this mean that results cannot be accurately extrapolated to humans, but it also means that some possibly successful treatments are being ruled out pre-clinically due to adverse responses in animals. In addition to producing misleading results, animal tests are also costly (usually at the expense of taxpayer funds) and time consuming.

It is also noted that the MRFF through its administrative bodies (NHMRC, HMRO, ARC etc) funds a considerable amount of basic/fundamental science. Such basic/fundament research does not always afford a measurable evaluation. By its nature it does not aim to result in practical outcomes and indeed it often does not. Contopoulos-Ioannidis et al (5) examined articles in six highly cited basic science journals over a five-year period and found that fewer than 10% of highly promising basic science discoveries from animal research enter routine clinical use within 20 years. HRA submits there be a higher emphasis on translational research and less basic/fundamental and curiosity driven animal-based research.

HRA questions whether the MRFF currently has sufficient mechanisms in place for monitoring or evaluating basic or fundamental research, particularly after a lengthy period of time has passed, after which it would be hoped that there would be some application of the learnings.

HRA submits that there needs to be an administrative system in place to identify those projects which undertake research using animals. Monitoring and measuring outcomes is inherently difficult when there is no background information regarding the number and types of research projects that have involved animal testing and their success or otherwise. This differentiation needs to be identified from the outset to enable a measure of success of a particular model that is being funded (animal, non-animal, basic science, translational etc).

Transparency and sharing of key information

HRA submits that in order to monitor and evaluate the MRFF's performance there needs to be transparency in measuring such performance with regular reporting to the MRFF from the various administering bodies. The need for transparency in animal research was agreed upon by a motion passed in the Australian senate in 2020 and this would be one such method of putting this into practice (6). Currently, from our perspective, the administration support system does not operate effectively. For example, a request from HRA (7) in 2020 seeking information on a specific MRFF grant (confirming whether any grants awarded from the funding stream used animal models) was unable to be provided due to various administering agencies and independent research organisations holding the information, which had not been made available to the MRFF. There needs to be greater collaboration to ensure this information is available. For all research grants received by the administering bodies from the MRFF there is no publicly available information as to which projects use animal testing or adopt human-relevant alternatives. This information should be available to the MRFF and it must be monitored. The MRFF must ascertain which funded projects established translational research, if any, providing tangible outcomes in human health with a view to changing the methods and direction of research in future distribution rounds.

Further, HRA submits that research data, which includes animal-based data, be shared in a timely manner to prevent unnecessary duplication in research and duplication of resources. This is particularly crucial for animal-based research to prevent unnecessary repetition of research and wasted resources and wasted time.

HRA submits there is a need for a thorough assessment of performance of grants awarded and administered at specific timelines, for example, at two, five and 10 year intervals (relevant to project length) where outcomes are monitored to allow for integration of knowledge.

In summary, Humane Research Australia submits that:

- that in order to monitor, measure and evaluate its performance, with the objective of better patient outcomes, the MRFF must include the ability to identify those projects which are animal-based research, non-animal alternative research and those which are basic fundamental research to enable a reliable method of evaluation;

- that translational research needs to be a measurement of MRFF's performance and that the MRFF offer the opportunity for research translation by engaging in a transparent

process with consumers, the public and key stakeholders who have a keen interest in better ways to do research.

It is noted, according to the Department of Health, that 'the MRFF aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability'. HRA respectfully submits that with an extremely high failure rate of animal-based medical research to predict therapeutic outcomes for humans, this aim risks failure and needs to be mitigated in ways as suggested in this submission.

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References

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