hra
humane research australia
ending animal experimentation

31 March 2020

Director
Listings and Threat Abatement, Environmental Biosecurity Office
Department of Agriculture, Water and the Environment
GPO Box 787
Canberra ACT 2601
exotic.species@awe.gov.au

Dear Director,

RE: Proposed importation of domesticated Ferrets (Mustela putorius furo) for research purposes

Thank you for the opportunity to provide a submission to the above proposal. I am writing on behalf of Humane Research Australia, a not for profit organisation that challenges the use of animals in research and promotes the use of more humane and scientifically valid methodologies.

My feedback to the proposal rests upon the question:

Why the species selected is the best species suitable for the research to be undertaken (if there another suitable species available from within Australia why is this species not being used?).

I note that the applicant has made many claims as to the value of ferrets in research and stated that they are 'internationally recognised as the gold standard species for multiple disease models'. However, no references are made to substantiate these claims, nor is any evidence provided of treatments or vaccinations of which ferret research has been crucial. Is this not a reasonable expectation of the applicant, rather than making assertions? I ask that this information be requested, before the proposal be considered further. I would also like to note the limitation of this question in restricting the research type to animal models only.

Humans differ from other animals anatomically, genetically and metabolically, meaning data derived from animals cannot be extrapolated to humans with sufficient accuracy. In fact, the Food and Drugs Administration (FDA), U.S. confirms that nine out of ten drugs 'proven' successful in animal tests fail in human trials, which represents a 90% failure rate. This not only questions the efficacy and very base argument for using animals, but critically raises the question about all the drugs that failed in animals which might have worked in humans.

Understandably, when a drug or other medical treatment is developed it must be tested in an entire living system. **However, using non-human species is using the wrong system. This is evident by the failure to develop a vaccine for any of the coronaviruses that have caused outbreaks in the past 20 years, despite extensive animal research.** Rather than asking what animal model we can use that may best represent human pathology, **pre-clinical testing needs to be conducted in such a way that eliminates the risk of**

species differences and is instead directly applicable to humans. Minor intricacies can have profound impacts and noting that there are even differences between humans in terms of susceptibility to COVID-19, this would only be exacerbated between species.

Scientists closely involved in the search for a treatment or a vaccine against COVID-19 are increasingly recognising the fact that animal tests are unreliable to predict human reactions. According to Tal Zaks, medical director of Moderna, a biotech company in the United States, *"I don't think proving this in an animal model is on the critical path to getting this to a clinical trial".* Karen Maschke, editor of the journal Ethics & Human Research, pointed out that animal studies are often poor predictors of what will work in humans.[1]

Fortunately, human- relevant research is possible. One example is the "MIMIC" (Modular IMmune In vitro Construct), an in vitro model of the human immune system "*The information you get from this type of test is far and beyond what you'd get out of a mouse study*," says Michael Rivard, vice president of corporate development at VaxDesign, "*both because it's humans and because you can see the effect across a spectrum of genotypes*".[2]

HRA is concerned that there is no guarantee an effective animal model will be found. The coronavirus could mutate, keeping scientists in catch-up mode. Or it could weaken and fade away before a model is perfected. This means researchers are wasting valuable time.

We therefore propose that this proposal be rejected, and human-relevant research be used. This would have no impact on safety. Advanced in vitro technologies (such as MIMIC, "organs on a chip" human lung tissue cultures and others) must aim for a prediction rate of 85 to 90 % in order to be accepted at the regulatory level, whereas the "animal model" achieves a prediction rate of only 10% according to the FDA. A **testing strategy based on a battery of in vitro tests using human material would be far more relevant, timely and cost effective than pursuing animal tests.**

Additionally, on page 11 the applicant states "*Domestic ferrets, if not properly vaccinated or cared for, can harbor certain diseases that are transmissible to humans*". HRA has a concern that there are not vaccinations for all diseases that are transmittible to humans, and this poses a threat at a time where extreme measures are being taken to control the spread of viruses.

I trust you will forward this submission to the Minister for consideration and would be grateful to be informed of the outcome. Further reference sources are provided below, and I am happy to discuss our concern or provide more detail if needed.

Yours sincerely,

Rachel Smith
Campaigns and Communications Manager
Humane Research Australia

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[1] https://www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing/

[2] https://www.fiercepharma.com/vaccines/vaxdesign-offers-an-alternative-to-animal-studies

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Additional Resources:

"MIMIC" (Modular IMmune In vitro Construct) A Clinical Trial in a Test Tube
https://www.ncbi.nlm.nih.gov/pubmed/19807200

https://www.humanvaccinesproject.org/

https://www.pcrm.org/news/ethical-science/vitro-human-immune-cells-effective-evaluating-new-vaccines

https://www.pcrm.org/news/ethical-science/fighting-zika-virus-computer-assisted-approaches

https://www.pcrm.org/news/ethical-science/new-human-based-model-test-influenza-effects

HRA's report Better Ways to Do Research.
http://www.humaneresearch.org.au/_literature_249860/Better_ways_to_do_research

Artificial intelligence applications to contain COVID-19 (ICT Works)
https://www.ictworks.org/artificial-intelligence-coronavirus-covid-19/#.XnP2OogzbIU

HRA Podcast – Covid10 – Why animal research is not the answer
https://www.podomatic.com/podcasts/humaneresearchaustralia/episodes/2020-03-23T20_09_5707_00