

February 17, 2021

Michael F. Chiang, M.D. Director National Eye Institute

Via e-mail: chiangmf@nei.nih.gov

Dear Dr. Chiang:

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters worldwide. On June 15, 2020, we sent a detailed letter to the U.S. Department of Health and Human Services Office of Inspector General urging Principal Deputy Inspector General Christi Grimm to investigate, assess, and take corrective action regarding the apparent egregious waste of National Institutes of Health (NIH) research grants—worth up to billions of taxpayer dollars each year—and the apparent failure of NIH-funded protocols to reduce and replace animal use in experiments as required by federal provisions.¹

Based on the new information presented below, we urge the National Eye Institute (NEI) to cancel the taxpayer funding—amounting to a total of \$775,500 for FY2019 and FY2020—granted to Karl Kador of the University of Missouri–Kansas City (UMKC) for any and all renewals of his protocols and insist that he reimburse the taxpayer funds that he used to acquire, breed, confine, and maintain animals deemed by the University of Missouri System (UM) unnecessary, non-essential, noncritical, or extraneous for experiments that the UM categorized as unnecessary, extraneous, noncritical, non-essential, ramped down, disposable, or nonpriority or described using similar terminology and—according to documents obtained by PETA through Freedom of Information Act requests—then euthanize them in response to the COVID-19 pandemic.

Euthanizing Animals 'Extraneous' to NEI-Funded Experiments Wastes Taxpayer Funds

Kador conducts the NEI-funded protocol "Tissue Engineered Cell Transplantation for Glaucoma and Optic Neuropathies"

¹People for the Ethical Treatment of Animals. (2020, June 15). Request to the U.S. Department of Health and Human Services regarding the COVID-19 contingency plans at U.S. universities. https://www.peta.org/wp-content/uploads/2020/06/20-06-15-Request-to-HHS-OIG-regarding-COVID-19-contingency-plans-at-US-universities.pdf.

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(5R01EY028946).² Per its COVID-19 response plan, UM notified its staff "about ramping down research activities where possible," which led to the destruction of animals deemed unnecessary, extraneous, noncritical, or non-essential or described using similar terminology by UM. After this directive was issued, animals involved in Kador's protocol were killed and their deaths were logged in "euthanasia record" forms for the Laboratory Animal Research Core Hospital Hill facility for the dates March 18, March 27, June 22, and June 23.⁴

The fact that the laboratory led by Kador had unnecessary, non-essential, noncritical, or extraneous animals in the first place should raise significant red flags, especially since his experiments are funded by taxpayers who should not have to foot the bill for such waste.

Kador's NEI-Funded Protocol Failed to Reduce and Replace Animal Use

The presence of unnecessary, non-essential, noncritical, or extraneous animals in the NEI-funded protocol led by Kador flies in the face of regulations designed to minimize the use of animals in experiments.

NIH-supported language requiring that the experimental use of animals be minimized is included in the Health Research Extension Act of 1985, the NIH Revitalization Act of 1993, the eighth edition of the *Guide for the Care and Use of Laboratory Animals*, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training:

- The Health Research Extension Act of 1985 states, "The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals ... to include in its application or contract proposal ... (1) assurances satisfactory to the Director of NIH that ... (B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the ... use of research or testing methods that limit the use of animals or limit animal distress [emphasis added]."5
- The NIH Revitalization Act of 1993 states, "The Director of NIH ... shall prepare a plan ... for the National Institutes of Health to conduct or support research into ... methods of such research and experimentation that reduce the number of animals used in such research [emphasis added]."

²NIH. (n.d.). *Tissue engineered cell transplantation for glaucoma and optic neuropathies*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project_info_details.cfm?aid=9685226&icde=53390442. This protocol has been funded since FY2018.

³University of Missouri. (n.d.). *Ramp-down letter*. https://research.missouri.edu/about/files/ramp-down-letter.pdf.

⁴University of Missouri. (2020). *Euthanasia record: Laboratory Animal Research Core Hospital Hill facility*. https://www.peta.org/wp-content/uploads/2021/01/2020-March-
June Euthanasia Records University of Missouri.pdf.

⁵Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). https://olaw.nih.gov/policies-laws/hrea-1985 htm.

⁶NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). https://grants.nih.gov/grants/olaw/pl103-43.pdf.

- The eighth edition of the Guide for the Care and Use of Laboratory Animals states, "The Guide ... endorses the following principles: consideration of alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals [emphasis added]."
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985) states, "The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results [emphasis added]."8

When Kador, an NEI-funded experimenter, buys, breeds, traps, and/or uses animals who at any time—not just during the COVID-19 pandemic—can be deemed unnecessary, non-essential, noncritical, or extraneous or described using similar terminology, he squanders limited research funds, which are provided by taxpayers, and flouts the bedrock "3Rs" principle of reducing, replacing, and refining the use of animals in experimentation that is enshrined in government regulations and policies.

Under this standard, the number of unnecessary, non-essential, noncritical, or extraneous animals used in Kador's experiments should have been zero from the start since they weren't relevant to his projects. Also, because taxpayer funds were used to acquire, breed, confine, and/or maintain unnecessary, non-essential, noncritical, or extraneous animals who were then so easily euthanized and disposed of in response to COVID-19, UMKS should reimburse the NEI for this fiscal waste.

Furthermore, the Congressional Research Service has found that during the COVID-19 pandemic, "[s]uspending research may result in additional costs for activities such as animal care" and that "[r]estarting research, when conditions permit, may also incur costs for staff time and supplies to ... reestablish laboratory animal populations." Taxpayers and the NEI should not be responsible for the additional costs associated with reestablishing laboratory animal populations since university systems like UM deemed many animals to be unnecessary, non-essential, noncritical, or extraneous to experiments and because doing this at taxpayers' expense would appear to violate the aforementioned federal regulations and policies that mandate minimizing the use of animals in experiments.

Request for Research Accountability and Modernization

We urge you to cancel the funding granted to Kador's project 5R01EY028946 and seek reimbursement for any and all NEI funds wasted to acquire, breed, confine, and/or maintain animals whom he and/or UM deemed unnecessary, non-essential,

⁷National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Guide for the care and use of laboratory animals*. https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
⁸National Research Council Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Appendix B: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training*. https://www.ncbi.nlm.nih.gov/books/NBK54048/

⁹Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the federal research and development enterprise*. https://crsreports.congress.gov/product/pdf/R/R46309

noncritical, or extraneous or described using similar terminology and then euthanized. Moreover, we encourage the NEI to redirect the funds it initially granted to Kador to projects using three-dimensional human tissue models of the eye that can better mimic the functions of human tissues and organs and to advance human-relevant research by ending the use of animals in experiments.^{10,11}

You can contact me at <u>ShalinG@peta.org</u> or 757-962-8325. We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

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¹⁰Bell, C. M., Zack, D. J., & Berlinicke, C. A. (2020). Human organoids for the study of retinal development and disease. *Annual Review of Vision Science*, *6*, 91-114. https://doi.org/10.1146/annurev-vision-121219-081855

¹¹O'Hara-Wright, M., & Gonzalez-Cordero, A. (2020). Retinal organoids: A window into human retinal development. *Development*, *147*(24). https://doi.org/10.1242/dev.189746