



February 17, 2021

Diana W. Bianchi, M.D.
Director
National Institute of Child Health and Human Development

Via e-mail: diana.bianchi@nih.gov

Dear Dr. Bianchi:

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. 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 information presented below, we urge the National Institute of Child Health and Human Development (NICHD) to cancel taxpayer funding—amounting to \$641,755 for FY2018—awarded to Lee A. Niswander of the University of Colorado Boulder (CU Boulder), and Trevor J. Williams and David E. Clouthier of the University of Colorado Denver (CU Denver), for any and all renewals of their protocols, and insist that they reimburse the taxpayer funds used to acquire, breed, confine and/or maintain the animals used in experiments whom CU Boulder 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—euthanized in response to COVID-19.

Euthanizing Animals Extraneous to NICHD-Funded Experiments Wastes Taxpayer Funds

Niswander, Williams and Clouthier conduct the NICHD-funded protocol “Phenotyping Embryonic Lethal Knockout Mice with Neural Crest and

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 US 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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Neural Defects” (5R01HD081562).² Per its COVID-19 response plan, on March 16, 2020, CU Boulder urged staff to identify “unnecessary” animals for euthanasia.³ On March 17, 2020, a representative from the “niswander lab” [*sic*] requested the euthanasia of mice confined “in room A2B44 on rack5 [*sic*].”⁴

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

NICHD-Funded Protocol Failed to Reduce and Replace Animal Use

The presence of “unnecessary,” non-essential, noncritical, or extraneous animals in NICHD-funded experiments led by Niswander, Williams, and Clouthier flies in the face of existing regulations designed to minimize the use of animals in experiments.

NIH-supported language requiring the minimization of the experimental use of animals is present in the Health Research Extension Act of 1985, the NIH Health 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 National Institutes of Health 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*].”⁶

²NIH. (n.d.). *Phenotyping embryonic lethal knockout mice with neural crest and neural defects*. Research Portfolio Online Reporting Tools (RePORT): Project Information. https://projectreporter.nih.gov/project_info_details.cfm?aid=9522839&icde=51842897

³University of Colorado–Boulder. (2020, March 16). *Research & Innovation Office COVID-19 resources*. https://www.colorado.edu/researchinnovation/research-innovation-office-covid-19-resources#vivarium_considerations-2651

⁴Brown, H. (2020, March 17). *Re: OAR guidance following suspension of research activities*. https://www.peta.org/wp-content/uploads/2021/01/2020-03-17_RE-OAR-guidance-following-suspension-of-research-activities.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]*.”⁷
- 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 Niswander, Williams, and Clouthier, all of whom are NICHD-funded experimenters, buy, breed, trap, and/or use animals who at any time—not just during the COVID-19 pandemic—can be deemed to be “unnecessary,” non-essential, noncritical, extraneous or described using similar terminology, they squander limited research funds, which are provided by taxpayers, and flout 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 the experiments led by Niswander, Williams, and Clouthier should have been zero from the start since they weren’t relevant to their project. Also, because taxpayer funds were used to acquire, breed, confine, and/or maintain these “unnecessary,” non-essential, noncritical, or extraneous animals who were then so easily euthanized and disposed of in response to COVID-19, CU Boulder should reimburse the NICHD for this fiscal waste.

Furthermore, the Congressional Research Service (CRS) has found that during the COVID-19 pandemic, “[s]uspending research may result in additional costs for activities such as animal care,” and “[r]estarting research, when conditions permit, may also incur costs for staff time and supplies to ... reestablish laboratory animal populations.”⁹ Taxpayers and NICHD should not be responsible for the additional costs associated with “reestablishing laboratory animal populations” since universities like CU Boulder deemed many of them to be “unnecessary,” non-essential, noncritical, or extraneous to the experiments and because repopulating animals in laboratories at taxpayers’ expense would appear to violate the aforementioned federal regulations and policies that mandate minimizing the use of animals in experiments.

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>

Request for Research Accountability and Modernization

We urge you to cancel the funding granted to Niswander, Williams, and Clouthier's project 5R01HD081562, and we urge you to seek reimbursement from them for any and all NICHD funds wasted in part to acquire, breed, confine and/or maintain the animals who the experimenters and/or CU Boulder deemed "unnecessary," non-essential, noncritical, or extraneous or described using similar terminology and then euthanized. Moreover, we encourage NICHD to redirect the funds it initially granted to these experimenters to instead now focus on human-relevant, non-animal research methods, as described in PETA's Research Modernization Deal.¹⁰

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

Sincerely yours,

A handwritten signature in black ink that reads "Shalin G. Gala". The signature is written in a cursive style with a large, looping initial "S".

Shalin G. Gala
Vice President, International Laboratory Methods
Laboratory Investigations Department

¹⁰People for the Ethical Treatment of Animals. (2021). *The Research Modernization Deal 2021*. <https://www.peta.org/wp-content/uploads/2020/12/PETA-2021-Research-Modernization-Deal.pdf>