

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

EOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

July 30, 2021

Re: Animal Welfare Assurance A3646-01 [OLAW Cases 1N & 1P]

Dr. Jon Reuter Assistant Vice Chancellor for Research Integrity and Compliance University of Colorado – Boulder 3100 Marine Street, UCB 563 (b) (4) Boulder, CO 80309

Dear Dr. Reuter,

Thank you for your recent communication of April 16, 2021 in response to OLAW's request for information regarding allegations made by People for the Ethical Treatment of Animals (PETA). According to the information provided, OLAW understands that, regarding research by Dr. Lee Niswander (grant 5R01HD081562), at the beginning of the COVID-19 pandemic the Office of Animal Resources (OAR) euthanized animals that were already slated for euthanasia for study purposes as approved in Dr. Niswander's protocol. Regarding Dr. Amy Palmer (grant 5DP1GM114863), at the beginning of the pandemic Dr. Palmer instructed the Office of Animal Resources (OAR) to euthanize one mouse when the University shut down for the pandemic when care for the animal could no longer be provided safely.

The following language stated by PETA " unnecessary, extraneous, noncritical, non-essential, ramped down, disposable or nonpriority" was never used at any time. At no time did CU Boulder or OAR require euthanasia of animals as part of a COVID-19 response.

CU Boulder has a process in place where the IACUC committee reviews protocols establishing that the 3 Rs are met and number justification has been provided, minimizing the number of animals required to obtain valid results of the research. In addition, CU Boulder also has a disaster plan in place where in the event it is not possible to transport animals to another location, or conditions become such that animal care cannot be provided, implementation of a humane euthanasia plan is put into place.

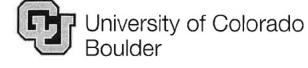
OLAW appreciates your cooperation with this matter and the transparency of your program, and we find no cause for further action by this office at this time.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S Date: 2021.07.30 13:03:14 -04'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



Jon Reuter, Assistant Vice Unancellor for Research Integrity and Compliance 3100 Marine St, UCB 563, Office 25 Boulder, CO 80309 jon reuter@colorado.edu

t 303 735-5809

April 16, 2021

Re: Animal Welfare Assurance A3646-01 (OLAW Case IN)

Brent Morris, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

Dear Dr. Morris,

In response to your official request regarding allegations from People for the Ethical Treatment of Animals (PETA) of waste of National Institutes of Health (NIH) resources wherein animals^{*} were euthanized in response to COVID-19 please see the following:

Dr. Lee Niswander (grant 5R01HD081562):

At the beginning of the COVID-19 pandemic the Office of Animal Resources (OAR) euthanized animals that were already slated for euthanasia for study purposes as approved in Dr. Niswander's protocol. The following language stated by PETA "unnecessary, extraneous, noncritical, nonessential, ramped down, disposable or nonpriority" was never used at any time.

Dr. Amy Palmer (grant 5DP1GM114863):

At the beginning of the pandemic Dr. Palmer instructed the Office of Animal Resources (OAR) to euthanize one mouse when the University shut down for the pandemic. The student approved on Dr. Palmers' protocol responsible for the welfare of the animal was classified as a high health risk category unable to go onto campus. The following language stated by PETA "unnecessary, extraneous, noncritical, non-essential, ramped down, disposable or nonpriority" was never used at any time.

At no time did CU Boulder or OAR require euthanasia of animals as part of a COVID-19 response.

CU Boulder has a process in place where the IACUC committee reviews protocols establishing that the 3 R's are met and number justification has been provided minimizing the number of animals required to obtain valid results of the research. In addition, CU Boulder also has a disaster plan in place where in the event it is not possible to transport animals to another location, or conditions become such that animal care cannot be provided, implementation of a humane euthanasia plan is put into place.

CU Boulder maintains its commitment to the health and welfare of animals used in research. Should you have any questions regarding this report, please contact Christopher A. Lowry, PhD. IACUC Chair at christopher.lowry@colorado.edu or Althea R. Lantron, IACUC Director, at <u>althea.lantron@colorado.edu</u>.

Sincerely,

(b) (6)

Jon Reuter, Assistant Vice Chancellor of Research Integrity and Compliance

Cc: Christopher A. Lowry, IACUC Chair Althea R. Lantron, Director, IACUC Director Sara Hashway, Director, Office of Animal Resources

1 Page

Ward, Joan (NIH/OD) [E]

Ward, Joan (NIH/OD) [E] From: Monday, April 19, 2021 6:52 PM Sent: To: Morse, Brent (NIH/OD) [E] Cc: RE: Response for OLAW Case 1N Subject:

(b) (6)

Thank you

^{(b) (6)} for the response. Dr. Morse will respond soon.

Regards, Joan

Joan Ward **Program Specialist** Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Dr., Suite 2500 Bethesda, MD 20892 301-496-7163 wardjoa@od.nih.gov

From:

(b) (6)

Sent: Monday, April 19, 2021 4:29 PM To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov> Cc: Jon D Reuter < Jon.Reuter@Colorado.EDU>; Sara Hashway < Sara.Hashway@colorado.edu>; Christopher Lowry <christopher.lowry@colorado.edu>; Althea Lantron <Althea.Lantron@Colorado.EDU> Subject: Response for OLAW Case 1N

Good Afternoon,

Please find attached our response to OLAW Case A3646-1N.

(b) (6)

Thank you,



Morse, Brent (NIH/OD) [E]

From:	Ward, Joan (NIH/OD) [E]
Sent:	Monday, April 19, 2021 6:52 PM
To:	(b) (6)
Cc:	Morse, Brent (NIH/OD) [E]
Subject:	RE: Response for OLAW Case 1N
Follow Up Flag:	Follow up
Flag Status:	Flagged

Thank you (b) (6) for the response. Dr. Morse will respond soon.

Regards, Joan

Joan Ward Program Specialist Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Dr., Suite 2500 Bethesda, MD 20892 301-496-7163

wardjoa@od.nih.gov

From:

(b) (6)

Sent: Monday, April 19, 2021 4:29 PM To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov> Cc: Jon D Reuter <Jon.Reuter@Colorado.EDU>; Sara Hashway <Sara.Hashway@colorado.edu>; Christopher Lowry <christopher.lowry@colorado.edu>; Althea Lantron <Althea.Lantron@Colorado.EDU> Subject: Response for OLAW Case 1N

Good Afternoon,

Please find attached our response to OLAW Case A3646-1N.

Thank you,

(b) (6)





DEPARTMENT OF HEALTH & HUMAN SERVICES

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

April 6, 2021

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 480-3387

Re: Animal Welfare Assurance A3646-01 [OLAW Case 1N]

Dr. Jon Reuter Assistant Vice Chancellor for Research Integrity and Compliance University of Colorado – Boulder 3100 Marine Street, UCB 563 (b) (4) Boulder, CO 80309

Dear Dr. Reuter,

The Office of Laboratory Animal Welfare (OLAW) has received from People for the Ethical Treatment of Animals (PETA), allegations regarding the waste of National Institutes of Health (NIH) resources at your institution by Lee A. Niswander (grant 5R01HD081562) and Amy E. Palmer (grant 5DP1GM114863), wherein animals were 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.

As authorized under section V. A. 4. of the PHS Policy, and as referenced in your Animal Welfare Assurance for Humane Care and Use of Laboratory Animals, OLAW is requesting that your institution provide an explanation of the circumstances surrounding the above allegation. Specifically, please respond whether or not animals on PHS-funded activities were euthanized after being designated as "unnecessary," "extraneous", "noncritical", "non-essential", "ramped down", "disposable", or "nonpriority" or described using similar terminology. If so, please provide an explanation to the circumstances.

Also, please confirm that your institution has a process, or processes, in place to minimize the number of animals required to obtain valid results on PHS-funded activities. In addition, confirm that your institution has a disaster plan established that defines "the actions necessary to prevent animal pain, distress, and deaths..." such that "Animals that cannot be relocate or protected from the consequences of the disaster must be humanely euthanized." Please confirm that this plan was followed in response to the COVID-19 pandemic effects on your institution.

We appreciate the consideration of this matter by the University of Colorado – Boulder and your cooperation as the Institutional Official and ask that you please provide the requested information by April 26, 2021. Please contact me if I can be of assistance.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S Date: 2021.04.06 16:36:22 -04'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

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

Page 1 of 4

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Washington, D.C. 1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles 2154 W. Sunset Blvd. Los Angeles, CA 90026 323:644:PETA

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Info@peta.org PETA.org

Affiliates: • PETA Asia

- + PETA India
- · PETA Freedo
- · PETA Australia
- · PETA Germany
- PETA Netherloads
- · PETA Eoundation [U.K.]

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. <u>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</u>

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. <u>https://www.colorado.edu/researchinnovation/research-innovation-office-covid-19-</u> resources#vivarium_considerations-2651

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

⁴Brown, H. (2020, March 17). Re: OAR guidance following suspension of research activities. <u>https://www.peta.org/wp-content/uploads/2021/01/2020-03-17_RE-OAR-guidance-following-suspension-of-research-activities.pdf</u>

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

- 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.

Animals. <u>https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf</u> 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/

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*

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

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 ^{(b) (6)} or at ^{(b) (6)} We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

		(b) (6)

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



Public Health Service

National Institutes of Health Eunice Kennedy Shriver National Institute of Child Health and Human Development Bethesda, Maryland 20892

February 19. 2021

(b) (6)

People for the Ethical Treatment of Animals 501 Front Street Norfolk, Virginia 23510

Dear Mr. Gala:

I am writing to acknowledge receipt of your February 17, 2021 letter concerning unnecessary euthanasia of animals in response to COVID-19 involving NICHD-funded experiments at University of Colorado, Boulder and University of Colorado, Denver. Because of the nature of your concerns involving animal welfare, I have referred your letter to NIH's Office of Laboratory Animal Welfare to investigate and take appropriate steps to address any findings of non-compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals by these institutions.

Sincerely,

(b) (6)

Diana W. Bianchi, M.D. Director *Eunice Kennedy Shriver* National Institute of Child Health and Human Development National Institutes of Health

cc: Dr. Brent Morse

Morse, Brent (NIH/OD) [E]

(b) (6)

From:	NICHD Director's Office
Sent:	Friday, February 19, 2021 11:43 AM
To:	(b) (6)
Cc:	Morse, Brent (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]
Subject:	Response to 17 Feb letter from PETA
Attachments:	PETA_response to Feb 17 letter_02192021.pdf
Follow Up Flag:	Follow up
Flag Status:	Flagged

Thank you for your message. Please find attached a response from Dr. Diana Bianchi pertaining to this matter.

Office of the Director *Eunice Kennedy Shriver* National Institute of Child Health and Human Development National Institutes of Health

From:

Dear

(b) (6)

Sent: Wednesday, February 17, 2021 11:03 AM To: Bianchi, Diana (NIH/NICHD) [E] <<u>diana.bianchi@nih.gov</u>> Subject: For Dr. Bianchi from PETA -- re apparent waste of NICHD resources at CU Boulder and CU Denver

Diana W. Bianchi, M.D.

Director

National Institute of Child Health and Human Development

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

Dear Dr. Bianchi:

Please find enclosed a letter on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters concerning disturbing new information we have obtained about the University of Colorado Boulder and the University of Colorado Denver's apparent waste of NICHD resources for the euthanasia of animals in response to COVID-19.

Thank you in advance for your consideration of this important issue, and we look forward to your response.

Best regards,

(b) (6)