



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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>

FOR EXPRESS MAIL:

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

August 2, 2021

Re: Animal Welfare Assurance
A3269-01 [OLAW Case 40]

Dr. Alison Lakin
Associate Vice Chancellor
for Regulatory Compliance
University of Colorado Health Sciences Center
13001 East 17th Place
Anschutz Medical Campus Bldg. 500
Denver, Colorado 80262

Dear Dr. Lakin,

Thank you for your communication of April 15, 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, Grant# 5R01HD081562 was not active during the COVID-19 pandemic. That grant funding ended in summer 2019 and there were no animals that remained on the grant in 2020. Therefore, no animals used on the grant could have been euthanized or affected by the COVID-19 pandemic. The University of Colorado Denver, Anschutz Medical Campus did not suspend and/or end any experiments as a result of COVID-19 due to animal facility and research staff managing animal-based studies being classified as essential personnel. As a result, the University did not direct research or animal facility staff to euthanize animals due to the COVID pandemic.

It is understood that there are processes in place to minimize the number of animals required to obtain valid results. The IACUC reviews animal number requests as part of the IACUC protocol review and approval process.

The University also confirmed that there is a disaster plan that outlines your response to a wide array of disasters. The plan spells out the scenarios for when euthanasia of animals would be implemented, but that is always a last resort, and only used if it is not possible to ensure the health, welfare, and appropriate housing of the animals. The decision on when it is appropriate to euthanize animals in the event of a disaster is under the direction of the Attending Veterinarian. The euthanasia portion of the disaster plan was not implemented during the COVID-19 pandemic.

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: 2021.08.02 08:16:01 -04'00'

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

cc: IACUC contact



April 15, 2021

Animal Welfare Assurance # D16-00171

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7892
Bethesda, Maryland 20892-7982

Dear Dr. Morse,

With respect to your letter of April 6, 2021, regarding the People for the Ethical Treatment of Animals (PETA), allegations regarding the waste of National Institutes of Health (NIH) resources (grant 5R01HD081562) at our institution by Trevor J. Williams and David E. Clouthier, 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.

Your request that our institution provide an explanation of the circumstances surrounding the allegation is addressed below.

1. Grant # 5R01HD081562 was not active during the COVID-19 pandemic. Grant # 5R01HD081562 funding ended in summer 2019 and there were no animals that remained on this grant in 2020. Therefore, no animals used on this grant could have been euthanized or affected by the COVID-19 pandemic.

The University of Colorado Denver | Anschutz Medical Campus did not suspend and/or end any experiments due to COVID-19. The institution communicated frequently with all animal research staff through emails and campus FAQs. An early communication asked researchers “to plan for potential phased reductions of research activities with animals.” This communication was in accordance with our IACUC reviewed and approved disaster plan. As indicated in our disaster plan, conditions were monitored closely during the campus closure to determine what actions were appropriate. The conditions at our institution allowed for animal facility and research staff managing animal based studies to be classified as essential personnel. The campus experienced no severe shortage of staff or necessary supplies. As a result, the University did not direct research or animal facility staff to euthanize animals due to the COVID pandemic. Research staff were permitted to continue all in progress studies.



The campus did request that research groups pause the start of new studies for approximately 2 months and vendor orders were suspended with the exception for specialized circumstances.

2. The University confirms that there are processes in place to minimize the number of animals required to obtain valid results.

The University of Colorado Denver | Anschutz Medical Campus IACUC thoroughly reviews animal number requests as part of their IACUC protocol review and approval process as outlined in our Assurance.

3. The University confirms that we have a disaster plan that outlines our response to a wide array of disasters.

The animal program at the University of Colorado Denver | Anschutz Medical Campus has a disaster plan that is reviewed and approved by the IACUC annually. The plan spells out the scenarios for when euthanasia of animals would be implemented, but that is always a last resort, and only used if it is not possible to ensure the health, welfare, and appropriate housing of the animals. The decision on when it is appropriate to euthanize animals in the event of a disaster is under the direction of the Attending Veterinarian.

The euthanasia portion of the disaster plan was not implemented during the COVID-19 pandemic. Our animal care providers are considered essential workers and they provided, and continue to provide, the normal standard of animal care at our institution during the COVID-19 pandemic.

I hope this clarification satisfactorily addresses your concerns.

Please let me know if you require further information.

Sincerely,

 (b) (6)

Alison Lakin RN, LLB, LLM, PhD
Associate Vice Chancellor for Regulatory Compliance
University of Colorado Denver | Anschutz Medical Campus

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Tuesday, April 20, 2021 11:55 AM
To: Douse, Mark; Ward, Joan (NIH/OD) [E]
Cc: Lakin, Alison
Subject: RE: Emailing: Lakin UCO 3269-40

Thank you Dr. Douse. I will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Douse, Mark <MARK.DOUSE@CUANSCHUTZ.EDU>
Sent: Tuesday, April 20, 2021 10:23 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: Lakin, Alison <ALISON.LAKIN@CUANSCHUTZ.EDU>
Subject: Re: Emailing: Lakin UCO 3269-40

Animal Welfare Assurance D16-00171

Dear Dr. Morse,

Please find attached Dr. Lakin's response to your letter of April 6, 2021 regarding OLAW Case A3269-40.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Mark Douse

Mark A. Douse, PhD
Director

Office for Research Committee Support (ORCS)

University of Colorado Denver | Anschutz Medical Campus

Voice: (b) (6)

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Wednesday, April 7, 2021 7:49 AM

To: Lakin, Alison <ALISON.LAKIN@CUANSCHUTZ.EDU>

Cc: CLAC, IACUC <IACUC@CUANSCHUTZ.EDU>; Douse, Mark <MARK.DOUSE@CUANSCHUTZ.EDU>

Subject: FW: Emailing: Lakin UCO 3269-40

Dear Dr. Lakin,

Attached please find Dr. Brent Morse's response to a PETA complaint for OLAW Case A3269-40.

If you have any questions feel free to contact Dr. Morse by phone or by email.

Regards,

Joan

Joan Ward

Program Specialist

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Dr., Suite 2500

Bethesda, MD 20892

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wardjoa@od.nih.gov

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April 6, 2021

Re: Animal Welfare Assurance
A3269-01 [OLAW Case 40]

Dr. Alison Lakin
Associate Vice Chancellor
for Regulatory Compliance
University of Colorado Health Sciences Center
13001 East 17th Place
Anschutz Medical Campus Bldg. 500
Denver, Colorado 80262

Dear Dr. Lakin,

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 (grant 5R01HD081562) at your institution by Trevor J. Williams and David E. Clouthier, 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 – Denver 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.

Page 2 – Dr. Lakin
April 6, 2021
OLAW Case A3269-40

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2021.04.06 15:57:27
-04'00'

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

cc: IACUC contact



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

PEOPLE FOR
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info@peta.org
PETA.org

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>

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (UK)

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 (b) (4) 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 (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>