



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

July 28, 2021

Re: Animal Welfare Assurance  
A3304-01 [OLAW Case 3X]

Dana L. Director, Ph.D.  
Vice President for Research Operations  
And Student Affairs  
Oregon Health and Science University  
3181 SW Sam Jackson Park Rd.  
Portland, OR 97239-3098

Dear Dr. Director,

Thank you for your recent communication of May 28, 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:

- 1) OHSU did not categorize any animals as "unnecessary", "extraneous", "noncritical", "non-essential", "disposable", or describe them by any other similar terminology in response to the COVID-19 pandemic.
- 2) The IACUC approves only the minimal number of animals required to obtain valid research results. Scientific justification for the number of animals requested is required to attain protocol approval from the IACUC.
- 3) OHSU has a disaster plan that defines actions to prevent animal pain, distress, and deaths from the consequences of a disaster. Proactive steps taken in March 2020 by your institution included a "stop" on the ordering and importation of additional animals. The institution directed investigators to reduce rodent colonies, for example by discontinuing breeding for future experiments and halting ordering of new animals.
- 4) When laboratory personnel could not safely enter the facilities to monitor the animals and ensure their welfare, the only ethical option was to conduct euthanasia. These actions, as defined in the OHSU Disaster Plan, were such that animals that could not be relocated or protected from the consequences of the disaster were humanely euthanized.

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: 2021.07.28 08:00:46 -04'00'

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

cc: IACUC contact  
Director, Animal Care & Use program



May 28, 2021

Brent Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Research & Innovation Office

tel 503 494-1083  
fax 503 494-1099

Dana Director, PhD  
Vice President of Research  
Administration & Senior Staff  
Officer

[director@ohsu.edu](mailto:director@ohsu.edu)  
[www.ohsu.edu/research](http://www.ohsu.edu/research)

Mail code: L335  
3181 S.W. Sam Jackson Park Rd.  
Portland, OR 97239-3098

Dear Dr. Morse:

Oregon Health & Science University (OHSU), in accordance with Assurance D16-00195 (A3304-01) and PHS Policy IV.F.3., provides this explanation of circumstances surrounding allegations from the People for the Ethical Treatment of Animals (PETA) of waste of National Institutes of Health (NIH) resources at our institution. This explanation applies to the following:

Funding Agency	Investigator	Award	Protocol Title
NIEHS	Stephen Lloyd	1R56ES027632-01A1	The Roles of BER and TLS in Limiting Aflatoxin-Induced Carcinogenesis
NIEHS	Stephen Lloyd	5R01ES031086-02	Role of Base Excision Repair in Limiting Hepatocellular Carcinomas
NIAID	Scott Landfear	5R33AI127591-05	Development of Novel Therapeutics for Leishmaniasis
NIMH	Brian O'Roak	5R01MH113926-04	Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism risk

As we indicated in our response to PETA on August 6, 2020, OHSU did not categorize any animals as “unnecessary”, “extraneous”, “noncritical”, “non-essential”, “disposable”, or describe them by any other similar terminology in response to the COVID-19 pandemic. All animals used in research at OHSU are essential in addressing critically important scientific questions. Animal models are used only when non-animal models are unavailable as suitable alternatives.

The Institutional Animal Care and Use Committee (IACUC) conducts rigorous review prior to approval of the numbers of animals used in research. Investigators must justify the numbers of animals they request in their IACUC proposals through statistical power analysis based on known or expected variation of experimental endpoints. The IACUC

approves only the minimal number of animals required to obtain valid research results. Scientific justification for the number of animals requested is required to attain protocol approval from the IACUC.

OHSU entered Modified Operations for Research on March 23, 2020 due to the impacts of the COVID-19 pandemic. As a biomedical research and healthcare institution, OHSU acted to protect the health and safety of our patients, our employees and their families, and the health and welfare of the animals under our care.

OHSU has a disaster plan that defines actions to prevent animal pain, distress, and deaths from the consequences of a disaster. Proactive steps taken in March 2020 by our institution included a "stop" on the ordering and importation of additional animals. The institution directed investigators to reduce rodent colonies, for example by discontinuing breeding for future experiments and halting ordering of new animals. These actions, as detailed in our disaster plan, conserved precious resources, such as personal protective equipment (PPE), needed for the care of animals present in our facilities at that time.

In addition, the institution carefully reviewed ongoing experimental timelines, making adjustments to minimize physical contacts among laboratory personnel. When laboratory personnel could not safely enter the facilities to monitor the animals and ensure their welfare, the only ethical option was to conduct euthanasia. These actions, as defined in the OHSU Disaster Plan, were such that animals that could not be relocated or protected from the consequences of the disaster were humanely euthanized.

Planning for a "worst case scenario" included preparation for a limited husbandry and veterinary workforce and training of laboratory personnel to assist in husbandry duties. Through careful management of physical distancing among personnel and judicious use of PPE, the husbandry and veterinary staff resources of the centralized vivarium executed all normal duties in delivering care and ensuring animal welfare.

OHSU is committed to protecting the welfare of the animals we use in answering critical scientific questions for the benefit of both humans and animals. Should you have any questions regarding this response, please contact (b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dana L. Director, Ph.D.

Vice President of Research Administration & Senior Staff Officer  
Institutional Official  
Oregon Health & Science University

cc: Attending Veterinarian  
IACUC Chair  
Director, Animal Care & Use Program

## Morse, Brent (NIH/OD) [E]

---

**From:** Walker, Keri (NIH/OD) [E]  
**Sent:** Tuesday, June 1, 2021 8:01 AM  
**To:** Morse, Brent (NIH/OD) [E]  
**Subject:** FW: OHSU A3304-01 Case 3X  
**Attachments:** response to PETA allegations final signed.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

See attached.

Keri

**From:** (b) (6)  
**Sent:** Friday, May 28, 2021 11:52 AM  
**To:** Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>  
**Cc:** Dana Director <director@ohsu.edu>  
**Subject:** RE: OHSU A3304-01 Case 3X

Dear Ms. Walker,

Please find attached the requested explanation from Oregon Health & Science University regarding allegations from People for the Ethical Treatment of Animals (PETA) of waste of National Institutes of Health resources.

Respectfully,

(b) (6)



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

May 10, 2021

Re: Animal Welfare Assurance  
A3304-01 [OLAW Case 3X]

Dana L. Director, Ph.D.  
Vice President for Research Operations  
Oregon Health and Science University  
3181 SW Sam Jackson Park Rd.  
Portland, OR 97239-3098

Dear Dr. Director,

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 NIEHS-funded investigator, Dr. Stephen Lloyd under protocols titled, "The Roles of BER and TLS in Limiting Aflatoxin-Induced Carcinogenesis" (1R56ES027632-01A1) and "Role of Base Excision Repair in Limiting Hepatocellular Carcinomas" (5R01ES031086-02), wherein animals were categorized as "unnecessary," "extraneous," "noncritical," "non-essential," "ramped down," "disposable," "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 relocated 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 Oregon Health and Science University and your cooperation as the Institutional Official and ask that you please provide the requested information by **May 31, 2021**. Please contact me if I can be of assistance.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.  
Morse -S  
Date: 2021.05.10 13:38:21 -04'00'

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

cc: IACUC contact  
Director, Animal Care & Use program





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

May 11, 2021

Re: Animal Welfare Assurance  
A3304-01 [OLAW Case 3X]

**Addendum**

Dana L. Director, Ph.D.  
Vice President for Research Operations  
Oregon Health and Science University  
3181 SW Sam Jackson Park Rd.  
Portland, OR 97239-3098

Dear Dr. Director,

The Office of Laboratory Animal Welfare (OLAW) has received from People for the Ethical Treatment of Animals (PETA), additional allegations regarding the waste of National Institutes of Health (NIH) resources at your institution by NIAID-funded investigator, Dr. Scott Landfear, under the protocol titled, "Development of Novel Therapeutics for Leishmaniasis" (5R33AI127591-05), and NIMH-funded investigator, Dr. Brian O'Roak, under the protocol titled, "Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism Risk" (5R01MH113926-04), wherein animals were categorized as "unnecessary," "extraneous," "noncritical," "non-essential," "ramped down," "disposable," "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 relocated 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 Oregon Health and Science University and your cooperation as the Institutional Official and ask that you please provide the requested information **by May 31, 2021**. Please contact me if I can be of assistance.

Sincerely,

**Brent C. Morse -S** Digitally signed by Brent C. Morse -S  
Date: 2021.05.11 08:19:03 -04'00'

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

cc: IACUC contact  
Director, Animal Care & Use program



February 17, 2021

Rick Woychik, Ph.D.  
Director  
National Institute of Environmental Health Sciences

Via e-mail: [NIEHSDirector@nih.gov](mailto:NIEHSDirector@nih.gov)

Dear Dr. Woychik:

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.<sup>1</sup>

**Based on the new information presented below, we urge the National Institute of Environmental Health Sciences (NIEHS) to cancel the taxpayer funding—amounting to \$308,000 in FY2017<sup>2</sup> and \$357,057 in FY2021<sup>3</sup>—granted to experimenter Stephen Lloyd of the Oregon Health & Science University (OHSU) for any and all renewals of his protocols, and insist that he reimburses the taxpayer funds used to acquire, breed, confine and maintain the animals used in experiments whom OHSU 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.**

<sup>1</sup>People 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>

<sup>2</sup> NIH. (n.d.). *The Roles Of BER And TLS in Limiting Aflatoxin-Induced Carcinogenesis: 1R56ES027632-01A1*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

[https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=9527499&icde=53581510](https://projectreporter.nih.gov/project_info_details.cfm?aid=9527499&icde=53581510)

<sup>3</sup> NIH. (n.d.). *Role of Base Excision Repair in Limiting Hepatocellular Carcinomas: 5R01ES031086-02*. Research Portfolio Online Reporting Tools (RePORT): Project Information. [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=10077479&icde=53581431](https://projectreporter.nih.gov/project_info_details.cfm?aid=10077479&icde=53581431)

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

Norfolk  
501 Front St.  
Norfolk, VA 23510  
757-622-PETA

Berkeley  
2855 Telegraph Ave.  
Ste. 301  
Berkeley, CA 94705  
510-763-PETA

[info@peta.org](mailto:info@peta.org)  
[PETA.org](http://PETA.org)

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands

Obtained by Rise for Animals.

**Euthanizing Animals Extraneous to NIEHS-Funded Experiments Wastes Taxpayer Funds**  
Dr. Lloyd conducted and/or conducts the NIEHS-funded protocols titled, “The Roles of BER and TLS in Limiting Aflatoxin-Induced Carcinogenesis” (1R56ES027632-01A1) and “Role of Base Excision Repair in Limiting Hepatocellular Carcinomas” (5R01ES031086-02). Per its COVID-19 response

plan, OHSU notified its staff that “the university’s research mission has been curtailed,”<sup>4</sup> and on March 23, 2020, OHSU transitioned to “modified operations” in response to COVID-19.<sup>5</sup> As a result, animals assigned to Lloyd’s aforementioned protocol were euthanized in March 2020.<sup>6</sup> This was verified in a correspondence with OHSU staff.<sup>7,8,9</sup>

The fact that the laboratory led by Lloyd had any 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.

### **Lloyd’s NIEHS-Funded Protocol Failed to Reduce and Replace Animal Use**

The presence of any unnecessary, non-essential, noncritical, or extraneous animals in NIEHS-funded experiments led by Lloyd 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 National Institutes of 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*].”<sup>10</sup>

<sup>4</sup>OHSU. (2020, February 28). *OHSU coronavirus (COVID-19) response*.

<https://news.ohsu.edu/2020/02/28/preparing-for-the-novel-coronavirus-at-ohsu>

<sup>5</sup>OHSU. (n.d.). *Research and Innovation*. <https://www.ohsu.edu/research-innovation>

<sup>6</sup>OHSU. (n.d.). *Euthanized due to COVID-19*. <https://www.peta.org/wp-content/uploads/2021/02/Euthanized-due-to-COVID-19-Redacted.pdf>

<sup>7</sup>Kuske, R. (2021, February 9). *Response to PETA’s 2/3/21 amended request*. <https://www.peta.org/wp-content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf>

<sup>8</sup>Kuske, R. (2021, February 11). *Response to PETA’s 08/28/20 & 12/16/20 requests*. <https://www.peta.org/wp-content/uploads/2021/02/Response-to-PETAs-082820-121620-requests.pdf>

<sup>9</sup>eIACUC. (2021, January 6). *Role of Base Excision Repair following Oxidative Stress (TR01\_IP00000145)*. <https://www.peta.org/wp-content/uploads/2021/02/IP00145-Redacted.pdf>

<sup>10</sup>Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <https://olaw.nih.gov/policies-laws/hrea-1985.htm>



- 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].”<sup>11</sup>
- 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].”<sup>12</sup>
- 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].”<sup>13</sup>

When Lloyd, and NIEHS-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 the experiments led by Lloyd should have been zero from the start since they weren’t relevant to his 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, OHSU should reimburse the NIEHS 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.”<sup>14</sup> Taxpayers and NIEHS should not be responsible for the additional costs associated with “reestablishing laboratory animal populations” since universities 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.

### **Request for Research Accountability and Modernization**

<sup>11</sup>NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <https://grants.nih.gov/grants/olaw/pl103-43.pdf>

<sup>12</sup>National 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>

<sup>13</sup>National 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/>

<sup>14</sup>Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the federal research and development enterprise*. <https://crsreports.congress.gov/product/pdf/R/R46309>

We urge you to cancel the funding granted to Lloyd's projects 1R56ES027632-01A1 and 5R01ES031086-02, and to seek reimbursement from him for any and all NIEHS funds wasted to acquire, breed, confine and/or maintain the animals who he and/or OHSU deemed unnecessary, non-essential, noncritical, extraneous or described using similar terminology and then euthanized. Moreover, we encourage NIEHS to redirect the funds it initially granted to Lloyd to instead now focus on human-relevant, non-animal research methods, as described in PETA's Research Modernization Deal.<sup>15</sup>

You can contact me at (b) (6) We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

(b) (6)

---

<sup>15</sup>People 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>



February 17, 2021

Hugh Auchincloss, M.D.  
Principal Deputy Director  
National Institute of Allergy and Infectious Diseases

Via e-mail: [auchinclossh@niaid.nih.gov](mailto:auchinclossh@niaid.nih.gov)

Dear Dr. Auchincloss:

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.<sup>1</sup>

**Based on the new information presented below, we urge the National Institute of Allergy and Infectious Diseases (NIAID) to cancel the taxpayer funding—amounting \$446,184 in FY2021<sup>2</sup>—granted to experimenter Scott Landfear of the Oregon Health & Science University (OHSU) for any and all renewals of his protocols, and insist that he reimburses the taxpayer funds used to acquire, breed, confine and maintain the animals used in experiments whom OHSU 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 NIAID-Funded Experiments Wastes Taxpayer Funds**

Landfear conducts the NIAID-funded protocol titled, “Development of Novel Therapeutics for Leishmaniasis” (5R33AI127591-05). Per its

<sup>1</sup>People 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>

<sup>2</sup> NIH. (n.d.). *Development of Novel Therapeutics For Leishmaniasis: 5R33AI127591-05*. Research Portfolio Online Reporting Tools (RePORT): Project Information. [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=10059160&icde=53581610](https://projectreporter.nih.gov/project_info_details.cfm?aid=10059160&icde=53581610)

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

Norfolk  
501 Front St.  
Norfolk, VA 23510  
757-622-PETA

Berkeley  
2855 Telegraph Ave.  
Ste. 301  
Berkeley, CA 94705  
510-763-PETA

[info@peta.org](mailto:info@peta.org)  
[PETA.org](http://PETA.org)

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands

Obtained by Rise for Animals.

COVID-19 response plan, OHSU notified its staff that “the university’s research mission has been curtailed,”<sup>3</sup> and on March 23, 2020, OHSU transitioned to “modified operations” in response to COVID-19.<sup>4</sup> As a result, animals assigned to Landfear’s aforementioned protocol were euthanized in March 2020.<sup>5</sup> This was verified in a correspondence with OHSU staff.<sup>6,7,8</sup>

The fact that the laboratory led by Landfear had any 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.

### **Landfear NIAID-Funded Protocol Failed to Reduce and Replace Animal Use**

The presence of any unnecessary, non-essential, noncritical, or extraneous animals in NIAID-funded experiments led by Landfear 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 National Institutes of 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*].”<sup>9</sup>
- 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*].”<sup>10</sup>
- 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,*

<sup>3</sup>OHSU. (2020, February 28). *OHSU coronavirus (COVID-19) response*.

<https://news.ohsu.edu/2020/02/28/preparing-for-the-novel-coronavirus-at-ohsu>

<sup>4</sup>OHSU. (n.d.). *Research and Innovation*. <https://www.ohsu.edu/research-innovation>

<sup>5</sup>OHSU. (n.d.). *Euthanized due to COVID-19*. <https://www.peta.org/wp-content/uploads/2021/02/Euthanized-due-to-COVID-19-Redacted.pdf>

<sup>6</sup>Kuske, R. (2021, February 9). *Response to PETA's 2/3/21 amended request*. <https://www.peta.org/wp-content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf>

<sup>7</sup>Kuske, R. (2021, February 11). *Response to PETA's 08/28/20 & 12/16/20 requests*. <https://www.peta.org/wp-content/uploads/2021/02/Response-to-PETAs-082820-121620-requests.pdf>

<sup>8</sup>eIACUC. (2021, January 6). *Delivery of Synthetic Organic Compounds as Broad Spectrum Anti- Parasitic Drugs (TR01\_IP00000383)*. <https://www.peta.org/wp-content/uploads/2021/02/IP00383-Redacted.pdf>

<sup>9</sup>Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <https://olaw.nih.gov/policies-laws/hrea-1985.htm>

<sup>10</sup>NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <https://grants.nih.gov/grants/olaw/pl103-43.pdf>



*computer simulations, and/or mathematical models) to reduce or replace the use of animals [emphasis added].*<sup>11</sup>

- 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].*”<sup>12</sup>

When Landfear, an NIAID-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 the experiments led by Landfear should have been zero from the start since they weren’t relevant to his 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, OHSU should reimburse the NIAID 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.”<sup>13</sup> Taxpayers and NIAID should not be responsible for the additional costs associated with “reestablishing laboratory animal populations” since universities 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.

### **Request for Research Accountability and Modernization**

We urge you to cancel the funding granted to Landfear’s project 5R33AI127591-05, and to seek reimbursement from him for any and all NIAID funds wasted to acquire, breed, confine and/or maintain the animals who he and/or OHSU deemed unnecessary, non-essential, noncritical, extraneous or described using similar terminology and then euthanized. Moreover, we encourage

---

<sup>11</sup>National 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>

<sup>12</sup>National 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/>

<sup>13</sup>Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the federal research and development enterprise*. <https://crsreports.congress.gov/product/pdf/R/R46309>

NIAID to redirect the funds it initially granted to Landfear to instead now focus on human-relevant, non-animal research methods, as described in PETA's Research Modernization Deal.<sup>14</sup>

You can contact me at [REDACTED] (b) (6) We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

[REDACTED] (b) (6)

---

<sup>14</sup>People 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>



February 17, 2021

Joshua A. Gordon, M.D., Ph.D.  
Director  
National Institute of Mental Health

Via e-mail: [joshua.gordon@nih.gov](mailto:joshua.gordon@nih.gov)

Dear Dr. Gordon:

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.<sup>1</sup>

**Based on the new information presented below, we urge the National Institute of Mental Health (NIMH) to cancel the taxpayer funding—amounting to \$499,244 for FY2020—granted to experimenter Brian O'Roak of the Oregon Health & Science University (OHSU) for any and all renewals of his protocols, and insist that he reimburses the taxpayer funds used to acquire, breed, confine and maintain the animals used in experiments whom OHSU 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 NIMH-Funded Experiments Wastes Taxpayer Funds**

O'Roak conducts the NIMH-funded protocol titled, "Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism Risk" (5R01MH113926-04).<sup>2</sup> Per its COVID-19 response plan,

<sup>1</sup>People 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>

<sup>2</sup>NIH. (n.d.). *Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master*

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

Norfolk  
501 Front St.  
Norfolk, VA 23510  
757-622-PETA

Berkeley  
2855 Telegraph Ave.  
Ste. 301  
Berkeley, CA 94705  
510-763-PETA

[info@peta.org](mailto:info@peta.org)  
[PETA.org](http://PETA.org)

#### Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands

Obtained by Rise for Animals.

OHSU notified its staff that “the university’s research mission has been curtailed,”<sup>3</sup> and on March 23, 2020, OHSU transitioned to “modified operations” in response to COVID-19.<sup>4</sup> As a result, animals assigned to O’Roak’s aforementioned protocol were deemed non-essential and euthanized during months of March,<sup>5,6,7,8,9</sup> May<sup>10</sup> and June,<sup>11</sup> 2020. This was verified in a correspondence with OHSU staff.<sup>12,13</sup>

The fact that the laboratory led by O’Roak had any 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.

### **O’Roak’s NIMH-Funded Protocol Failed to Reduce and Replace Animal Use**

The presence of any unnecessary, non-essential, noncritical, or extraneous animals in NIMH-funded experiments led by O’Roak 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 National Institutes of 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

---

*Regulator of Autism Risk: 5R01MH113926-04*. Research Portfolio Online Reporting Tools (RePORT): Project Information. *Funded from 2017*.

[https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=9929658&icde=53561143](https://projectreporter.nih.gov/project_info_details.cfm?aid=9929658&icde=53561143)

<sup>3</sup>OHSU. (2020, February 28). *OHSU coronavirus (COVID-19) response*.

<https://news.ohsu.edu/2020/02/28/preparing-for-the-novel-coronavirus-at-ohsu>

<sup>4</sup>OHSU. (n.d.). *Research and Innovation*. <https://www.ohsu.edu/research-innovation>

<sup>5</sup>OHSU (n.d.). *Tbr1- Mouse Master List*. <https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List-Redacted.pdf>

<sup>6</sup>OHSU (n.d.). *Tbr1 Mouse List Line-1*. <https://www.peta.org/wp-content/uploads/2021/02/Line-1-Redacted.pdf>

<sup>7</sup>OHSU (n.d.). *Tbr1 Mouse List Line-2*. <https://www.peta.org/wp-content/uploads/2021/02/Line-2-Redacted.pdf>

<sup>8</sup>OHSU (n.d.). *Tbr1 Mouse List Line-3*. <https://www.peta.org/wp-content/uploads/2021/02/Line-3-Redacted.pdf>

<sup>9</sup>OHSU (n.d.). *Tbr1 Mouse List Line-4*. <https://www.peta.org/wp-content/uploads/2021/02/Line-4-Redacted.pdf>

<sup>10</sup>OHSU (n.d.). *Tbr1- Mouse Master List*. <https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List-Redacted.pdf>

<sup>11</sup>OHSU (n.d.). *Tbr1- Mouse Master List*. <https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List-Redacted.pdf>

<sup>12</sup>Kuske, R. (2021, February 9). *Response to PETA’s 2/3/21 amended request*. <https://www.peta.org/wp-content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf>

<sup>13</sup>eIACUC. (2021, January 6). *Advanced genome editing for new molecular models of autism (TR01\_IP00000077)*. <https://www.peta.org/wp-content/uploads/2021/02/IP000077-Redacted.pdf>



... use of *research or testing methods that limit the use of animals* or limit animal distress [*emphasis added*].”<sup>14</sup>

- 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*].”<sup>15</sup>
- 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*].”<sup>16</sup>
- 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*].”<sup>17</sup>

When O’Roak, an NIMH-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 the experiments led by O’Roak should have been zero from the start since they weren’t relevant to his 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, OHSU should reimburse the NIMH 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.”<sup>18</sup> Taxpayers and NIMH should not be responsible for the additional costs associated with “reestablishing laboratory animal populations” since universities deemed many of them to be unnecessary, non-essential, noncritical, or extraneous to the experiments and because repopulating animals in laboratories at

---

<sup>14</sup>Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <https://olaw.nih.gov/policies-laws/hrea-1985.htm>

<sup>15</sup>NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <https://grants.nih.gov/grants/olaw/pl103-43.pdf>

<sup>16</sup>National 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>

<sup>17</sup>National 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/>

<sup>18</sup>Congressional Research Service. (2020, April 10). *Effects of COVID-19 on the federal research and development enterprise*. <https://crsreports.congress.gov/product/pdf/R/R46309>

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 O'Roak's project 5R01MH113926-04 and to seek reimbursement from him for any and all NIMH funds wasted to acquire, breed, confine and/or maintain the animals who he and/or OHSU deemed unnecessary, non-essential, noncritical, extraneous or described using similar terminology and then euthanized. Moreover, we encourage NIMH to redirect the funds it initially granted to O'Roak to instead now focus on human-relevant, non-animal research methods, as described in PETA's Research Modernization Deal.<sup>19</sup>

You can contact me at [REDACTED] (b) (6) We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

[REDACTED] (b) (6)

---

<sup>19</sup>People 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>

## Walker, Keri (NIH/OD) [E]

---

**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Monday, May 10, 2021 12:03 PM  
**To:** Walker, Keri (NIH/OD) [E]  
**Subject:** New case for OHSU A3304  
**Attachments:** 2021-02-17\_Request\_to\_NIEHS[2].pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Keri,

Please use this email and the attached file to open a case for A3304. Oregon Health and Science University. Assign it to me and please let me know the case number. Thank you.

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

**From:** Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>  
**Sent:** Wednesday, February 24, 2021 7:07 PM  
**To:** (b) (6)  
**Cc:** Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>  
**Subject:** Your letters to NIMH, NIAID, NIEHS, and NIGMS

Dear (b) (6)

We are in receipt of your letters to my colleague, Dr. Joshua Gordon, Dr. Hugh Auchincloss, and Dr. Rick Woychick. I also previously wrote to you regarding your letter to my colleague Dr. Jon Lorsch.

NIH takes seriously the welfare of laboratory animals. If you have concerns about the welfare of laboratory animals, please contact the Director of the Office of Laboratory Animal Welfare at 6705 Rockledge Drive, Suite 360, Bethesda, Maryland 20892-7982, or by email at [olaw@od.nih.gov](mailto:olaw@od.nih.gov).

Sincerely,  
Michael S Lauer, MD

Michael S Lauer, MD  
NIH Deputy Director for Extramural Research  
1 Center Drive, Building 1, Room 144  
Bethesda, MD 20892  
Phone: 301-496-1096  
Email: [Michael.Lauer@nih.gov](mailto:Michael.Lauer@nih.gov)