February 17, 2021

Shemia Fagan, J.D. Oregon Secretary of State

Via e-mail: <u>audits.sos@oregon.gov</u>

Dear Secretary Fagan,

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters worldwide to share some troubling information we have obtained about the performance of Oregon Health & Science University (OHSU) regarding the apparent waste of state resources allocated to animal research activities. In that regard, we request that your office audit the university and investigate the apparent fiscal waste of taxpayer money in crude animal experimentation.

Based on the information presented below, we request, as part of any audit your office pursues into this matter, that you: 1) seek reimbursement of any and all state funds used to acquire, breed, confine and/or maintain the animals used in experiments whom OHSU categorized as unnecessary, extraneous, noncritical, nonessential, ramped down, disposable, nonpriority and/or described using similar terminology and—according to documents obtained by PETA through Freedom of Information Act (FOIA) requests euthanized in response to COVID-19; and, 2) ensure that current state-funded research activities involving such animals are permanently terminated, that new state-funded research activities that include such animals are no longer approved, and that the breeding and acquisition of such animals for state-funded research activities are prohibited.

Euthanizing Unnecessary Animals in OHSU Experiments Wastes Taxpayer Funds

In FY2020 OHSU totaled \$40 million in state appropriations,¹ part of which may have been used to support animal experimentation activities. According to new documents obtained by PETA through FOIA requests, at least 205 animals assigned to the following National Institutes of Health (NIH)-funded protocols—which likely also involve the use of Oregon state money, personnel, property, equipment, and



PETA

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 PETA.org

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (U.K.)

¹ OHSU. (n.d.). *Financial Statements and Supplementary Information*. https://www.ohsu.edu/sites/default/files/2020-11/ohsu-financial-stmt-audited-fy20.pdf

space by OHSU for such activities—were deemed unnecessary, extraneous, noncritical, nonessential or similar terminology and killed in response to a directive issued by OHSU amid the COVID-19 pandemic in which the university transitioned to "modified operations" on March 23, 2020:²

- The protocol titled, "Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism Risk,"³ is led OHSU's Brian O'Roak.⁴
- The protocols titled, "Role of Base Excision Repair in Limiting Hepatocellular Carcinomas,"⁵ and, "The Roles of BER and TLS in Limiting Aflatoxin-Induced Carcinogenesis,"⁶ are led by OHSU's Stephen Lloyd.⁷
- The protocol titled, "Development of Novel Therapeutics for Leishmaniasis,"⁸ is led by OHSU's Scott Landfear.⁹

The euthanasia of animals related to O'Roak's, Lloyd's, and Landfear's aforementioned NIHfunded protocols, and potentially other non-NIH-funded studies¹⁰¹¹ stemming from OHSU's response to COVID-19, was logged in university euthanasia record forms corresponding to dates

https://projectreporter.nih.gov/project_info_details.cfm?aid=10077479&icde=53581431

⁶ 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

² OHSU. (n.d.). *Research and Innovation*. <u>https://www.ohsu.edu/research-innovation</u>

³ eIACUC. (2021, January 6). Advanced genome editing for new molecular models of autism (TR01_IP00000077). https://www.peta.org/wp-content/uploads/2021/02/IP00077_Redacted.pdf

⁴ NIH. (n.d.). Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism Risk: 5R01MH113926-04. Research Portfolio Online Reporting Tools (RePORT): Project Information. Funded from 2017.

⁵ NIH. (n.d.). *Role of Base Excision Repair in Limiting Hepatocellular Carcinomas: 5R01ES031086-02*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

⁷ 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

⁸ 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

⁹ eIACUC. (2021, January 6). *Delivery of Synthetic Organic Compounds as Broad Spectrum Anti- Parasitic Drugs* (*TR01_IP00000383*). <u>https://www.peta.org/wp-content/uploads/2021/02/IP00383_Redacted.pdf</u>

¹⁰ eIACUC. (2021, January 6**Redacted** *murine studies*. (*TR01_IP00000450*). <u>https://www.peta.org/wp-content/uploads/2021/02/IP00450_Redacted.pdf</u>

¹¹ eIACUC. (2021, January 6). **Redacted** *lab IACUC protocol.* (*TR01_IP00002053*). https://www.peta.org/wp-content/uploads/2021/02/IP2053 Redacted.pdf

in , March ^{12,13,14,15,16,17,18,19,20,21} May,²² and June²³ 2020. This has further been verified in a correspondence with OHSU staff.^{24,25}

The fact that laboratories led by OHSU's employees had animals deemed unnecessary, extraneous, noncritical, non-essential or similar terminology in the first place should raise significant red flags, especially since their experiments are funded and/or supported by taxpayers who should not have to foot the bill for such waste.

OHSU Protocols Failed to Reduce and Replace Animal Use

The presence of unnecessary, non-essential, noncritical, or extraneous animals in OHSU laboratories flies in the face of existing regulations designed to minimize the use of animals in experiments.

Government policy 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

¹⁴ OHSU (n.d.). Lab Public Records Request 2. <u>https://www.peta.org/wp-</u>

content/uploads/2021/02/Lab PublicRecordsRequest Page2 Redacted.pdf

¹² OHSU (n.d.). *Euthanized due to COVID-19*. <u>https://www.peta.org/wp-content/uploads/2021/02/Euthanized-due-to-COVID-19_Redacted.pdf</u>

¹³ OHSU (n.d.). Lab Public Records Request 1. <u>https://www.peta.org/wp-</u> content/uploads/2021/02/Lab_PublicRecordsRequest_Page1_Redacted.pdf

¹⁵ OHSU (n.d.). *Mouse Report*. <u>https://www.peta.org/wp-content/uploads/2021/02/Mouse-report-</u> combined_Redacted.pdf

¹⁶ OHSU (n.d.). *Mice Euthanized for Shutdown*. <u>https://www.peta.org/wp-content/uploads/2021/02/miceeuthanizedforshutdown_Redacted.pdf</u>

¹⁷ OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List_Redacted.pdf</u>

¹⁸ OHSU (n.d.). *Tbr1 Mouse List Line-1*. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-1</u> <u>Redacted.pdf</u> ¹⁹ OHSU (n.d.). Tbr1 Mouse List Line-2. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-2</u> <u>Redacted.pdf</u>

²⁰OHSU (n.d.). Tbr1 Mouse List Line-3. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-3_Redacted.pdf</u>
²¹OHSU (n.d.). Tbr1 Mouse List Line-4. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-4_Redacted.pdf</u>

²² OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-</u> List Redacted.pdf

²³ OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List_Redacted.pdf</u>

²⁴ Kuske, R. (2021, February 9). *Response to PETA's 2/3/21 amended request*. <u>https://www.peta.org/wp-content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf</u>

²⁵ Kuske, R. (2021, February 11). *Response to PETA's 08/28/20 & 12/16/20 requests*. <u>https://www.peta.org/wp-content/uploads/2021/02/Response-to-PETAs-082820-121620-requests.pdf</u>

instruction or training in the ... use of *research or testing methods that limit the use of animals* or limit animal distress."²⁶ [*Emphasis added*]

- 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."²⁷ [Emphasis added]
- 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."²⁸ [Emphasis added]
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985) states, "The animals selected for a procedure should be of an appropriate species and quality and *the minimum number required to obtain valid results.*"²⁹ [*Emphasis added*]

When OHSU 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, some of which is likely provided by Oregon 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 aforementioned experiments should have been zero from the start since they weren't relevant to the protocols led by OHSU's employees. Also, since state taxpayer funds were likely 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 state of Oregon for this fiscal waste.

Furthermore, as 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."³⁰ Oregon taxpayers should not be responsible for any of the additional costs associated with "reestablishing laboratory animal populations" since OHSU deemed many of them to be unnecessary, non-essential, noncritical, or extraneous to the experiments and because repopulating animals in laboratories at taxpayers'

²⁶Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <u>https://olaw.nih.gov/policies-laws/hrea-1985.htm</u>

 ²⁷NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <u>https://grants.nih.gov/grants/olaw/pl103-43.pdf</u>
 ²⁸National 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

²⁹National 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*. <u>https://www.ncbi.nlm.nih.gov/books/NBK54048/</u>

³⁰Congressional 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>

expense would appear to violate the aforementioned federal regulations and policies that mandate minimizing the use of animals in experiments.

Request for Research Accountability

This information seems to corroborate the apparent waste of state funds by OHSU on activities supporting experiments—and/or on the animals used in them—that the school deemed unnecessary, extraneous, noncritical, non-essential, ramped down, disposable, or nonpriority or described using similar terminology and euthanized in response to COVID-19. Such seeming waste of precious resources by OHSU does a disservice to the research enterprise, Oregon taxpayers, and the animals who paid for this with their lives.

We urge you to audit OHSU's actions in this matter and, if you corroborate the issues we have raised, hold the university accountable by requiring it to reimburse Oregon for apparent fiscal waste of state taxpayer funds with respect to the university's animal experiments, and also ensuring that current state-funded research activities involving such animals are permanently terminated, that new state-funded research activities that include such animals are no longer approved, and that the breeding and acquisition of such animals for state-funded research activities are prohibited.

We will share with your office any new, relevant information we receive on this regard. If you have any questions, please contact me at <u>ShalinG@peta.org</u> or at 757-962-8325. We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

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