February 17, 2021

Meredith Stein, CPA Director Office of Management Assessment National Institutes of Health

Via e-mail: steinme@od.nih.gov; omainfo@nih.gov; mailto:omainfo@nih.gov; omainfo@nih.gov; omainfo@nih.gov; omainfo@nih.gov; mailto:omainfo@nih.gov; mailto:omainfo@nih.gov; mailto:omainfo@nih.gov; mailto:omainfo@nih.gov<

Dear Director Stein,

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 follow-up with you on the status of our June 15, 2020, complaint that is pending with the Office of Management Assessment (OMA), as well as to share disturbing new information we have obtained that supplements our complaint.

Based on the information presented below, we respectfully urge your office to investigate, assess, and take corrective action regarding the apparent egregious waste of National Institutes of Health (NIH) research funding and the apparent failure of NIH-funded protocols to reduce and replace animal use in experiments as required by federal provisions.

Complaint History

On June 15, 2020, we submitted a detailed complaint to the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) regarding the troubling problem of at least 66 universities across the country deeming many of their NIH-funded experiments (which in total received more than \$12 billion in NIH taxpayer grants in FY2019)—and the animals used in them—to be extraneous, non-essential, or noncritical or describing them using similar terminology in response to COVID-19, resulting in the massive euthanasia of such animals confined in laboratories and a waste of taxpayer funds.¹

On June 23, 2020, we were notified by the HHS OIG Public Affairs that our complaint was forwarded to the then-OMA Director Michael D. Shannon.² We have not received a reply from OMA regarding our serious concerns.

¹People for the Ethical Treatment of Animals. (2020, June 15). *Request to HHS OIG Regarding 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>



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²HHS-OIG Public Affairs. (2020, June 23). RE: RE: [For HHS OIG, from PETA] re request for investigation into apparent waste at NIH and failure to reduce/replace animal use.

New Records PETA Obtained Supplementing Our June 15, 2020, Complaint According to new documents received so far by PETA through Freedom of Information Act requests, we confirmed that the following universities have euthanized animals deemed unnecessary, non-essential, extraneous, or surplus or described using any other similar language in response to university ramp-down directives due to the COVID-19 pandemic. The aforementioned animals were assigned to projects that received funding from NIH agencies cumulatively totaling more than \$6 million.

1. University of Colorado Boulder (CU Boulder): On March 16, 2020, CU Boulder urged staff to identify "unnecessary" animals for euthanasia.³

- Amy Palmer, from CU Boulder, conducts the protocol titled, "Regulation of Cell Signaling by Transition Metal Dynamics" (5DP1GM114863), which in FY2018 received a total of \$770,000 from the National Institute of General Medical Sciences (NIGMS), the National Center for Complementary and Integrative Health (NCCIH), and NIH Office of the Director (NIH OD).⁴ On March 18, 2020, at least one mouse confined in the vivarium was euthanized following the suggestion made by a member of the "Palmer Lab."⁵
- Bradley Olwin, from CU Boulder, conducts the protocols titled, "Mechanisms Regulating Muscle Stem Cell Homeostasis" (R01AR049446) and "Replicative Potential of Muscle Stem Cells" (R0AR070360), which in FY2020 received \$674,218 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).^{6,7} On March 18, 2020, "based on the recommendations in the chancellors [*sic*] email regarding ongoing research," a research assistant with the "Olwin lab" requested euthanasia of such "unnecessary" mice who were confined in 45 cages located "in rooms A2B32 and A2B34" and included photos of these animals marked for euthanasia, noting, "[t]his represents the largest amount we can cull from

⁴NIH. (n.d.). *Regulation of cell signaling by transition metal dynamics*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project_info_details.cfm?aid=9533658&icde=51828567 ⁵Janiszewski, L. (2020, March 18). *Fwd Single mouse*. <u>https://www.peta.org/wp-</u> <u>content/uploads/2021/01/2020-03-18_Fwd-Single-mouse.pdf</u>

⁶NIH. (n.d.). *Mechanisms regulating muscle stem cell homeostasis*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project_info_details.cfm?aid=9966715&icde=52050302

⁷NIH. (n.d.). *Replicative potential of muscle stem cells*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://www.peta.org/wp-content/uploads/2021/02/2020-06-23 For-HHS-OIG-from-PETA-re-request-for-investigation.pdf

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

https://projectreporter.nih.gov/project info details.cfm?aid=9984871&icde=52050302

our colonies without severely disrupting future research or catastrophic financial loss due to irreplaceable animals."⁸

• Lee A. Niswander, from CU Boulder, conducts the protocol titled, "Phenotyping Embryonic Lethal Knockout Mice with Neural Crest and Neural Defects" (5R01HD081562), which in FY2018 received \$641,755 from National Institute of Child Health and Human Development.⁹ On March 17, 2020, a representative from the "niswander lab" [*sic*] requested the euthanasia of mice confined "in room A2B44 on rack5 [*sic*]."¹⁰

2. University of Missouri (UM): On March 20, 2020, UM notified its staff "about ramping down research activities where possible,"¹¹ which led to the destruction of animals whom UM deemed unnecessary, extraneous, noncritical, or non-essential or described using similar terminology.

 Sarah Dallas, from UM Kansas City (UMKC), received \$654,301 since FY2013 from NIAMS for her current and/or prior protocols titled, "Optimizing Normal Collagen Replacement in Osteogenesis Imperfecta" (1R21AR062346),¹² "Dynamics of Assembly of Bone Matrix Proteins" (5R01AR051517),¹³ and, "Extracellular Vesicle Mediated Cell-Cell Communication in Bone" (5R21AR071563);¹⁴ and received \$341,951 in FY2020 from the National Institute on Aging (NIA) for the protocol titled, "Role of Extracellular Vesicles in Bone-Muscle Crosstalk with Aging" (5P01AG039355/6165). The euthanasia of animals related to Dallas' protocols was logged in "euthanasia record" forms for the Laboratory Animal Research Core Hospital Hill facility, corresponding to March, April, May, and June 2020.¹⁵

¹⁰Brown, 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>

https://projectreporter.nih.gov/project info details.cfm?aid=8502630&icde=52160240

https://projectreporter.nih.gov/project_info_details.cfm?aid=8712107&icde=53353289

https://projectreporter.nih.gov/project_info_details.cfm?aid=9433617&icde=53353289

⁸Dalla Betta, N. C. (2020, March 18). *Re: [OAR Announcement] OAR guidance following suspension of research activities*. <u>https://www.peta.org/wp-content/uploads/2021/01/2020-03-18 RE-OAR-guidance-following-suspension-of-research-activities.pdf</u>

⁹NIH. (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

¹¹University of Missouri. (n.d.). *Ramp-down letter*. <u>https://research.missouri.edu/about/files/ramp-down-letter.pdf</u>.

¹²NIH. (n.d.). *Optimizing normal collagen replacement in osteogenesis imperfecta*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

¹³NIH. (n.d.). *Dynamics of assembly of bone matrix proteins*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

¹⁴NIH. (n.d.). *Extracellular vesicle mediated cell-cell communication in bone*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

¹⁵University of Missouri. (2020). Euthanasia Record. Laboratory Animal Research Core Hospital Hill Facility. <u>https://www.peta.org/wp-content/uploads/2021/01/2020-March-</u> June Euthanasia Records University of Missouri.pdf

- Mark Johnson, affiliated to UMKC, conducts the NIA-funded protocols titled, "Animal Exercise and Analysis Core" (5P01AG039355/6162), and "Estrogen Receptor Mediated Regulation of Bone-Muscle Crosstalk" (5P01AG039355/6166), which received \$611,969 in FY2020.^{16,17} The euthanasia of animals assigned to Johnson's protocols was logged in "euthanasia record" forms for the Laboratory Animal Research Core Hospital Hill facility, corresponding to March, April, May, and June 2020.¹⁸
- Karl Kador, from UMKC, conducts the protocol titled, "Tissue Engineered Cell Transplantation for Glaucoma and Optic Neuropathies" (5R01EY028946), which has received funding from the National Eye Institute (NEI) totaling \$775,500 since FY2018.¹⁹ After the university directive was issued, animals involved in Kador's protocol were killed and their deaths were logged in "euthanasia record" forms for the Laboratory Animal Research Core Hospital Hill facility for the dates March 18, March 27, June 22, and June 23.²⁰

3. Oregon Health & Sciences University (OHSU): Per its COVID-19 response plan, OHSU notified its staff that "the university's research mission has been curtailed."²¹ On March 23, 2020 the university transitioned to "modified operations" ²² and in response, animals that were non-critical or non-essential were euthanized.

• Brian O'Roak, from OHSU conducts the protocol titled, "Characterizing Patient-Specific Tbr1 Mutations: Understanding a Master Regulator of Autism Risk" (5R01MH113926-04), which received \$499,244 in FY2020 from the National Institute Mental Health (NIMH).²³ According to university euthanasia records and verification from a correspondence with

Information.https://projectreporter.nih.gov/project_info_details.cfm?aid=9934998&icde=0

June Euthanasia Records University of Missouri.pdf.

¹⁶NIH. (n.d). *Animal exercise and analysis core*. Research Portfolio Online Reporting Tools (RePORT): Project

Information.https://projectreporter.nih.gov/project_info_details.cfm?aid=9934993&icde=0

¹⁷NIH. (n.d). *Estrogen receptor mediated regulation of bone-muscle crosstalk*. Research Portfolio Online Reporting Tools (RePORT): Project

¹⁸University of Missouri. (2020). *Euthanasia Record. Laboratory Animal Research Core Hospital Hill Facility*. <u>https://www.peta.org/wp-content/uploads/2021/01/2020-March-</u>

June_Euthanasia_Records_University_of_Missouri.pdf

¹⁹NIH. (n.d.). *Tissue engineered cell transplantation for glaucoma and optic neuropathies*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project_info_details.cfm?aid=9685226&icde=53390442.

²⁰University of Missouri. (2020). *Euthanasia record: Laboratory Animal Research Core Hospital Hill facility*. <u>https://www.peta.org/wp-content/uploads/2021/01/2020-March-</u>

²¹OHSU. (2020, February 28). *OHSU coronavirus (COVID-19) response*. https://news.ohsu.edu/2020/02/28/preparing-for-the-novel-coronavirus-at-ohsu

²² OHSU. (n.d.). *Research and Innovation*. https://www.ohsu.edu/research-innovation

²³NIH. (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.

https://projectreporter.nih.gov/project_info_details.cfm?aid=9929658&icde=53561143

OHSU staff,^{24,25,26} mice assigned to this protocol were euthanized on dates in March, ^{27,28,29,30,31} May,³² and June³³ 2020.

- OHSU's Stephen Lloyd conducted and/or conducts the National Institute of Environmental Health Sciences (NIEHS)-funded protocols titled, "The Roles of BER and TLS in Limiting Aflatoxin-Induced Carcinogenesis" (1R56ES027632-01A1), which received \$308,000 in FY2017,³⁴ and "Role of Base Excision Repair in Limiting Hepatocellular Carcinomas" (5R01ES031086-02), that received \$357,057 in FY2021.³⁵Animals assigned to Lloyd's aforementioned protocols were euthanized in March 2020.³⁶ This was verified in a correspondence with OHSU staff.^{37,38,39}
- The protocol titled, "Development of Novel Therapeutics for Leishmaniasis," (5R33AI127591-05) led by OHSU's Scott Landfear, received \$446,184 in FY2021 from the National Institute of Allergy and Infectious Diseases (NIAID).⁴⁰ Mice in this protocol- deemed non-essential

https://projectreporter.nih.gov/project_info_details.cfm?aid=9527499&icde=53581510

²⁴ eIACUC. (2021, January 6). Advanced genome editing for new molecular models of autism

⁽*TR01_IP00000077*). <u>https://www.peta.org/wp-content/uploads/2021/02/IP00077_Redacted.pdf</u> ²⁵ Kuske, R. (2021, February 9). *Response to PETA's 2/3/21 amended request*. <u>https://www.peta.org/wp-</u> content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf

²⁶ 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>

²⁷ OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List Redacted.pdf</u>

²⁸ OHSU (n.d.). *Tbr1 Mouse List Line-1*. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-1</u> Redacted.pdf

²⁹ OHSU (n.d.). *Tbr1 Mouse List Line-2*. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-2</u> Redacted.pdf

³⁰OHSU (n.d.). Tbr1 Mouse List Line-3. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-3_Redacted.pdf</u>

³¹ OHSU (n.d.). *Tbr1 Mouse List Line-4*. <u>https://www.peta.org/wp-content/uploads/2021/02/Line-4</u> Redacted.pdf

³² OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List Redacted.pdf</u>

³³ OHSU (n.d.). *Tbr1- Mouse Master List*. <u>https://www.peta.org/wp-content/uploads/2021/02/Tbr1-Mouse-Master-List_Redacted.pdf</u>

³⁴ NIH. (n.d.). *The Roles Of BER And TLS in Limiting Aflatoxin-Induced Carcinogenesis: 1R56ES027632-01A1*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

³⁵ 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

³⁶OHSU. (n.d.). *Euthanized due to COVID-19*. <u>https://www.peta.org/wp-content/uploads/2021/02/Euthanized-due-to-COVID-19</u>. <u>Redacted.pdf</u>

³⁷Kuske, R. (2021, February 9). *Response to PETA's 2/3/21 amended request*. <u>https://www.peta.org/wp-</u>content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf

³⁸Kuske, 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>

³⁹eIACUC. (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

⁴⁰ 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

were euthanized in March,⁴¹ which is verified in a correspondence with OHSU staff.^{42,43,44}

The fact that the laboratories led by these experimenters had unnecessary, nonessential, noncritical, or extraneous animals in the first place should raise significant red flags, especially since their experiments are funded by taxpayers who should not have to foot the bill for such waste.

Based on this new supplementary information, we urge your office to investigate and follow-up on our full request detailed in our complaint dated June 15, 2020, and, if noncompliance is corroborated, to ensure that the experimenters adhere to federal mandates to reduce and/or replace the use of animals in experiments. Since—as we described above—experimenters deemed animals to be extraneous, non-essential, or noncritical or described using similar terminology and subsequently killed them, there is no reason to continue wasting public resources to support activities conducive to their acquisition, breeding, confinement, and maintenance, nor for any repopulation of these animal laboratories.

You can contact me at <u>ShalinG@peta.org</u> or 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

⁴¹ OHSU. (n.d.). *Euthanized due to COVID-19*. <u>https://www.peta.org/wp-content/uploads/2021/02/Euthanized-due-to-COVID-19</u> Redacted.pdf

⁴² eIACUC. (2021, January 6). *Delivery of Synthetic Organic Compounds as Broad Spectrum Anti-Parasitic Drugs (TR01_IP00000383)*. <u>https://www.peta.org/wp-</u> content/uploads/2021/02/IP00383 Redacted.pdf

content/uploads/2021/02/IP00383 Redacted.pdf ⁴³ Kuske, R. (2021, February 9). *Response to PETA's 2/3/21 amended request*. <u>https://www.peta.org/wp-</u> content/uploads/2021/02/2021-02-09-Responsive-docs-sent-in-previous-FOIA.pdf

⁴⁴ 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>