



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*

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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

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*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/IP00077-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

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<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 [ShalinG@peta.org](mailto:ShalinG@peta.org) or at 757-962-8325. We look forward to your reply regarding this important matter. Thank you.

Sincerely yours,

A handwritten signature in black ink that reads "Shalin G. Gala". The signature is written in a cursive style with a large, looping initial "S".

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

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<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>