February 17, 2021

Robert H. Carter, M.D.

Director

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Via e-mail: carterrob@mail.nih.gov

Dear Dr. Carter:

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. 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 Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to cancel the taxpayer funding—amounting to a combined total of \$1,328,519—granted to experimenters Bradley Olwin of the University of Colorado Boulder (CU Boulder) and Sarah Dallas of the University of Missouri (UM) for any and all renewals of their protocols, and insist that they reimburse the taxpayer funds that they used to acquire, breed, confine, and maintain animals deemed by CU Boulder and UM "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 NIAMS-Funded Experiments Wastes Taxpayer Funds**

Olwin conducts the NIAMS-funded protocols "Mechanisms Regulating Muscle Stem Cell Homeostasis" (R01AR049446)<sup>2</sup> and "Replicative

<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*. <a href="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">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</a>

https://projectreporter.nih.gov/project\_info\_details.cfm?aid=9966715&icde=52050302

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<sup>&</sup>lt;sup>2</sup>NIH. (n.d.). *Mechanisms regulating muscle stem cell homeostasis*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

Potential of Muscle Stem Cells" (R0AR070360).<sup>3</sup> Per its COVID-19 response plan, on March 16, 2020, CU Boulder urged staff to identify "unnecessary" animals for euthanasia.<sup>4</sup> 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 our colonies without severely disrupting future research or catastrophic financial loss due to irreplaceable animals."<sup>5</sup>

Having received NIAMS funding, UM's Dallas conducts and/or conducted protocols titled, "Optimizing Normal Collagen Replacement in Osteogenesis Imperfecta" (1R21AR062346);<sup>6</sup> "Dynamics of Assembly of Bone Matrix Proteins" (5R01AR051517);<sup>7</sup> and, "Extracellular Vesicle Mediated Cell-Cell Communication in Bone" (5R21AR071563).<sup>8</sup> Per its COVID-19 response plan, UM notified its staff "about ramping down research activities where possible," which led to the destruction of animals deemed extraneous, noncritical, or non-essential or described using similar terminology. The euthanasia of animals related to Dallas's protocols per UM's response to COVID-19 was logged in "euthanasia record" forms for the Laboratory Animal Research Core Hospital Hill facility, corresponding to March, April, May, and June 2020.<sup>10</sup>

The fact that the laboratories led by Olwin and Dallas had "unnecessary," non-essential, 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.

<sup>&</sup>lt;sup>3</sup>NIH. (n.d.). *Replicative potential of muscle stem cells*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project\_info\_details.cfm?aid=9984871&icde=52050302

<sup>&</sup>lt;sup>4</sup>University of Colorado–Boulder. (2020, March 16). *Research & Innovation Office COVID-19 resources*. <a href="https://www.colorado.edu/researchinnovation/research-innovation-office-covid-19-resources#vivarium\_considerations-2651">https://www.colorado.edu/researchinnovation/research-innovation-office-covid-19-resources#vivarium\_considerations-2651</a>

<sup>&</sup>lt;sup>5</sup>Dalla Betta, N. C. (2020, March 18). *Re: [OAR Announcement] OAR guidance following suspension of research activities.* https://www.peta.org/wp-content/uploads/2021/01/2020-03-18 RE-OAR-guidance-following-suspension-of-research-activities.pdf

<sup>&</sup>lt;sup>6</sup>NIH. (n.d.). *Optimizing normal collagen replacement in osteogenesis imperfecta*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project\_info\_details.cfm?aid=8502630&icde=52160240

<sup>&</sup>lt;sup>7</sup>NIH. (n.d.). *Dynamics of assembly of bone matrix proteins*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project\_info\_details.cfm?aid=8712107&icde=53353289

<sup>&</sup>lt;sup>8</sup>NIH. (n.d.). *Extracellular vesicle mediated cell-cell communication in bone*. Research Portfolio Online Reporting Tools (RePORT): Project Information.

https://projectreporter.nih.gov/project\_info\_details.cfm?aid=9433617&icde=53353289

<sup>&</sup>lt;sup>9</sup>University of Missouri. (n.d.). *Ramp-down letter*. <a href="https://research.missouri.edu/about/files/ramp-down-letter.pdf">https://research.missouri.edu/about/files/ramp-down-letter.pdf</a>
<a href="https://research.pdf">https://research.missouri.edu/about/files/ramp-down-letter.pdf</a>
<a href="https://research.missouri.edu/about/files/ramp-down-letter.pdf">

https://www.peta.org/wp-content/uploads/2021/01/2020-March-

June\_Euthanasia\_Records\_University\_of\_Missouri.pdf

Olwin's and Dallas's NIAMS-Funded Protocols Failed to Reduce and Replace Animal Use The presence of "unnecessary," non-essential, noncritical, or extraneous animals in the NIAMS-funded experiments led by Olwin and Dallas flies in the face of regulations designed to minimize the use of animals in experiments.

NIH-supported language requiring that the experimental use of animals be minimized is included in the Health Research Extension Act of 1985, the NIH 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]."11
- 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]." 12
- 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]." 13
- 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]." 14

When NIAMS-funded experimenters buy, breed, trap, and/or use 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, they squander limited research funds, which are provided by taxpayers, and flout the bedrock "3Rs" principle of reducing, replacing, and refining the use of animals in experimentation that is enshrined in government regulations and policies.

<sup>&</sup>lt;sup>11</sup>Health Research Extension Act of 1985, Publ. L. No. 99-158. (1985). <a href="https://olaw.nih.gov/policies-laws/hrea-1985.htm">https://olaw.nih.gov/policies-laws/hrea-1985.htm</a>

<sup>&</sup>lt;sup>12</sup>NIH Revitalization Act of 1993, Publ. L. No. 103-43. (1993). <a href="https://grants.nih.gov/grants/olaw/pl103-43.pdf">https://grants.nih.gov/grants/olaw/pl103-43.pdf</a>
<sup>13</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>&</sup>lt;sup>14</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/

Under this standard, the number of "unnecessary," non-essential, noncritical, or extraneous animals used in Olwin's and Dallas's experiments should have been zero from the start since they weren't relevant to their projects. Also, because taxpayer funds were used to acquire, breed, confine, and/or maintain "unnecessary," non-essential, noncritical, or extraneous animals who were then so easily euthanized and disposed of in response to COVID-19, CU Boulder should reimburse the NIAMS 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 that "[r]estarting research, when conditions permit, may also incur costs for staff time and supplies to ... reestablish laboratory animal populations." Taxpayers and the NIAMS 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 experiments and because doing this 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 Olwin's projects AR049446 and AR070360, and Dallas's projects 5R21AR062346, 5R01AR051517, and 5R21AR071563, and we urge you to seek reimbursement from them for any and all NIAMS funds wasted to acquire, breed, confine and/or maintain the animals whom they deemed "unnecessary," non-essential, noncritical, or extraneous or described using similar terminology and then euthanized. Moreover, we encourage the NIAMS to redirect the funds it initially granted to Olwin and Dallas to projects using 3-D human tissue models that—as the NIAMS has itself pointed out—can "closely mimic functions of human tissues or organs" and "replace animal testing." <sup>16</sup>

You can 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,

Shalin G. Gala

Vice President, International Laboratory Methods

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<sup>&</sup>lt;sup>15</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

<sup>&</sup>lt;sup>16</sup>National Institute of Arthritis and Musculoskeletal and Skin Diseases. (2014, November 24). *Roundtable on opportunities and challenges in developing 3-dimensional human tissue models to study musculoskeletal and skin physiology and pathophysiology*. <a href="https://www.niams.nih.gov/about/meetings-events/roundtables/roundtable-opportunities-and-challenges-developing-3-dimensional">https://www.niams.nih.gov/about/meetings-events/roundtables/roundtable-opportunities-and-challenges-developing-3-dimensional</a>