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The Honorable Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins,

I am writing to follow up on report language I included in the House passed FY20 Labor-HHS Appropriations bill that requests more transparency and accountability about NIH's intramural primate research.

As you are aware, I remain concerned about primate research at your agency for reasons related to animal welfare, scientific efficacy, and government spending. When I submitted this report language earlier this year, publicly-available data for FY14 through FY17 showed that NIH's use of primates in painful intramural research (USDA pain categories D & E) rose by a disturbing 49 percent. Unfortunately, I have discovered that the NIH's primate research problem is worse than previously thought.

Since last spring, NIH primate use data from FY13 and FY18 have been made available, and an analysis by the taxpayer watchdog White Coat Waste Project found that the NIH's use of primates in painful research increased by a staggering 73 percent between 2013 and 2018.¹ Specifically, the number of primates used in painful tests with pain relief (USDA pain category D) grew by 58 percent (from 941 to 1490 animals). Even more disturbing is that the NIH's painful primate research where no pain relief is provided (USDA pain category E) increased by 370 percent (from 73 to 268 animals) from FY13 to FY18.^{2,3}

Documents filed with the USDA show that the NIH held or experimented on a total of 7,038 primates in 2018, more than any other federal agency. Of these animals, 1,758 were used in

¹ <https://blog.whitecoatwaste.org/2019/06/19/progress-funding-panel-directs-nih-to-cut-primate-testing/>
²

<https://acis.aphis.edc.usda.gov/ords/f?p=118:36::NO::FCSTEA, YNCENNSE:441.2013&cs=17646F67EE5F2669677BB588BCA35694B> (2013)

³
<https://acis.aphis.edc.usda.gov/ords/f?p=118:36::NO::FCSTEA, YNCENNSE:441.2018&cs=1526B98E655B79E652E155DB650AAF366> (2018)

significantly painful tests, 1,551 were used in minimally invasive tests, and 3,729 were held for breeding or future use.

These drastic increases in NIH's painful intramural primate use are particularly concerning to me because they are at odds with NIH's various commitments to reduce wasteful animal research and your personal acknowledgement of the limitations of animal models and advocacy for alternatives. In its 2016-20 Strategic Plan, NIH stated, "Petri dish and animal models often fail to provide good ways to mimic disease or predict how drugs will work in humans, resulting in much wasted time and money while patients wait for therapies. To address that challenge, NIH, DARPA, and FDA are collaborating to develop 3D platforms engineered to support living human tissues and cells, called tissue chips or organs-on-chips."⁴ Additionally, during the April 2019 NIH budget hearing, you acknowledged these efficacy problems and cited NIH efforts to develop alternatives to animal testing through its National Center for Advancing Translational Sciences (NCATS). While this is a promising program that received over \$800 million from Congress in FY19,⁵ it appears that these efforts are not having the real-life impact of actually reducing animal testing. On the contrary, since NCATS was established in late 2011, NIH primate research has increased dramatically.

I am increasingly concerned that NIH primate research appears poised to continue moving in the wrong direction. Two separate reports issued last year by NIH about its primate research program uncritically called for continued and increased primate use, and neither mentioned any efforts to reduce or replace primate use, or develop and utilize alternatives.^{6,7} For these reasons I would like to gain a better understanding of whether NIH researchers are properly educated about methods that reduce and replace primate use, and if those responsible for reviewing and approving NIH intramural primate research are adequately scrutinizing the scientific and ethical merits of proposed projects.

To address these concerns, I am asking that you please provide my office with answers to the following questions about NIH's intramural primate research:

1. Do experts in alternative methods review intramural NIH primate research projects before they are approved and funded? If so, please describe this process.
2. Within NCATS, is there any effort focused on identifying alternatives to primate research specifically? If so, please describe this work.
3. Has the NIH performed or commissioned formal systematic reviews of its intramural primate research programs to assess their quality, efficacy, and translational success? If so, please describe these efforts and provide the results.
4. Provide my office with copies of all NIH's Column E explanations for primate research filed with USDA from FY13-19.

⁴ <https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf>

⁵ <https://ncats.nih.gov/about/center/budget>

⁶ <https://orip.nih.gov/sites/default/files/508%20NHP%20Evaluation%20and%20Analysis%20Final%20Report%20-%20Part%201.pdf>

⁷ https://orip.nih.gov/sites/default/files/NHP%20Evaluation%20and%20Analysis%20Final%20%20Report%20-%20Part%202%20Final%20508%2021Dec2018_002.pdf

5. How much taxpayer funding did NIH spending on intramural primate research each year from FY13-19?

Thank you for the work you do to continue the important mission of the National Institutes of Health. I appreciate your cooperation in helping to ensure that critical taxpayer dollars are spent on research that is scientifically and ethically justified and appropriately humane to all subjects involved, and I look forward to your response.

Sincerely;

A handwritten signature in blue ink that reads "Lucille Roybal-Allard". The signature is written in a cursive, flowing style.

LUCILLE ROYBAL-ALLARD
Member of Congress