

United States Senate

WASHINGTON, DC 20510-0609

November 22, 2022

Via Electronic Transmission

Dr. Arati Prabhakar, Director
The Office of Science and Technology Policy
1650 Pennsylvania Avenue
Washington, D.C. 20504

Dear Dr. Prabhakar:

We call on you to immediately institute a government-wide pause of all ongoing and new viral Gain-of-Function (GoF) and Dual Use Research of Concern (DURC) studies in the life sciences involving all enhanced pathogens of pandemic potential (ePPP) due to the current lack of research oversight, clear guidelines, and potential risks of outbreaks from laboratory accidents.¹ These experiments pose extreme threats to public health if the altered pathogens are accidentally or deliberately released.²

In addition to research projects defined in current guidelines, we ask for the moratorium to include studies that enhance the virulence or transmissibility of any pathogen to produce an ePPP and studies that confer efficient human transmissibility on a pathogen of even modest virulence. Precedent for implementing a government-wide pause on risky research was established in 2014 when, amidst biosafety and biosecurity concerns in national laboratories, the Obama Administration's Office of Science and Technology Policy (OSTP) implemented a similar pause for certain studies in the U.S.³

Ambiguous, Narrow Guidelines

The National Institutes of Health (NIH) is responsible for creating and implementing U.S. government oversight policies for ePPP DURC/GoF experiments.⁴ As part of its duties, NIH must develop and implement "federal policies that promote the responsible conduct and oversight of life sciences research, with a focus on the areas of biosafety and recombinant DNA activities, biosecurity, and emerging biotechnologies."⁵ NIH consults with a U.S. Department of Health and Human Services (HHS) federal advisory committee, the National Science Advisory Board for Biosecurity (NSABB), for federal policy

¹ The Intercept, *Experimenting With Disaster* (Nov. 1, 2022) available at <https://theintercept.com/series/experimenting-with-disaster/>.

² Todd Kuiken, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*, Congressional Research Service (May 26, 2022) available at <https://crsreports.congress.gov/product/pdf/R/R47114>.

³ The Barack Obama White House, *Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research*, Blog (Oct. 17, 2017) available at <https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>.

⁴ National Institutes of Health, *About Us*, Office of Science Policy (accessed Nov. 8, 2022) available at <https://osp.od.nih.gov/#policy>.

⁵ *Id.*

recommendations related to biosecurity and DURC/GOF projects.⁶ A designated NIH employee manages the NSABB meetings and agendas.⁷

In January 2020, NIH formally requested the NSABB to evaluate, analyze, and provide specific revision recommendations to OSTP and HHS on the effectiveness of U.S. DURC policies, including the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) policy guidance.⁸ Ironically, NSABB evaluation paused for over two years due to the COVID-19 pandemic while viral gain-of-function research continued without guideline improvements.⁹

In February 2022, NIH reconvened the NSABB and renewed its formal request for the NSABB to assess ePPP DURC/GOF oversight policy guidelines and then recommend revisions. The final recommendations will not be finalized for several months.¹⁰ In addition to NIH's request for policy reform, scientific community members are also seeking clearer guidance, tighter scrutiny, expansion of experiments included for risk review, and guidelines for foreign-based projects.¹¹ Also, expert scientific witnesses unanimously testified in an August 2, 2022 Senate hearing that U.S. government oversight of viral GOF research should be increased and that the potential risks far outweigh any benefits.¹² It is incumbent upon the OSTP to take the responsible, urgent action to pause these studies until new clear policies and procedures are issued.

NIH Oversight Failures

We are extremely troubled about the enduring culture of noncompliance at NIH and the alarming reports about their failure to properly oversee domestic and foreign-based dangerous DURC/GOF research projects, enforce grant requirements, or conduct appropriate research risk assessments of studies involving ePPPs.¹³ From media reports, it is evident that NIH does not inventory its funded DURC/GOF research projects involving dangerous ePPPs, which raises questions as to how NIH may scrutinize ongoing projects for risk assessment review of techniques that manipulate dangerous pathogens.¹⁴

In October 2022, research experiments involving enhanced coronavirus and monkeypox pathogens were prominently featured in negative national media headlines because of their potential to unleash pandemics into the U.S., as well as concerns that the P3CO risk assessment oversight policy may not have been

⁶ National Institutes of Health, *Charter*, National Science Advisory Board for Biosecurity (accessed Nov. 8, 2022) available at <https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb/#charter>.

⁷ *Id.*

⁸ National Institutes of Health, *Charge to the National Science Advisory Board for Biosecurity*, NIH Office of Science Policy (Jan. 23, 2020) available at https://osp.od.nih.gov/wp-content/uploads/Wolinetz-NSABB_Charge.pdf.

⁹ National Institutes of Health, *National Science Advisory Board for Biosecurity to convene*, New Releases (Feb. 16, 2022) available at <https://www.nih.gov/news-events/news-releases/national-science-advisory-board-biosecurity-convene>.

¹⁰ *Id.*; National Institutes of Health, 2022 Charge to the NSABB, NSABB (Feb. 28, 2022) available at https://osp.od.nih.gov/wp-content/uploads/Tabak_and_Jorgenson-2022_Charge_to_the_NSABB.pdf.

¹¹ Max Kozlov, *Risky 'gain-of-function' studies need stricter guidance say US researchers*, NATURE (May 3, 2022) available at <https://www.nature.com/articles/d41586-022-01209-w>.

¹² U.S. Senate Committee on Homeland Security and Governmental Affairs, *Revisiting Gain of Function Research: What the Pandemic Taught Us and Where Do We Go From Here*, Subcommittee on Emerging Threats and Spending Oversight (Aug. 3, 2022) available at <https://www.hsgac.senate.gov/subcommittees/etso/hearings/revisiting-gain-of-function-research-what-the-pandemic-taught-us-and-where-do-we-go-from-here>.

¹³ Jocelyn Kaiser, *NIH says grantee failed to report experiment in Wuhan that created a bat virus that made mice sicker*, SCIENCE (Oct. 21, 2021) available at <https://www.science.org/content/article/nih-says-grantee-failed-report-experiment-wuhan-created-bat-virus-made-mice-sicker>.

¹⁴ Helen Branswell, *Boston University researchers' testing of lab-made version of Covid virus draws government scrutiny*, STAT NEWS (Oct. 17, 2022) available at <https://www.statnews.com/2022/10/17/boston-university-researchers-testing-of-lab-made-version-of-covid-virus-draws-government-scrutiny/>.

followed.¹⁵ For example, on October 14, 2022, when a pre-print article detailed experiments in which Boston University researchers inserted an Omicron SARS-CoV-2 variant gene into a deadlier legacy coronavirus strain, public concerns about potential risks from the experiments quickly followed.¹⁶ An NIH spokesperson stated that NIH wished Boston University would have informed them about its intention to do the work.¹⁷ Wishing that a federal grantee communicates research plans is not an acceptable NIH research oversight program and could potentially be a dereliction of NIH duties. Risky NIH ePPP research was also featured in negative media headlines that same week about NIH staff researcher projects involving the lethal monkeypox virus.¹⁸ It was widely publicized that HHS declared a monkeypox public health emergency in August 2022 and the White House designated a National Monkeypox Response Coordinator.^{19, 20} It is unknown if the NIH monkeypox genetic manipulation experiments underwent a P3CO risk assessment.²¹

NIH Offshored Risky Research to China During Moratorium

We are also deeply concerned about NIH's failure to fully respond to Congressional oversight inquiries into the bat coronavirus research that was offshored before the COVID-19 pandemic through a non-profit organization, EcoHealth Alliance (EcoHealth), to the Wuhan Institute of Virology (WIV) in China when such research was restricted by the OSTP moratorium.²² In April 2020, NIH suspended EcoHealth's research grant after receiving allegations from the scientific community that the "current crisis was precipitated by the release from Wuhan Institute of Virology of the coronavirus responsible for COVID-19," instead of identifying potential problems through annual or other internal NIH grant oversight reviews.²³ Throughout its two-year investigation, NIH suspended the EcoHealth grant before terminating the WIV's subaward portion in August 2022 based on NIH's determination that EcoHealth and the WIV violated multiple material breaches of the grant award terms, including failure to produce requested research records, lab books and other supporting documentation required to be maintained.²⁴ In fact, EcoHealth's president, Peter Daszak, was a former NIH grant peer reviewer with first-hand knowledge of NIH's research grant requirements and was also the direct recipient of multi-million dollar research grant awards from NIH for nearly two decades.²⁵ Despite Peter Daszak's intimate knowledge of NIH grant requirements, NIH determined that one material award breach by EcoHealth was its failure to execute an

¹⁵ Ewen Callaway and Max Kozlov, *Which COVID studies pose a biohazard? Lack of clarity hampers research*, NATURE (Oct. 21, 2022) available at <https://www.nature.com/articles/d41586-022-03344-w>.

¹⁶ Jocelyn Kaiser, *Was a study that created a hybrid COVID-19 virus too risky?*, SCIENCE (Oct. 18, 2022) available at <https://www.science.org/content/article/was-study-created-hybrid-covid-19-virus-too-risky>.

¹⁷ Ibid 7.

¹⁸ Jocelyn Kaiser, *Making Trouble*, Science (Oct. 19, 2022) available at <https://www.science.org/content/article/u-s-weighs-crackdown-experiments-could-make-viruses-more-dangerous>.

¹⁹ HHS.gov, *Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency* (Aug. 4, 2022) available at <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.

²⁰ The White House, *President Biden Announces Team to Lead Monkeypox Response* (Aug. 2, 2022) available at <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/02/president-biden-announces-team-to-lead-monkeypox-response/>.

²¹ Ibid 16.

²² Doc Marshall, *Sen. Marshall Connects Dr. Fauci to EcoHealth Alliance's Gain-of-Function Research Projects in China*, Press Releases (Aug. 3, 2022) available at <https://www.marshall.senate.gov/newsroom/press-releases/sen-marshall-connects-dr-fauci-to-ecohealth-alliances-gain-of-function-research-projects-in-china-2/>.

²³ Meredith Wadman, et al., *Partial transcript of email exchanges in which NIH cuts off grant funding to EcoHealth Alliance, NIH's acing of bat coronavirus grant a 'horrible precedent'* (Apr. 30, 2020) available at https://www.science.org/doi/10.1126/science.abc5616/full/lauer.daszak.nih_grant_killed.partial_email_transcripts.april_2020.pdf.

²⁴ U.S. House of Representatives Committee on Oversight and Reform, *NIH letter to The Honorable James Comer* (Aug. 19, 2022) available at https://republicans-oversight.house.gov/wp-content/uploads/2022/08/NIH-Letter-to-Congress-regarding-EHA_Comer.pdf.

²⁵ Sharon Lerner, *Details Emerge About Coronavirus Research at Chinese Lab*, THE INTERCEPT available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

enforceable subcontract with the WIV, which is the contract NIH relied upon to pay hundreds of thousands of dollars to the WIV through EcoHealth each year.²⁶ NIH's review, prompted by external scientific community sources and not by NIH internal review processes, also determined that EcoHealth was negligent by nearly two years in failing to report to NIH its coronavirus research experiment at the WIV that had created a version of the coronavirus that sickened and killed humanized mice.²⁷

Laboratory Accidents

During the Obama Administration, the Biological Defense Research and Development Subcommittee of the Committee on Homeland and National Security of the National Science and Technology Council reported that “work with infectious agents in the laboratory always involves risk.”²⁸ During the Biden Administration in August 2021, the Office of the Director of National Intelligence reported that the U.S. Intelligence Community officially acknowledged the possibility that the first SARS-CoV-2 human infection could have resulted from a laboratory-associated incident.²⁹ In June 2022, an expert group convened by the World Health Organization (WHO) to investigate the COVID-19 origins reported that SARS-CoV-2 could have been introduced into the human population through a laboratory incident.³⁰

U.S. laboratories are not exempt from laboratory accidents. Hundreds of laboratory accidents reported to NIH, previously concealed from the public, have been revealed in thousands of documents obtained through Freedom of Information Act requests.³¹ Examples of lab accidents reported to the NIH include:

- A February 2020 report that a university researcher conducted unauthorized research that created an HIV pseudo virus containing Marburg glycoprotein M78 in a Biosafety Level 2 laboratory and created enough virions to test novel peptide inhibitors of viral entry.³²
- A September 2016 report that a university researcher suffered a needlestick while working in a BSL-3 laboratory with the Chikungunya virus and did not report the accident until after developing symptoms.³³
- Since the COVID-19 outbreak, NIH received at least two dozen reports of U.S. research in violation of approval guidelines involving recombinant or synthetic nucleic acid (r/sNA) molecules.³⁴

²⁶ Matt Field, *NIH to terminate part of EcoHealth Alliance grant after its Wuhan partners refuse to deliver information on coronavirus studies*, Bulletin of the Atomic Scientists (Aug. 24, 2022) available at <https://thebulletin.org/2022/08/nih-to-terminate-ecohealth-alliance-grant-after-its-wuhan-partners-refuse-to-deliver-information-on-coronavirus-studies/>; Ibid 26.

²⁷ Jocelyn Kaiser, *NIH says grantee failed to report experiment in Wuhan that created a bat virus that made mice sicker*, SCIENCE (Oct 21, 2021) available at <https://www.science.org/content/article/nih-says-grantee-failed-report-experiment-wuhan-created-bat-virus-made-mice-sicker>.

²⁸ Committee on Homeland and National Security of the National Science and Technology Council, *Fast Track Action Committee Report: Biosafety and Biosecurity*, Subcommittee on Biological Defense Research and Development (Jan. 2017) available at <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/NSTC/ftac-bio-report.pdf>.

²⁹ Office of the Director of National Intelligence, *Unclassified Summary of Assessment on COVID-19 Origins*, Intelligence Community Assessment (Aug. 27, 2021) available at <https://www.dni.gov/files/ODNI/documents/assessments/Unclassified-Summary-of-Assessment-on-COVID-19-Origins.pdf>.

³⁰ World Health Organization, *Preliminary Report of the SAGO*, Scientific Advisory Group for the Origins of Novel Pathogens (June 9, 2022) available at <https://cdn.who.int/media/docs/default-source/scientific-advisory-group-on-the-origins-of-novel-pathogens/sago-report-09062022.pdf>.

³¹ Ibid 1; Judicial Watch, *Multiple Cases of Illegal Molecular Research Reported to NIH*, JW Weekly Update (June 3, 2022) available at <https://www.judicialwatch.org/multiple-cases-of-illegal-molecular-research-reported-to-nih/>.

³² *Id.*

³³ Ibid 1.

³⁴ *Id.*

- Some universities reported that in violation of NIH guidelines, researchers created recombinant viruses involving the SARS-COV-2 virus with other pathogens including a modified Vaccinia Ankara expressing spike proteins, some in a Biosafety Level 2 laboratory.³⁵

An intrinsic threat that powerful ePPP viruses can escape from high-containment, high-security laboratories and spark an outbreak with much greater lethality than the world just experienced during the Covid-19 pandemic is plausible.³⁶

Enforcement of the Stevens Amendment

We also request that the OSTP remind NIH of its obligation to enforce federal appropriation law requirements, known as the Stevens Amendment, which require research projects supported with HHS financial assistance to publicly disclose specific grant costs.³⁷ The NIH Grants Policy requires grant recipients to comply with the law and provide the transparency taxpayers deserve; however, the Government Accountability Office (GAO) reported that NIH and its grantees consistently fail to follow this law.³⁸ GAO further reported that NIH officials admitted to not monitoring Stevens Amendment compliance.³⁹

In Boston University's recent publication about its Omicron gene-manipulation experiment, the university acknowledged funding from four NIH grants, a partial disclosure which led to questions about the university's need to comply with the P3CO risk assessment process.⁴⁰ To address the numerous questions, Boston University issued a statement that P3CO review was not required because the NIH grants did not directly fund the research but instead were used to help develop the tools and platforms used in the research.⁴¹ Speculation and concern about Boston University's compliance with the P3CO guidelines could have been thwarted if Boston University had complied with the Stevens Amendment requirements to disclose the percentage and dollar amounts of project costs directly funded by NIH grants.

As the advances in biotechnology have made research exceedingly more dangerous, increased protections and regulations have become more necessary. The COVID-19 outbreak has been devastating, and until clear ePPP research policies are implemented, it is critically important for the OSTP to immediately institute increased protections for the public from these potentially lethal pathogens. The OSTP can implement safeguards today to prevent the possibility of an American-based viral outbreak by issuing a new government-wide moratorium on GOF/DURC studies involving enhanced pathogens of pandemic potential. Please provide a written response to this letter by December 7, 2022.

³⁵ Ibid 22.

³⁶ Ibid 11.

³⁷ Public Law 117-103, Division H, Title V, Section 505 of the Consolidated Appropriations Act of 2022 *available at* <https://www.congress.gov/bill/117th-congress/house-bill/6833?q=%7B%22search%22%3A%5B%22isRelatedToAppropriations%3AY+AND+%28appropriationsFiscalYear%3A2022+OR+appropriationsFiscalYear%3A2023%29%22%5D%7D&s=1&r=1>.

³⁸ National Institutes of Health, *Grants Policy Statement* (accessed Oct. 31, 2022) *available at* https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.2.1_acknowledgement_of_federal_funding.html; and U.S. Government Accountability Office, *Agency Action Required to Ensure Grantees Identify Federal Contribution Amounts*, Grants Management (Mar. 14, 2019) *available at* <https://www.gao.gov/products/gao-19-282>.

³⁹ *Id.*

⁴⁰ Ibid 7.

⁴¹ Boston University, *NEIDEL Researchers Refute UK Article about COVID Strain*, THE BRINK STAFF (Oct. 17, 2022) *available at* <https://www.bu.edu/articles/2022/neidel-researchers-refute-uk-article-about-covid-strain/>.

Very respectfully,

A handwritten signature in blue ink that reads "R. W. Marshall". The signature is fluid and cursive, with the first name and last name clearly legible.

Roger Marshall, M.D.
United States Senator

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive style, with the first name "Chuck" being more prominent.

Charles E. Grassley
United States Senator

A handwritten signature in blue ink that reads "Joni Ernst". The signature is written in a cursive style, with the first name "Joni" being more prominent.

Joni Ernst
United States Senator

A handwritten signature in blue ink that reads "Marsha Blackburn". The signature is written in a cursive style, with the first name "Marsha" being more prominent.

Marsha Blackburn
United States Senator

A handwritten signature in blue ink that reads "Marco Rubio". The signature is written in a cursive style, with the first name "Marco" being more prominent.

Marco Rubio
United States Senator