Additional Questions for the Record
Dr. Lawrence A. Tabak, D.D.S., PhD., Senior Official Performing the Duties of the Director, National Institute of Health

The Honorable Cathy McMorris Rodgers

1. Dr. Tabak's current title is Senior Official Performing the Duties of the NIH Director.
A. How long has Dr. Tabak held this title?

NIH response
Dr. Tabak has held this title since July 15, 2022, the effective date of the delegation of authority signed by the Secretary, HHS.

B. What was Dr. Tabak's previous title?

NIH response
Prior to the Performing the Duties of the NIH Director title, Dr. Tabak served as the Acting Director, NIH, for 210 days, in accordance with the Federal Vacancies Reform Act.

C. How long does Dr. Tabak anticipate remaining in this current position, with the current title?

NIH response
He plans to perform the delegated duties until the position of Director, NIH is filled. In accordance with the Federal Vacancies Reform Act, he will again serve as Acting Director, NIH, upon the President submitting a nomination for the Director, NIH, position to the Senate.

D. Please explain the legal framework of your current position and role under the Federal Vacancies Reform Act,8 as well as the legal timeline under which Dr. Tabak can maintain his role in its current capacity.

NIH response
The Federal Vacancies Reform Act of 1998[1] (FVRA) allows senior officials to perform the duties of most Senate-confirmed positions in an acting capacity when the position would otherwise be vacant, but it limits the time during which someone can hold the "Acting" title to 210 days. After that point, agency officials still have the authority to perform the duties of the position but cannot use the "Acting" title.

Effective July 15, 2022, Secretary Becerra re-appointed Dr. Tabak to the position of Deputy Director of NIH and delegated to him all of the delegable duties of the NIH Director to allow for the continuity of NIH's operations and fulfillment of the duties and responsibilities of the NIH Director position in accordance with the FVRA 5 U.S.C. §§ 3345 – 3349d for the period of time until the NIH Director position is filled permanently. In keeping with the requirements of the FVRA, Dr. Tabak's title changed from "Acting Director, NIH" to "Performing the Duties of the NIH Director" but there was no change in his authorities, responsibilities, or role as the head of NIH.

[1] https://www.gsa.gov/cdnstatic/Vacancies_Reform_Act_1998.pdf

Upon the President naming a nominee for the NIH Director position, Dr. Tabak's title will revert back to "Acting Director, NIH." While Dr. Tabak's official title may change due to the requirements of the FVRA, his authorities and responsibilities remain the same until the NIH Director position is filled permanently.

2. On February 14, 2023, the National Academies of Sciences, Engineering, and Medicine (NASEM) released a report entitled, Advancing Anti-Racism, Diversity, Equity, and Inclusion in STEMM Organizations.9 This report was funded and supported by the National Institutes of Health and National Science Foundation, and the process spanned two-plus years.

A. Please specify how much funding NIH provided towards this report, and the timeline for providing the funding.

NIH response
The amount of the NIH award to support the study, Advancing Anti-racism, Diversity, Equity, and Inclusion in Science, Technology, Engineering, Mathematics and Medicine (STEMM) Organizations: A Consensus Study, was $340,000, and the period of performance is 9/17/2021 to 6/30/2023.

B. It is my understanding the report was the result of a letter sent by former Chairwoman of the U.S. House Committee on Science, Space, and Technology Eddie Bernice Johnson requesting the study.10 Please explain NIH's participation in the production of this study.

NIH response
The National Academies of Sciences, Engineering, and Medicine (NASEM) provides independent, objective analysis and advice to the nation and conducts other activities to solve complex problems and inform public policy decisions. The approach to studies employed by NASEM ensures that sponsors, such as NIH, receive independent and authoritative advice. Given this rigorous process and the intention to protect the integrity of the objective approach, the NIH did not directly participate in the production of the study. The NIH point of contact functioned as a program lead whose role was to monitor the progress of the study, provide updates on study progress to NIH leaders, and coordinate interim progress updates by the NASEM project leaders for the NIH Institutes that contributed funds to support the study.

C. Please explain how funding this report aligns and supports NIH's overarching mission to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

NIH response
NIH is the steward of medical and behavioral research for the Nation. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In addition, the NIH mission invests in biomedical and behavioral research to turn scientific discoveries into better health for all. We know that bringing diverse perspectives, backgrounds, and skillsets to

complex scientific problems enhances scientific productivity[2]. In general, a lack of diversity of undergraduates with STEMM degrees strongly contributes to the lack of diversity in the biomedical research workforce.

The NASEM study identifies conditions that create systemic barriers and impede the full talent pool from pursuing and advancing in STEMM careers. NIH provided funding for the report to help inform NIH's ongoing efforts to improve the diversity of the scientific workforce and address structural racism in biomedical research and to foster the advancement of the best science possible to benefit all Americans.

3. Since 2015, National Institutes for Health (NIH) extramural grants have been awarded to conduct gender-transition studies on children and youth starting as young as 8-years-old. This grant, titled, "The Impact of Early Medical Treatment in Transgender Youth,"11 was the first grant of its kind giving puberty blockers and opposite-sex hormones to minors. Instead of focusing on the risks or safety of the experimental use of these drugs on children, this project examines if earlier medical intervention might decrease other mental health issues within a 2-year timetable. As of 2021, this study has been renewed to evaluate and monitor the longer-term effects of puberty blockers and opposite-sex hormones on participants for up to four more years. Recent reports indicate that two youths involved in the study committed suicide.12 Please answer, in specific detail, the following questions regarding this study.

A. Please explain how NIH approved this study under the requirements of the HHS Policy for the Protection of Human Subjects13 and specific requirements involving children as human subjects.

B. Please provide specific details of the approval process, specifically the engagement and participation with the Institutional Review Board, including details on the members, backgrounds, any change forms approved, the rationale and ethical standards provided for the grants, and any proof that children could give informed consent required by law.

C. Please provide proof that minors can give full and informed consent for use of drugs that directly impact the development of their bodies, minds, and sexual function.

D. Please explain the NIH justification for using minors as human subjects when use of these drugs and hormones can cause life-long damage and substantial increased health risks.

<u>NIH Response for A-D</u>

The premise of the question and subpart D contain factual inaccuracies. NIH funding is not used for providing puberty blockers and other hormonal treatments for gender-affirming care to minors. In other words, NIH is not conducting any clinical trials or supporting grants that support clinical treatment for transgender youth. To gather additional data on potential health effects of existing medical treatments for transgender youth, NIH is funding observational studies to learn about potential health risks and benefits for youth already undergoing treatment. Findings from NIH-supported research help inform medical and health organizations that provide guidance and make recommendations for healthcare providers.

In 2015, NIH funded an observational study, "The Impact of Early Medical Treatment in Transgender Youth," on existing medical treatments already in use among transgender

[2] https://diversity.nih.gov/science-diversity/swd-seminar-series-hddis-may

youth. This means that researchers were only assessing the effectiveness of the treatments already underway, which are not provided by or financially supported by the award, and were not conducting a clinical trial comparing treatment to no treatment. Studies like this inform medical providers and parents about the risks and benefits of these treatments.

This study, like all NIH research involving human subjects, was reviewed for ethical concerns by a study section of investigators with related expertise and was approved by an Institutional Review Board (IRB) at each institution where the study is being conducted before the grant was awarded. The individuals in the study provided written informed consent or assent; and their parent(s) or legal guardian(s) provided consent for minors to participate. Procedures were approved by the IRB at each study site. Human subject protections are approved at the institutional level, and NIH receives receipt of that approval before providing funding. When adverse events occur, NIH policy stipulates that in studies required to have an IRB, all adverse events must be reported to the IRB and NIH[3]. NIH takes the health and well-being of the participants in its research studies very seriously. Trust from the community is at the foundation of all biomedical research and maintaining that trust is critical to the success of the projects we support.

NIH-funded research informs patients, medical providers, and parents about the risks and benefits of these treatments. We also know that youth who identify as transgender have higher rates of suicide, substance misuse, and mental health conditions and observational studies help us to understand the relationships, if any, between treatment and these outcomes.

The Honorable Morgan Griffith

1. In response to questions about whether NIH could have funded research at the Wuhan Institute of Virology (WIV) that involved SARS-CoV-2 or a progenitor virus, you testified that the viruses understudy by EcoHealth Alliance and the WIV with NIH funding:

> "[B]ear no relationship to SARS-CoV-2. They are genetically distinct. They are absolutely unrelated to SARS-CoV-2. That is the most important thing to understand. . . It would be equivalent to saying that a human is equivalent to a cow. That is how distant the sequences of the viruses that they were using in this work were to the actual SARS-CoV-2.

In sum, NIH is confident that it did not fund research involving SARS-CoV-2 or a progenitor virus at the WIV. You testified that the basis for your assessment is that NIH "approve[s] what [EcoHealth Alliance and WIV] are to do from their progress reports and from their publications they have done what they said they would do. The work was commensurate with the modest sums of money that we provided to them."

A. Is NIH basing its assessment that the viruses being studied by EcoHealth Alliance and WIV "bear no relationship to SARS-CoV-2" based solely on the progress reports submitted by EcoHealth, correspondence between EcoHealth and NIH, and related academic publications?

B. If NIH used other information to reach this conclusion, please provide that information or documentation.

[3] https://grants.nih.gov/policy/humansubjects/pre-and-post-award-processes/study-monitoring.htm

NIH Response A-B

The body of science produced under the grant to EcoHealth Alliance, including the bat coronavirus sequences identified by the researchers and published in the scientific literature, showed that the viruses studied were evolutionarily quite distant from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), and could not have been the source of the pandemic.[4]

2. Given EcoHealth's failure to immediately notify NIH about excessive virus growth in a key experiment and its failure to secure the lab notebooks and electronic files associated with this experiment, why does NIH believe EcoHealth Alliance's level of compliance with NIH grant terms for the Understanding the Risk of Bat Coronavirus Emergence grant is acceptable?

NIH Response

NIH's approach with cases of grant non-compliance, where a recipient has failed to comply with the terms and conditions of the award, is generally to provide our recipients with an opportunity to come into compliance through developing a corrective action plan (CAP) in an effort to preserve the research, when possible. This is consistent with the Uniform Administrative Regulations at 2 C.F.R. § 200.339[5] and as outlined in 45 C.F.R. § 75.372[6] and 75.371.[7] These regulations provide that in cases of non-compliance, a funding agency may impose specific award conditions. Where the agency determines that the noncompliance cannot be remedied through using specific award conditions, then the agency may take more severe actions, such as terminating an award in whole or in part, as outlined in 2 C.F.R. § 200.340.[8]

With grant award R01AI110964, NIH determined that one of the violations (failure of WIV to provide records) could not be remedied by imposing specific award conditions. Therefore, NIH terminated the subaward to WIV in an effort to remove the non-compliant component of the research project. Apart from the WIV subaward, NIH identified other violations of terms and conditions, which may be remedied through imposing specific award conditions. NIH had identified those same violations on two other awards (U01AI151797[9] and U01AI153420).[10] For those awards, NIH requested a CAP from EcoHealth Alliance and imposed specific award conditions on January 7, 2022. Between February and April, EHA provided the CAP to NIH, which NIH approved, and EHA implemented. The CAP focused primarily on rewriting the subaward agreements and improving monitoring and reporting conflicts of interest by its subawardees. Because EHA was able to successfully implement the CAP on the two U awards,

[4] https://www.niaid.nih.gov/diseases-conditions/coronavirus-bat-research
[5] https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.339
[6] https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFRb1309e6966399c7/section-75.372
[7] https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFRb1309e6966399c7/section-75.371
[8] https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340
[9] https://reporter.nih.gov/search/CPR2Ub0CFkWUNTbj0b-8XA/project-details/9968924
[10] https://reporter.nih.gov/search/WdyFNVOA9kiYSZOpkOMT1A/project-details/10033642

and the same violations were present with the R01, NIH determined that those violations under R01AI110964 can be remedied by imposing specific award conditions. Accordingly, NIH is allowing the remainder of the R01 award to proceed without the involvement of WIV, subject to specific award conditions (including biosafety and biosecurity risk mitigation measures, as needed), provided the specific aims and objective of the award can be successfully revised without significantly departing from the original peer-reviewed project. The specific award conditions will remain in place for approximately 3 years on all awards and include requiring EHA to send all subaward documents and reports to the National Institute of Allergy and Infectious Diseases for review with Office of Extramural Research oversight.

3. How does NIH know that it has in its possession all relevant information necessary to conclude that NIH funds were not used for research related to SARS-CoV-2 or a progenitor virus of SARS-CoV-2 prior to January 2020?

NIH Response

As noted in response to Question 1, the NIH has used the information that it has access to when assessing the viruses that EcoHealth Alliance and WIV were approved to study using NIH funds. The NIH is not aware of any evidence to support the claim that EcoHealth Alliance and/or WIV used NIH funds to conduct research on SARS-CoV-2 or a progenitor virus at WIV prior to the emergence of SARS-CoV-2. The NIH would welcome any such evidence that the Committee or others may possess.

The Honorable Michael Burgess, MD.

1. The HHS Inspector General recently reported that "despite identifying potential risks associated with research being performed under the EcoHealth awards, we found that NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements." In addition to EcoHealth's inability to obtain scientific documentation from its experiments at the Wuhan lab2, and its failure to file a 2019 progress report, the IG also determined that "EcoHealth claimed $89,171 in costs that did not meet Federal requirements. These costs included salaries exceeding the NIH salary cap, employee bonuses, travel costs, tuition costs, indirect costs."3 This audit covered all 3 NIH awards to EcoHealth between 2014 and 2021 and found $89,171 in unallowable costs.

A. Roughly how many awards does NIH issue a year?

NIH Response:

NIH supported 58,368 competing and non-competing awards for FY 2022, issuing grants to 2,707 academic universities, hospitals, small businesses, and other organizations throughout the U.S. and internationally. For FY 2021, NIH supported 56,792 competing and non-competing awards. This number includes all extramural grants and Other Transaction awards while research and development contracts are excluded. Spending related to supplemental appropriations for coronavirus response are also excluded.[11] Additional summary statistics on NIH grants are available (and may be exported from) the NIH Data Book section on Research Grants.[12]

[11] https://covid19.nih.gov/funding

[12] https://report.nih.gov/nihdatabook/category/6

B. If the OIG identified tens of thousands of dollars in unallowable costs in only three awards, have you taken any steps to identify how many taxpayer dollars have been misused by grant recipients across the board?4

NIH Response:
NIH worked with EcoHealth Alliance to recover unallowable costs, which were returned to the US Treasury on December 23, 2022.

The NIH Grants Policy Statement, which is a term and condition of every NIH grant award, clearly articulates federal cost principles (see section 7.2)[13] and allowability of costs/activities (see section 7.9).[14] The Grants Policy Statement outlines the appropriate entities that should be notified if an individual becomes aware of concerns associated with NIH grant funding, such as fraud, waste, and abuse; research misconduct; and non-criminal misuse of NIH grant funds (see section 2.3.10).[15] NIH also has a portal[16] for reporting concerns about different forms of misconduct and who to contact.

The NIH Office of the Director has staff who are dedicated to compliance reviews and interacting with other Federal agencies to identify and remedy unallowable costs. Other publicly known examples include cases from the U.S. Department of Justice related to Hunter College, Van Andel Research Institute, Duke University,[17] Columbia University,[18] and Scripps Research Institute.[19]

2. Dr. Tabak, with the NIH Reform Act of 2006, Congress established the Scientific Management Review Board (SMRB), an oversight board meant to make NIH more efficient.5 The NIH has not convened the SMRB since 2015. According to a review by the health-oriented news website STAT, the SMRB, "mysteriously stopped meeting seven years ago" and SMRB members do not know why.6

A. Please explain why the NIH has failed to convene the SMRB since 2015.

B. Who decided to stop convening the SMRB?

C. When was this decision made?

D. If the decision is in writing, please provide a copy to this Committee. If the decision is not in writing, why not?

NIH Response A-D
NIH prioritizes effective stewardship of taxpayer funds, both in ensuring our mission to support the most meritorious biomedical research and optimally organizing the agency to support this mission. To achieve these aims, we enthusiastically seek external input and advice and are

[13] https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.2_the_cost_principles.htm
[14] https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm
[15] https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.3.10_fraud__waste_and_abuse_of_nih_grant_funds.htm
[16] https://grants.nih.gov/help/report-a-concern
[17] https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related
[18] https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-95-million-settlement-columbia-university-improperly
[19] https://www.justice.gov/opa/pr/scripps-research-institute-pay-10-million-settle-false-claims-act-allegations-related

grateful to those sharing their expertise with NIH through Federal Advisory Committees. Participation in these groups takes substantial time and effort from the leading experts in the biomedical research community. NIH has over 140 advisory committees, for which experts provide their valuable time and effort in service to biomedical science and the public good. It is imperative that NIH employs their service effectively and efficiently.

NIH actively seeks advice and input from multiple advisory committees about its operations and functions. The NIH Advisory Committee to the Director (ACD), which was established in 1965, has routinely served as the primary federal advisory body to the NIH Director. ACD members are carefully selected to represent the academic and private sector biomedical research community, as well as representatives of the general public. This makes the ACD expertly positioned to have the depth and breadth of scientific knowledge, expertise, and experience needed to advise on NIH organizational issues. Like the SMRB, the ACD is charged with making recommendations concerning program development, resource allocation, NIH administrative regulation and policy, and other specific or general aspects of NIH policy. ACD working groups frequently include NIH Institute and Center (IC) Directors (ICD), who regularly serve as co-chairs or are members of ACD working groups. This ensures ICDs provide valuable insight into the ICs' current operations and mission-centered priorities. The working groups also include respected members of the biomedical research community with specialized expertise in each topic.

The charge of the ACD encompasses and expands on the charge of the SMRB by including questions of future scientific opportunity to advance the NIH mission. It has been a challenge to recruit, retain, manage, and staff these two Federal Advisory Committee Act committees. Additionally, NIH has numerous internal mechanisms outside SMRB by which it engages its ICDs on matters related to NIH's organizational structure. The NIH Reform Act includes a high level of specificity regarding the types of members that must be included in the SMRB. Ultimately, these restrictions in scope of charge and specificity of members introduce delays in selecting and appointing new members with relevant expertise for specific charges to the Board. In contrast, the ACD has the capability to quickly form working groups to help the committee tackle emerging issues, making it able to take on key questions and make recommendations about rapidly evolving topics.

3. Despite not meeting since 2015, the NIH claims the total annual cost of the Board is around $488,000, including 2 full time employees at a cost of just over $320,000.7 Without convening the SMRB I'm concerned that the NIH has diverted this funding reserved for the SMRB to other purposes.

A. Since the NIH has stopped convening this board in 2015, how has the NIH used the approximately $2.9 million it claims to have spent on board operations over the past six years?

B. Will NIH return to the U.S. Treasury the more than $2.9 million in funding that was not used for operating and supporting the SMRB?

C. Who are the NIH staff who were originally designated to be responsible for staff support of the SMRB?

D. What have these designated staff been working on since 2015 instead of supporting the SMRB?

E. Will the NIH reconvene the SMRB, and if so, when?

F. Can you provide a list of all recommendations voted on by the SMRB and the votes with respect to each recommendation?

G. For those recommendations that were supported by the SMRB, please provide the status of implementation of those recommendations?

NIH Response A-G
NIH did not receive specific appropriations for the costs of operating and supporting the SMRB. These costs were covered from general appropriations to the NIH Office of the Director that support a wide range of activities.

Since its establishment, the ACD—using input from about a dozen specialized working groups of experts—has made numerous recommendations for structural and functional changes at NIH. In addition to making the seminal recommendation directing the scientific focus of the National Center for Advancing Translational Sciences (NCATS) (based on the SMRB's recommendations to form a new center), the ACD has provided advice on numerous organizational activities such as: the restructuring of the National Children's Study; optimizing high-risk/high reward programs and applicant diversity; the mission, organization, and future of the National Library of Medicine; changing the culture to end sexual harassment; and Intramural Research Program planning.

Please find a summary of recommendations and votes by the SMRB below, along with the status of implementation and the parallel involvement of the ACD in these matters.

Charges to the SMRB (listed in chronological order)

SMRB Report	Major Recommendations	NIH Implementation
Deliberating Organizational Change and Effectiveness (DOCE) (link) November 2010	Established process by which SMRB should deliberate topics assigned for deliberation.	The DOCE charge did not result in any recommendations for NIH. Rather, the DOCE report and guiding principles have been used by the SMRB in their work.
Substance Use, Abuse, and Addiction (link) November 2010	Recommended creation of a new institute for all substance use, abuse, and addiction-related research and dissolution of NIAAA and NIDA.	NIH stakeholders, including members of Congress, strongly opposed the integration., NIH decided to "functionally integrate" substance use research rather than making a structural change within the agency.
NIH Intramural Program/Clinical Center (CC) (link) December 2010	• Include a budget line item for the CC • Expand the vision and role of the CC • Streamline the CC governance structure • Provide stable, adequate budget for fiscal viability and sustainability	The two ACD Working Groups described below were influential in changes made to the CC. 1) The ACD Long-Term Intramural Research Program (LT-IRP) Planning Working Group (implementation plan report, presentation) 2) The "Red Team" ACD Clinical Center Working Group (process presentation, implementation presentation)

SMRB Report	Major Recommendations	NIH Implementation
Translational Medicine and Therapeutics (TMAT) (link) December 2010	Create a new NIH Center with the mission of supporting and strengthening translational medicine	The establishment of NCATS was also recommended by the ACD and ultimately established by Congress.
Small Business Innovation Research/Small Business Technology Transfer Program (SBIR) (link) August 2013	• Decrease delays between application submission and fund disbursal • Improve the process for selecting and supporting commercially viable projects • Strengthen trans-NIH communication of best practices and pooling of resources and expertise	Many actions relevant to the SMRB's recommendations were already in process while the SMRB was deliberating.
Approaches to Assessing the Value of Biomedical Research (VOBR) (link) March 2014	• Better capture and communicate NIH's value. • Take a more coordinated and systematic approach in selecting study topics and utilizing a mix of study designs and methodologies.	While there were no structural changes resulting from these recommendations, the internal NIH staff in the NIH Office of Evaluation, Planning, and Reporting implemented these recommendations and frequently cite VOBR as the driver for capacity building activities.
Pre-college Engagement in Biomedical Science (PEBS) (link) January 2015	• NIH pre-college STEM activities need a rejuvenated, integrated focus on biomedical workforce preparedness, with special considerations for underrepresented minorities	Activities were independently underway such as the Scientific Education Partner Award Program (SEPA), the NIH Summer internship program, and the Health Disparities in Tribal Communities Summer Internship Program.
Grant Review, Award, and Management Process (GRAMP) (link) July 2015	• Improve NIH grant review, award, and management processes while reducing the burden on investigators and NIH staff and decreasing the time to decision or award.	Activities were independently underway and new activities are still ongoing: For example, the 21st Century Cures Act expanded NIH authority to use Prize competitions, such as the Eureka (for Exceptional, Unconventional Research Enabling Knowledge Acceleration) Prize Competitions. There is also an active ACD Diversity WG subcommittee on Peer review who just presented at the November 3, 2022 ACD meeting on the proposed new framework for peer review criteria.

4. Official reporting over the past few years as well as the recent investigation the Office of the Inspector General confirmed that NIH allowed grants to EcoHealth Alliance for years without proper oversight.

A. What happened at the NIH that allowed gain of function research to happen unchecked?

NIH Response

NIH takes the safety, security, and responsible conduct of the research it funds very seriously, and appropriate oversight is central to our mission. The NIH Grants Policy Statement serves as a term and condition of all NIH grant awards. By accepting a grant award, recipients agree to comply with the requirements, including compliance with relevant biosafety and biosecurity

guidelines, policies, and regulations. In addition to the standard terms and conditions of award outlined in the NIH Grants Policy Statement, NIH program staff may include additional programmatic terms dependent on the research and the specific need.

NIH did not approve funding for research anticipated to enhance the transmissibility or virulence of coronaviruses in humans.[20]

Per the OIG report, "In accordance with Federal requirements, NIH had policies and procedures in place for monitoring grant awards by reviewing financial and progress reports, taking action to implement enhanced monitoring for awards to EcoHealth Alliance, and reviewing research that could involve enhanced potential pandemic pathogens."

Nonetheless, NIH recognizes concerns surrounding research that may enhance pandemic potential – which was not the case for the EcoHealth Alliance grant. NIH has convened the National Science Advisory Board for Biosecurity (or NSABB). The Board recently issued a Proposed Biosecurity Oversight Framework for the Future of Science.[21]

B. What is the NIH doing moving forward to make sure this can never happen again?

NIH Response

The OIG report noted areas needed for improved oversight over the EcoHealth award: "Specifically, NIH did not ensure EcoHealth in a timely manner submitted a progress report that was 2 years late and that NIH concluded contained evidence of a virus with growth that should have been reported immediately; did not ensure EcoHealth publicly reported required subaward data; and did not follow proper procedures to terminate an award to EcoHealth."

NIH accepted the OIG's recommendations associated with these findings and is taking several steps to address them (see Appendix I on page 52 of the OIG report for NIH's response).[22] For example, NIH has taken measures to strengthen systems to improve the ability of NIH program staff to monitor NIH grants. These measures include:

- Incorporating additional audit controls for the timely receipt of progress reports to ensure that the latest information is reviewed by program officers.
- Implementing program scripts in the NIH grants system ("eRA") that send additional reminders to grant recipients and NIH staff of delinquencies if progress reports are either delayed or not fully reviewed and accepted. Should this happen, the system establishes a "red bar" to funding of the next non-competing renewal, which would trigger an action by the program staff.

NIH is also beginning an evaluation of how best to consider the OIG recommendation regarding enhanced oversight of grant recipients with foreign subrecipients within the framework of 2

[20] www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-misinformation-about-nih-support-specific-gain-function-research

[21] osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf

C.F.R. §§ 200.331 - 200.333,[23] Subrecipient Monitoring and Management (Uniform Administrative Regulations). NIH will also need to consider 2 C.F.R. § 200.100(c)[24] which states, "The Federal awarding agency may adjust requirements to a class of Federal awards or non-Federal entities when approved by the Office of Management and Budget. ... " NIH will also evaluate best practices across the government for overseeing awards issued to domestic recipients who in turn oversee foreign subrecipients. The results of this evaluation are anticipated to inform how NIH may implement the OIG recommendation.

5. Through grant funding at the NIH, we know that grant recipients have bought sufficient testing equipment that could have been used for increased COVID-19 testing.

A. Why did the NIH not utilize this testing equipment bought with federal funds?

NIH Response

The equipment purchased with NIH grant funds was purchased by NIH grant recipients to support extramural research (not intramural research). NIH funds that are allocated for NIH intramural support, are available for intramural purposes only. NIH does not commingle extramural and intramural funding. In the case of equipment purchased by NIH grant recipients to support extramural research activities, NIH research grants are made to an organization or institution, not to individual researchers, and follow the Uniform Administrative Regulations (2 CFR § 200).[25] Therefore, in accordance with 2 CFR § 200.313[26] title to equipment acquired with NIH funds vests upon acquisition with the institution unless there is a statute that authorizes NIH to vest in the title. Title vests with the institution for the originally authorized purpose. The equipment must be used by the institution as long as it's needed whether or not the grant program continues to be supported by NIH. Equipment may be used in other research activities supported by NIH in the following priority order: 1) activities under the NIH award which funded the original project, then 2) activities under Federal awards from other Federal awarding agencies to include consolidated equipment for information technology systems or shared instrumentation programs. When the original equipment is no longer needed by the recipient prior to the end of the project and where the equipment's acquisition cost is $5,000 or more, NIH has the right to require the transfer of title back to NIH or to an eligible third party named by the NIH awarding IC, see details at: Equipment and Supplies.[27]

During COVID, OMB issued a memo M-20-20[28] which allowed the flexibility for recipients to donate medical equipment to include PPE medical devices, medicines, and other medical supplies under Federal financial assistance to support COVID 19 emergency response activities. NIH supported this flexibility by issuing a FAQ[29] which allowed recipients to request prior approval to donate PPE and other lab supplies as outlined in the OMB Memo M-20-20 which provides the direct flexibility to Federal awarding agencies.

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[25] https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200?toc=1

[26] https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR8feb98c2e3e5ad2/section-200.313

[27]https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.3.3_property_management_system_standards.htm#Equipmen

[28] https://www.whitehouse.gov/wp-content/uploads/2020/04/M-20-20.pdf

[29] https://grants.nih.gov/faqs#/covid-19.htm?anchor=55849

B. Is there something Congress can do to ensure that this equipment, bought with taxpayer dollars, can be used in times of crisis in the future?

NIH Response
Recipients are currently allowed under 2 CFR § 200.313 to use equipment for multiple purposes to support other NIH project or Federal programs. As long as the equipment purchased for specific NIH projects is needed by the recipient, the title is retained by the recipient.

6. The National Institutes of Health (NIH) of health have made a purchase order for software to support the management of intellectual property owned by the Institutes. Fulfillment of that order is well beyond the scope initially proposed by the current contractor, leaving NIH having spent significant taxpayer resources without a product that is usable NIH-wide for technology transfer. NIH had requested that the system be ready to launch by August 2019. However, the software has only been made available in a test environment, and less than 20% of anticipated users currently have access to that system. This software system is now more than two years overdue for delivery to serve the NIH's critical needs and the taxpayers who funded this project. Further, the software being developed for use across the Institutes is not implemented by a provider that meets FedRAMP Moderate or High standards. FedRAMP Moderate or High is the "gold standard" of data security to protect government systems' most critical and valuable information.

A. How much has the NIH spent to date to develop and implement the system licensed for NIH wide technology transfer and intellectual property management related to (NIH) (PIID 5N93019P00220), and what is the expected expenditure for the remainder of the agreement?
NIH Response
NIH contracted with Inteum Company, LLC, for an invention, patent, licensing, and royalties management system in support of NIH's technology transfer infrastructure. The solution provided by Inteum is part of a larger, multi-year Enterprise Technology Transfer (ETT) project. The full ETT solution is hosted by Amazon Web Services (AWS), which is FedRamp compliant.

Inteum developed and deployed a solution that satisfies all functional requirements stated in the solicitation to the NIH stage environment within the requested 6 month timeframe following GAO's denial of Wellspring Worldwide's protest and the lifting of the stop work order. NIH is pleased with the performance of the system to date, as well as Inteum's responsiveness to NIH requirements and feedback.

NIH Response
To date, NIH has awarded $988,188.06 in the performance of this Purchase Order (5N93019P00220). This includes costs associated with delays caused by the protest of this contract as well as changes requested by NIH. One option period remains in the amount of $220,289.87.

B. At what stage is the project currently, and what is the best delivery date estimate?

NIH Response

The software required by the base year of the Purchase Order was delivered timely per the requirements of the solicitation (within 6 months following GAO's denial of Wellspring Worldwide's protest and the lifting of the stop work order) on June 12, 2020, and is now deployed to all NIH Institutes and Centers. No deliverables were delivered past the required dates of the original Purchase Order. The deliverables met all requirements of the solicitation including security requirements.

C. Why has this system taken over three years to deploy even though this product was referred to as a "commercial off the shelf or COTS" technology?

NIH Response
The goal of the project at large was the roll out of an Enterprise Technology Transfer (ETT) system (a multi-year effort) of which the COTS software was one part. Inteum fulfilled the requirement to deploy the COTS system to the stage environment at NIH within 6 months of award (which in this case was 6 months after the stop work order was lifted following the GAO's denial of Wellspring Worldwide's protest). Implementation of this product across NIH required standardization of processes used by each technology transfer group as well as the migration of legacy data from the previous systems in use at the NIH to ensure all legacy data were accurately and fully captured in the new system. This also required the training of users and coordination of the change management process within all NIH Institutes and Centers. Deployment to the users of NIH in the production environment was the responsibility of NIH, not the vendor.

The solicitation did not address the time frame in which NIH would deploy the solution, only that the solution be provided by the vendor to NIH within 6 months. NIH notes the process for deployment of a COTS system would have remained the same regardless of which product was purchased because the COTS product delivery was only the first step towards deploying an enterprise ETT system.

D. Considering foreign adversaries' cybercrime attempts at U.S. government systems, what is the NIH's plan for implementing procurement processes related to FedRamp Moderate or High-authorized systems?

NIH Response
Given the cyber threats of today and the federal requirements and guidance related to cloud services, the National Institutes of Health (NIH) has integrated FedRAMP into our acquisition processes for cloud contracts. Per the FedRAMP.gov website, the FedRAMP program provides "a standardized approach to security and risk assessment for cloud technologies and federal agencies." Essentially, FedRAMP compliance confirms that a Cloud Service Provider (CSP) has implemented security best practices that have been approved by the Federal government.

E. Has the NIH considered adding FedRAMP Moderate or High security requirements to this existing agreement (NIH) (PIID 5N93019P00220) or the software systems provided under that agreement?

NIH Response
NIH's ETT system is hosted by Amazon Web Services (AWS), which is FedRAMP compliant, and therefore no additional security is needed. As was noted in the solicitation, FedRamp

compliance was not mandatory for the part of the system provided by Inteum since NIH already had a solution for security independent of this acquisition. To create redundancy of FedRamp compliance with the vendor of this small part of the larger system would not offer any additional benefit.

F. Does the NIH see fit to recompete this agreement with new requirements for providers to be FedRAMP Moderate or High authorized?

NIH Response
NIH's ETT system is, and has been, FedRAMP compliant therefore no additional competition or increased funding is necessary. NIH does not plan to recompete this agreement.

G. If the NIH intends to supplement the security requirements of this system with further security protections, does NIH intend to purchase that security system or develop it in-house?

NIH Response
NIH does not intend to supplement the security requirements of this system as they are securely sitting on a FedRAMP compliant, secure cloud environment.

The Honorable Neal Dunn, M.D.

1. The Consolidated Appropriations Act of 2023 requested NIAID provide an update in the FY24 Congressional Justification on efforts NIAID has made to incorporate cellular immunity assessment into the wide range of COVID-19 and other disease studies being conducted and supported by NIH.

a. Has NIAID taken steps to incorporate cellular immunity assessment in such studies?

NIH Response
The National Institute of Allergy and Infectious Diseases (NIAID) has a longstanding portfolio of research that includes the characterization of cellular immune responses to pathogens and vaccines. While the role of antibodies in immunity to SARS-CoV-2 infection has been well studied, the contribution of cellular immunity, and T cells specifically, remains an active area of inquiry. Since the beginning of the SARS-CoV-2 pandemic, NIAID leveraged existing programs to provide critical resources for investigators and help characterize cellular responses to SARS-CoV-2 infection. NIAID also has integrated analysis of cellular immune responses into COVID-19 vaccine trials to understand their durability and to inform the use of boosters.

NIAID also investigates the ability of SARS-CoV-2-specific cellular immune responses to protect against new variants. NIAID-supported investigators are evaluating cellular immune responses to COVID-19 vaccination with novel vaccine adjuvants to mimic natural viral infection, aiming to induce robust cellular responses and enhance vaccine efficacy against variants. NIAID also is supporting efforts to incorporate immunogen design in the development of vaccine candidates that provide broad cell-mediated immunity to multiple SARS-CoV-2 variants and multiple coronaviruses. The fundamental knowledge these efforts impart will inform studies on other emerging and re-emerging infectious diseases.

b. If not, does NIAID have plans to do so?

NIH Response
NIAID will continue to study the durability and evolution of cellular immunity to SARS-CoV-2 infection and following COVID-19 vaccination. This will include assessments in key populations, including post-acute sequelae of SARS-CoV-2 (PASC), commonly known as Long COVID, patients. NIAID also will build on multidisciplinary and systems biology-based approaches to generate new strategies to prepare for, and respond to, emerging and re-emerging pathogens of public health concern.

c. Does NIAID intend to comply with Congress's request to provide an update on these efforts in the fiscal year 2024 Congressional Justification?

NIH Response
Yes, an update on cellular immunity efforts will be transmitted to Congress in the fiscal year 2024 Congressional Justification.

The Honorable Troy Balderson

1. Much of the public agrees that our agencies need to now return to their original, intended purposes and be proactive toward future pandemics, instead of retroactive to continue focusing on COVID-19 at the expense of the litany of other diseases and health challenges facing Americans.

A. What changes will your agencies make in preparation for the PHE ending on May 11th?

NIH Response
Effective May 12, 2023, NIH will no longer issue Emergency Notices of Funding Opportunity (NOFOs) related to COVID-19. Ongoing emergency awards will not be impacted and will retain all existing emergency flexibilities for the remainder of the current competitive segment. NIH will also no longer grant new Common Rule exceptions to the use of a Single IRB for multi-site research after the COVID-19 Public Health Emergency expires.

B. What resources and offices will continue to be dedicated to COVID-19?

NIH Response
The NIH has a wide array of ongoing research related to COVID-19 and will continue to support these efforts, many of which are Congressionally directed. Below are a few examples of major research endeavors related to COVID-19.

The National Institute of Allergy and Infectious Diseases (NIAID) has a historic dual mandate to pursue not only a robust research portfolio of infectious, immunologic, and allergic diseases, but also to provide a rapid research response to emerging and re-emerging infectious diseases and potential pandemics. When the COVID-19 pandemic began, NIAID facilitated the rapid development and testing of the first generation of COVID-19 vaccines by capitalizing on longstanding NIAID support for versatile vaccine platforms and structure-based antigen design as well as successful NIAID clinical trial networks. Following up on the development of effective vaccines, NIAID is continuing to assess the impact of SARS-CoV-2 variants on vaccines and therapeutics. NIAID also is supporting the development of next-generation COVID-19 vaccines

that could provide broader protection against SARS-CoV-2 infection and disease caused by emerging SARS-CoV-2 variants. This work was established using COVID-19 supplemental funding and also includes research on pan-coronavirus vaccines as well as mucosal vaccine approaches.

Advances in COVID-19 prevention and treatment also will be used to inform the development of medical countermeasures for other infectious disease threats. NIAID continues to prioritize the development of oral antivirals against SARS-CoV-2 and potential pandemic pathogens through the Antiviral Program for Pandemics (APP) and its nine multidisciplinary Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern. In addition, NIH will support, expand, and/or improve the large and rapidly scalable clinical trials networks and infrastructure which were crucial to the development of medical countermeasures for COVID-19 for use against other public disease threats. Through these and other pandemic preparedness efforts, NIH remains committed to supporting biomedical research to enhance our ability to address future pandemics.

The National Institute of Mental Health (NIMH) will continue to support research to understand the bidirectional relationship between SARS-CoV-2 infection and mental illnesses, as well as broader mental health impacts of the pandemic. These broader impacts include the loss of loved ones, loss of income, and other social and economic disruptions. One high-priority area of NIMH's continued research investment is understanding and mitigating the impact of COVID-19 on children's mental health, including impacts of COVID-19-related school disruptions. NIMH will also prioritize research focused on the mental health impacts of the pandemic for populations who experience health disparities and other marginalized populations, including: individuals with serious mental illnesses; older adults; and, medical personnel and other frontline workers. The COVID-19 pandemic exacerbated existing shortages in the mental health care workforce relative to service needs. To address this ongoing challenge, NIMH will continue to support research on telehealth, mobile health (mHealth), and other scalable interventions for pandemic-related mental health needs.

The NIH will continue to support the Researching COVID to Enhance Recovery (RECOVER) Initiative - a national patient-centered research effort to develop lasting treatment strategies for Long COVID, a debilitating condition affecting millions of people and their families.[30] Core to RECOVER's research efforts are observational cohort studies, the analysis of electronic health records, pathobiology studies, and clinical trials. Through the RECOVER investment, the US now has the world's largest, most diverse, and only deeply characterized cohort of Long COVID patients across the lifespan.

We have learned vital information about Long COVID from RECOVER, including the clinical spectrum in adults and children, risk factors for developing Long COVID, the impact of variants in vaccination, risk of developing new-onset conditions in Long COVID, and its impact on pre-existing conditions. RECOVER is launching a suite of clinical trials in 2023 that will include testing candidate therapies for symptoms described by patients as being most burdensome. These

[30] https://recovercovid.org/

studies will also help us to understand the underlying biology of Long COVID so we can fine-tune interventions moving forward.