



Reforming the National Institutes of Health Framework for Discussion

The Time is NOW to Build a Stronger NIH for the Future



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STRUCTURAL REFORM

Background

The National Institutes of Health's (NIH's) sprawling and siloed organizational structure has been an issue of longstanding interest to Congress and stakeholders. There are significant costs and complexities associated with administering an agency comprised of 27 Institutes and Centers (ICs), each with its own unique mission and priorities, budget, staff, programming, and operational systems. Decades of nonstrategic and uncoordinated growth created a system ripe for stagnant leadership, research duplication, gaps, misconduct, and undue influence. At the same time, adversarial countries continue to direct focus and funding towards biomedical science, making it all the more imperative for the U.S. to take the steps necessary to maintain its innovative edge. These shortcomings have and will continue to adversely affect the NIH's ability to respond appropriately to new scientific and public health challenges, as well as hinder America's ability to remain the world's pioneering leader of basic science and biomedical research innovation.

The goal of the structural reform proposed in this framework is to position the NIH to better succeed moving forward. Several of the changes contained in this proposal have been requested by prior Administrations or recommended by scientific bodies. By streamlining the currently existing 27 ICs into 15 revised ICs, our goal is to better align the missions of each institute and center and establish more coordinated overarching research goals, agendas, and constituencies. By encouraging each IC to utilize a holistic life stage approach, our goal is to eliminate the demographic- or disease-specific siloed nature of the current structure and ensure each IC is considering the whole individual and all populations across the entire lifespan. By providing clarity and transparency on funding lines, our goal is to ensure cohesive alignment and effective coordination across current activities and investments. The science of today is not accomplished in a silo. The nation's premier research institution should not be structured as such either.

Table 1. Current NIH Institutes and Centers

	Institutes and Centers	FY24 Funding	FY23 Success Rates*
1	National Cancer Institute (NCI)	\$7,224,159,000	16.1%
2	National Heart, Lung, and Blood Institute (NHLBI)	\$3,982,345,000	21.1%
3	National Institute of Dental and Craniofacial Research (NIDCR)	\$520,163,000	22.0%
4	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	\$2,310,721,000	22.9%
5	National Institute of Neurological Disorders and Stroke (NINDS)	\$2,603,925,000	21.6%
6	National Institute of Allergy and Infectious Diseases (NIAID)	\$6,562,279,000	20.8%
7	National Institute of General Medical Sciences (NIGMS)	\$3,244,679,000	36.3%
8	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	\$1,759,078,000	18.8%
9	National Eye Institute (NEI)	\$896,549,000	26.2%
10	National Institute of Environmental Health Sciences (NIEHS)	\$913,979,000	15.1%
11	National Institute on Aging (NIA)	\$4,507,623,000	24.0%
12	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	\$685,465,000	17.8%
13	National Institute on Deafness and Other Communication Disorders (NIDCD)	\$534,333,000	26.9%
14	National Institute of Nursing Research (NINR)	\$197,693,000	16.9%
15	National Institute on Alcohol Abuse and Alcoholism (NIAAA)	\$595,318,000	30.5%
16	National Institute on Drug Abuse (NIDA)	\$1,662,695,000	22.1%
17	National Institute of Mental Health (NIMH)	\$2,187,843,000	22.4%
18	National Human Genome Research Institute (NHGRI)	\$663,200,000	22.0%
19	National Institute of Biomedical Imaging and Bioengineering (NIBIB)	\$440,627,000	17.7%
20	National Institute on Minority Health and Health Disparities (NIMHD)	\$534,395,000	18.8%
21	National Center for Complementary and Integrative Health (NCCIH)	\$170,384,000	14.4%
22	John E. Fogarty International Center (FIC)	\$95,162,000	22.3%
23	National Center for Advancing Translational Sciences (NCATS)	\$928,323,000	26.8%
24	National Library of Medicine (NLM)	\$497,548,000	14.8%
25	NIH Clinical Center (CC)**		
26	Center for Scientific Review (CSR)**		
27	Center for Information Technology (CIT)**		
	Common Fund	\$672,401,000	14.6%
	Advanced Research Projects Agency for Health (ARPA-H)	\$1,500,000,000	
	Office of the Director (OD)	\$1,933,113,000	
	Buildings and Facilities (B&F)	\$350,000,000	
	TOTAL	\$48,174,000,000	21.4%

*Success rates are defined as the percentage of reviewed grant applications that receive funding (i.e., the likelihood of a project getting funded).

**Support Centers are funded through transfers from other accounts.

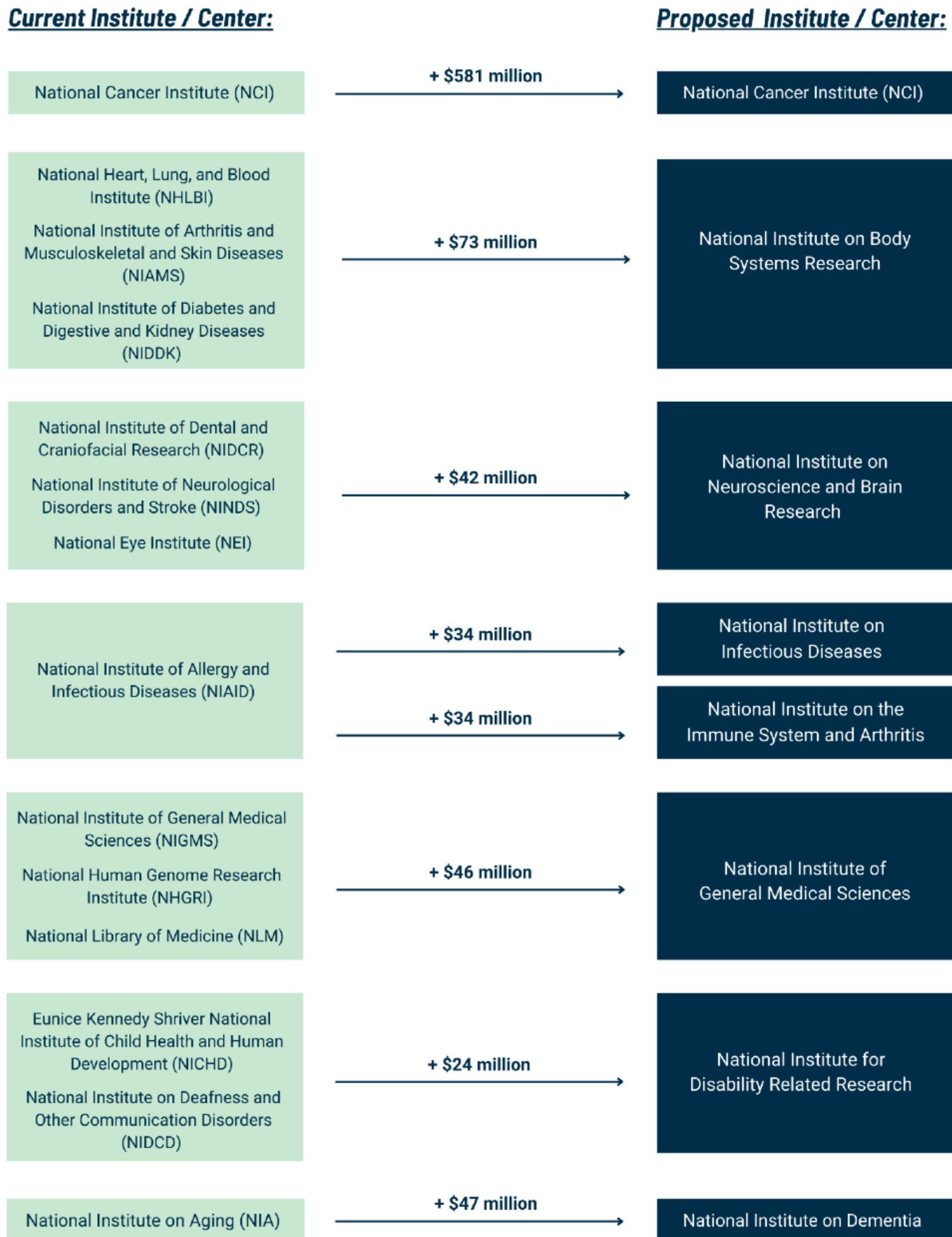
Table 2. Proposed NIH Institutes and Centers

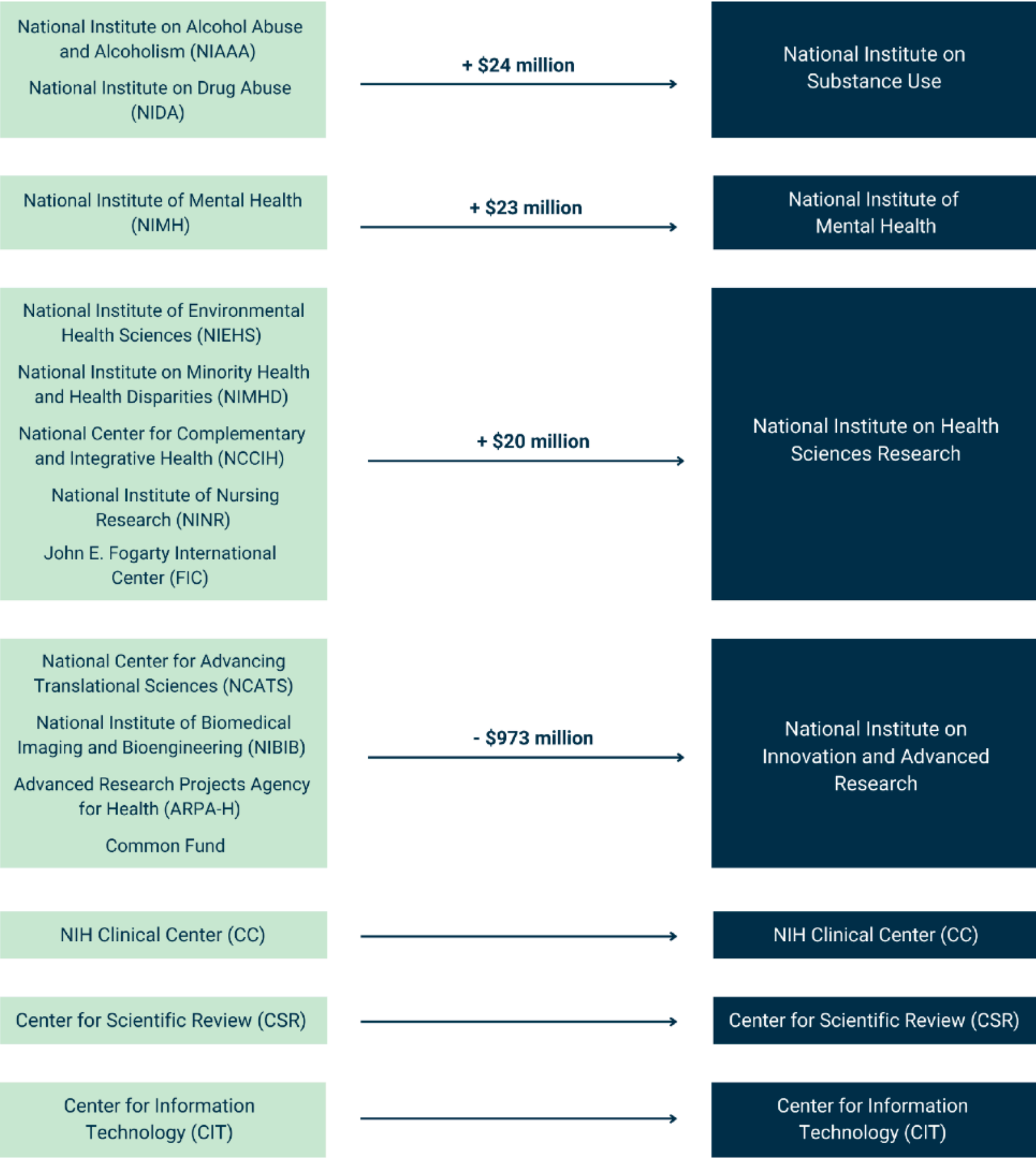
	Institutes and Centers	Proposed Funding
1	National Cancer Institute	\$7,805,169,000
2	National Institute on Body Systems Research	\$7,051,721,000
3	National Institute on Neuroscience and Brain Research	\$4,062,805,000
4	National Institute on Infectious Diseases	\$3,315,552,000
5	National Institute on the Immune System and Arthritis	\$3,315,552,000
6	National Institute of General Medical Sciences	\$4,451,630,000
7	National Institute for Disability Related Research	\$2,317,464,000
8	National Institute on Dementia	\$4,554,899,000
9	National Institute on Substance Use	\$2,281,695,000
10	National Institute of Mental Health	\$2,210,789,000
11	National Institute on Health Sciences Research	\$1,931,662,000
12	National Institute on Innovation and Advanced Research	\$2,568,004,000
13	NIH Clinical Center (CC)*	
14	Center for Scientific Review (CSR)*	
15	Center for Information Technology (CIT)*	
	Office of the Director (OD)	\$1,953,387,000
	Buildings and Facilities (B&F)	\$353,671,000
	TOTAL	\$48,174,000,000

*Support Centers are funded through transfers from other accounts.

¹ Congressional Research Service, "National Institutes of Health (NIH) Funding: FY1996-FY2024," R43341, 2023, <https://crsreports.congress.gov/product/pdf/R/R43341>.

Figure 1. A Stronger NIH for the Future





POLICY REFORM

Mission and Leadership Reform:

NIH Mission and Leadership Must Be Accountable, Integrated, and Agile

Background

The stated mission of the National Institutes of Health (NIH) 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.”² As the primary federal agency responsible for conducting and supporting medical, health, and behavioral research, the NIH plays a large and visible role in the training and funding of biomedical researchers, collection and dissemination of health information, and collaboration with the private sector to drive scientific advances.

Established in 1887 as a one-room Laboratory of Hygiene at the Marine Hospital in Staten Island, New York, the NIH now has the largest budget of the eight health-related agencies of the Public Health Service (PHS) within the Department of Health and Human Services (HHS).³ It consists of the Office of the Director (OD) and 27 separate components—20 research institutes, three research centers, the National Library of Medicine (NLM), and three support centers—each with its own mission, budget, staff, review office, and organizational apparatus. Each individual institute and center (IC) has separate research priorities and programming, which it plans and manages in coordination with the OD. These priorities can range from a particular aspect or area of a disease or condition, stage of human development, biomedical science, or scientific field. Through the annual appropriations process, Congress provides separate funding to the OD, each of the 24 ICs (20 institutes, three research centers, and NLM), the recently established Advanced Research Projects Agency for Health (ARPA-H), and a Buildings and Facilities account.

The creation of distinct institutes began in 1937 with the establishment of the National Cancer Institute (NCI) and proliferated through the 1970s.⁴ According to a National Academies of Science (now called the National Academies of Sciences, Engineering, and Medicine) study, the creation of new, named entities—generally established first as a named program at the office level, then advanced to a center, and finally, elevated to institute status—occurred most frequently at the request of specific health advocacy populations and often against the wishes of administrations.⁵

The Public Health Service Act (PHSA) provides the statutory basis for NIH programs. While additional direction may be provided through appropriations report language, Congress has generally deferred to

² The National Institutes of Health, “About the NIH”, *The NIH Almanac*, 2015, <https://www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih#:~:text=NIH%20is%20the%20steward%20of,and%20reduce%20illness%20and%20disability>.

³ Congressional Research Service, “National Institutes of Health (NIH) Funding: FY1996-FY2024,” *R43341*, 2023, <https://crsreports.congress.gov/product/pdf/R/R43341>.

⁴ Congressional Research Service, “The National Institutes of Health (NIH): Background and Congressional Issues,” *R41705*, 2019, <https://www.crs.gov/reports/pdf/R41705/R41705.pdf>.

⁵ National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (Washington: National Academies Press, 2003), <http://www.nap.edu/catalog/10779.html>.

the scientific and public health priorities established by the NIH through its strategic planning and grant-making activities. Over the years, Congress has maintained a consistently high level of interest in the NIH, due to the agency's large budget and funding of research grants, contracts, and other awards, as well as the widespread disease-specific advocates and general research support constituencies. Even still, the last authorization of appropriations occurred under the 21st Century Cures Act,⁶ which expired at the end of fiscal year (FY) 2020, and the last comprehensive reauthorization effort was nearly two decades ago through the NIH Reform Act of 2006.⁷ While there has been Congressional interest over the years in addressing the growing, and increasingly fragmented nature of the NIH, there has been no successful effort to streamline the currently existing ICs, largely due to outside factors and a strong deference towards the status quo. For example, the Scientific Management Review Board (SMRB) was created under the NIH Reform Act of 2006 with the directive to formally and publicly review the NIH's organizational structure at least once every seven years and provide advice and recommendations on restructuring and utilization of organizational authorities. While the board was initially launched with several working groups and a regular meeting schedule, it is now seemingly defunct, with both its most recent public meeting and report being released in 2015, nearly a decade ago.^{8,9}

There is also a growing need to address the stagnant nature of leadership at the NIH. As shown in Table 3, *NIH Institute and Center Director Tenure Length*, the current average tenure of the 27 IC Directors is approximately seven years. Several IC Directors have served in their current role for longer than a decade. For example, Dr. Anthony Fauci was the Director of the National Institute of Allergy and Infectious Diseases (NIAID) for 38 years before his retirement in 2022,¹⁰ and Dr. Richard Hodes has been the Director of the National Institute on Aging (NIA) for more than 30 years. This average tenure does not include prior work or experience in a different role or office within the NIH. The lack of turnover within NIH's leadership may contribute to an inability to adapt to evolving expectations in the workplace or to proactively change an existing workplace culture. Investigations conducted by the Committee on Energy and Commerce have raised concerns about the adequacy of the NIH's response to allegations of misconduct, including sexual harassment complaints, within the NIH and at grantee institutions.¹¹

⁶ P.L. 114-255.

⁷ P.L. 109-482.

⁸ National Institutes of Health, "Meetings", *NIH Scientific Management Review Board*.
<https://smrb.od.nih.gov/meetings.html>.

⁹ National Institutes of Health, "Reports", *NIH Scientific Management Review Board*.
<https://smrb.od.nih.gov/reports.html>.

¹⁰ NIH National Institute of Allergy and Infectious Diseases, "Statement by Anthony S. Fauci, M.D.", *NIAD News Release*, 2022, <https://www.niaid.nih.gov/news-events/statement-anthony-s-fauci-md>.

¹¹ Committee on Energy and Commerce Majority, "Evidence Uncovered by E&C Republicans Refutes Secretary Becerra's Assertion that HHS Takes Action to Prevent Sexual Abusers from Receiving Taxpayer Funding," *News Release*, 2024, <https://energycommerce.house.gov/posts/evidence-uncovered-by-e-and-c-republicans-refutes-secretary-becerra-s-assertion-that-hhs-takes-action-to-prevent-sexual-abusers-from-receiving-taxpayer-funding>.

Table 3. NIH Institute and Center Director Tenure Length

Institutes and Centers	Director	Tenure Length*
National Cancer Institute (NCI)	W. Kimryn Rathmell, MD, PhD, MMHC	< 1 year
National Eye Institute (NEI)	Michael F. Chiang, MD	3 years
National Heart, Lung, and Blood Institute (NHLBI)	Gary H Gibbons, MD	12 years
National Human Genome Research Institute (NHGRI)	Eric D. Green, MD, PhD	14 years
National Institute on Aging (NIA)	Richard Hodes, MD	31 years
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	George Koob, PhD	10 years
National Institute on Allergy and Infectious Diseases (NIAID)	Jeanne M. Marrazzo, MD, MPH	< 1 year
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	Lindsay A. Criswell, MD, MPH, DSC	3 years
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	Bruce J. Tromberg, PhD	5 years
National Institute of Child Health and Human Development (NICHD)	Diana W. Bianchi, MD	7 years
National Institute on Deafness and Other Communication Disorders (NIDCD)	Debara L. Tucci, MD, MS, MBA	5 years
National Institute of Dental and Craniofacial Research (NIDCR)	Rena D'Souza, DDS, MS, PhD	3 years
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Griffin P Rodgers, MD, MACP	17 years
National Institute on Drug Abuse (NIDA)	Nora D Volkow, MD	21 years
National Institute of Environmental Health Sciences (NIEHS)	Rick Woychik, PhD	4 years
National Institute of General Medical Sciences (NIGMS)	Jon R. Lorsch, PhD	11 years
National Institute of Mental Health (NIMH)	Joshua A. Gordon, MD, PhD	8 years
National Institute on Minority Health and Health Disparities (NIMHD)	Eliseo J. Perez-Stable, MD	9 years
National Institute of Neurological Disorders and Stroke (NINDS)	Walter J. Koroshetz, MD	9 years
National Institute of Nursing Research (NINR)	Shannon N. Zenk, PhD, MPH, RN, FAAN	3 years
National Library of Medicine (NLM)	Stephen Sherry, PhD (Acting)	2 years
Center for Information Technology (CIT)	Sean Mooney, PhD	< 1 year
Center for Scientific Review (CSR)	Noni Byrnes, PhD	5 years
Fogarty International Center (FIC)	Kathleen M. Neuzil, MD	< 1 year
National Center for Complementary and Integrative Health (NCCIH)	Helene M. Langevin, MD	5 years
National Center for Advancing Translational Sciences (NCATS)	Joni L. Rutter, PhD	1 year
NIH Clinical Center (CC)	James K. Gilman, MD	7 years

*Tenure lengths are approximate, based on publicly announced start dates. Tenure duration of 8-11 months is rounded up to a year and tenure duration of 1-7 months is rounded down.

Central to achieving the NIH's mission is the role of public-private partnerships. Particularly given the rising costs, scientific complexity, workforce training, and time involved in the research and development of pharmaceuticals and medical products, the NIH should view private sector involvement as a necessary collaborative effort. One approach the NIH has taken to engage with partners is through the Foundation for the NIH (FNIH). Established by law in 1990 and operational since 1996, FNIH is a 501(c)(3) charitable organization that raises private funding and facilitates research projects and programs, education and training, conferences and events, and other support activities between the NIH and its private partners.¹²

The NIH must be committed to strategically supporting our nation's role as a leader in scientific research and discovery and medical innovation, while remaining fully accountable to taxpayers. Stonewalling, deceit, and refusals to cooperate with congressional investigations and abide by important laws, such as the Freedom of Information Act (FOIA), is inconsistent with accountable government.¹³ The twin imperatives of maintaining the country's position of global scientific leadership, while also addressing past misconduct illustrates the need for a wholesale, robust review and reform of NIH policy, programming, and activities, as well as a comprehensive organizational restructuring.

Recommendations

- **Initiate and Complete a Comprehensive Review of the NIH** – establish a congressionally mandated commission to lead a comprehensive, wholesale review of the NIH's performance, mission, objectives, and programs. Such review should include regular, timely public reports and updates and conclude with clear, actionable recommendations for improvement. The commission should include a sunset to require Congress to revisit the recommendations and subsequent implementation, to avoid a similar outcome as the SMRB.
- **Support Innovation** – ensure the NIH is committed to and focused on promoting and bolstering innovation of new treatments and cures, including by encouraging public-private partnerships and collaboration. Resist the use of misguided tactics to pursue a specific agenda and manipulate commercial markets, thus derailing and stifling America's leadership in biomedical innovation.
- **Introduce Term Limits for IC Leadership** – limit every IC Director to a five-year term, with the ability to serve two, consecutive terms, if approved by the NIH Director.¹⁴

¹² Congressional Research Service, *R41705*.

¹³ House Committee on Energy and Commerce, "Interim Staff Report on Investigation into Risky MPXV Experiment at the National Institute of Allergy and Infectious Diseases," 118 Cong. (June 11, 2024); see also H. Select Subcomm. on Coronavirus Pandemic, "Staff Memorandum: Allegations of Wrongdoing and Illegal Activity by Dr. David Morens, Senior Advisor to National Institute of Allergy and Infectious Diseases former-Director, Dr. Anthony Fauci," 118 Cong. (May 22, 2024).

¹⁴ See also Select Subcommittee on the Coronavirus Pandemic, Committee on Oversight and Accountability, "An Evaluation of the Evidence Surrounding EcoHealth Alliance, Inc.'s Research Activities," *Interim Staff Report*, 2024, Recommendation II, 5, https://oversight.house.gov/wp-content/uploads/2024/04/2024.05.01-SSCP-Report_FINAL.pdf?source=email.

- Eliminate Silos Between ICs – require every IC to issue a biennial report outlining how the individual IC is utilizing a life stage approach throughout its activities, grant funding decisions, and research portfolio and priorities, including appropriately considering distinctions and factors related to sex and age, as well as rare diseases within each center’s purview.
- Enforce Financial Disclosure and Transparency Requirements – ensure NIH officials are held to and abide by financial transparency requirements and standards and require appropriate reporting and disclosure of royalty payments and other third-party financial benefits, including support from and affiliations with foreign institutions.¹⁵
- Address Misconduct and Expect Accountability – ensure the NIH is issuing and implementing comprehensive policies and procedures that enable full and robust oversight of investigations into allegations of misconduct, including sexual harassment, in both intramural and extramural research programs, as well as ensuring NIH whistleblower protections, trainings, and processes are sound. This should include clear processes for accountability and responsibility for actions, including designating appropriate chains of command and facilitating accessible reporting mechanisms.
- Improve Transparency from Partners – consider additional disclosure reporting and transparency requirements for donors, partners, and activities supported by the *FNH*, including any conflicts of interest related to leadership, funding, or project determinations.¹⁶

Funding Reform: NIH Funding Mechanisms Must Be Clear, Responsible, and Reflective of Congressional Intent

Background

The NIH is currently the largest single public funder of biomedical research in the world, covering a wide range of basic, clinical, and translational research. More than 84 percent of its budget is dedicated to funding extramural research through grants, contracts, and other awards to more than 300,000 individuals at over 2,500 hospitals, medical schools, universities, and other research institutes in every state in America.¹⁷ Another 10 percent of the NIH’s budget goes to intramural research at NIH-operated facilities, most of which is conducted by the nearly 6,000 NIH physicians and scientists located on the NIH campus, in Bethesda, Maryland.¹⁸

While overall authority for the NIH—including explicit authorization of individual ICs—has lapsed at times, and is currently expired, the NIH continues to operate under the authority provided by Section 301 of the Public Health Service Act (PHSA) and receives funding through the annual appropriations process. Nearly all of the NIH’s funding comes from annual discretionary appropriations through the Departments of Labor, Health and Human Services, and Education, and Related Agencies (LHHS)

¹⁵ See also H.R. 7853, Royalty Transparency Act.

¹⁶ Congressional Research Service, “Agency-Related Nonprofit Research Foundations and Corporations,” 2022, *R46109*, <https://www.crs.gov/reports/pdf/R46109/R46109.pdf>.

¹⁷ Congressional Research Service, *R41705*.

¹⁸ Congressional Research Service, “National Institutes of Health (NIH) Funding: FY1996-FY2024,” *R43341*, 2023, <https://crsreports.congress.gov/product/pdf/R/R43341>.

Appropriations Act, with smaller amounts coming from the Superfund Research Program within the Interior, Environment, and Related Agencies Appropriations Act. The NIH additionally receives mandatory funding for type 1 diabetes research, as well as other funding due to unique transfer and budgetary rules and sources.

Table 4. NIH Funding, FY1996-FY2025 Request
Program Level Funding in Current and Constant (FY2023) Dollars (Billions)

Fiscal Year	Program Level Current \$	% Change	Program Level Projected Constant FY2023 \$	% Relative to FY2003
1996	11.928	5.6%	26.780	
1997	12.741	6.8%	27.832	
1998	13.675	7.3%	28.893	
1999	15.629	14.3%	32.009	
2000	17.841	14.1%	35.225	
2001	20.459	14.7%	39.094	
2002	23.321	14.0%	43.136	
2003	27.167	16.5%	48.542	
2004	28.037	3.2%	48.297	-0.5%
2005	28.594	2.0%	47.413	-2.3%
2006	28.560	-0.1%	45.262	-6.8%
2007	29.179	2.2%	44.551	-8.2%
2008	29.607	1.5%	43.184	-11.0%
2009	30.545	3.2%	43.285	-10.8%
2010	31.238	2.3%	42.960	-11.5%
2011	30.916	-1.0%	41.335	-14.8%
2012	30.861	-0.2%	40.739	-16.1%
2013	29.316	-5.0%	37.989	-21.7%
2014	30.143	2.8%	38.238	-21.2%
2015	30.311	0.6%	37.685	-22.4%
2016	32.311	6.6%	39.317	-19.0%
2017	34.301	6.2%	40.681	-16.2%
2018	37.311	8.8%	43.173	-11.1%
2019	39.313	5.4%	44.548	-8.2%
2020	41.690	6.0%	46.431	-4.4%
2021	42.941	3.0%	46.659	-3.9%
2022	46.183	7.5%	47.979	-1.2%
2023	49.178	6.5%	49.178	1.3%
2024	48.811	-0.7%	47.253	-2.7%
2025 Proposed	50.174	2.8%	47.282	-2.6%

One such funding source is the PHS Evaluation Set-Aside, or the “PHS Evaluation Tap,” authorized by Section 241 of the PHSA.¹⁹ This transfer authority was initially crafted to allow the Secretary of HHS, with the approval of Congress, to redistribute a portion of eligible PHS agency funding across HHS for the “evaluation (directly, or by grants or contracts) of the implementation and effectiveness of such programs.”²⁰ It has also been used widely to bolster a large variety of programs and activities. For instance, the Agency for Healthcare Research and Quality (ARQH)’s entire discretionary budget was funded primarily through tap transfers from FY2003 to FY2014.²¹ In addition, this authority was used in 2021 to divert more than \$2 billion towards the crisis at the southern border from funds designated under the American Rescue Plan for the Strategic National Stockpile, COVID-19 testing efforts, and other health programs.²² While the set-aside is statutorily limited to not less than 0.2 percent and not more than 1 percent of eligible program appropriations, since FY2010, appropriations bills have delineated a higher maximum set-aside level of 2.5 percent of eligible appropriations. The bills often also direct the specific amounts of tap funding to be transferred to selected accounts and activities, though do not specify which account is the source of the transfer. Thus, in theory, the NIH’s total budget, or “program level,” should incorporate all available funding sources, including those transferred both in and out, though often, these totals omit the amounts transferred out.

This transfer authority is utilized as a mechanism to redistribute appropriated funds among PHS agencies and other HHS agencies, with limited congressional oversight. Historically, the NIH, with the largest budget among the PHS agencies, was the largest net donor of tap funds, rather than a net recipient. This shifted beginning with the FY 2015 appropriations bill, which included specific language outlining concerns at the loss of NIH funds due to frequent utilization of the tap. In more recent years, this authority has been used to transfer funding to a smaller number of programs or activities within HHS agencies—primarily at the NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and HHS’s Office of the Secretary (OS), with the largest share of tap transfers now going to the NIH.²³ For FY2024, \$1.4 billion from the ICs was transferred to the National Institute of General Medical Sciences (NIGMS), utilizing this authority.²⁴

Another often discussed facet of NIH funding is the assessment and evaluation of indirect costs, also referenced as “facilities and administrative costs” or “(F&A) costs.” Indirect costs include overhead expenses of the institution where research is being conducted (i.e., rent, utilities, and building maintenance, operation, and depreciation), as well as general and administrative expenses (i.e., payroll and salaries, office equipment, accounting and personnel departmental administration, and student services).²⁵ Over the past several decades, research institutions and universities have become increasingly reliant on NIH funding, employing federal dollars for the hiring of researchers and construction of laboratory facilities. Currently, the rates are generally negotiated and established between the grantee institution and the funding agency. While there is no existing universal cap on

¹⁹ Public Health Service Act Sec. 241, 42 U.S. Code § 238j.

²⁰ Public Health Service Act Sec. 241, 42 U.S. Code § 238j.

²¹ Congressional Research Service, “Labor, Health and Human Services, and Education: FY2024 Appropriations,” 2024, R47936, <https://www.crs.gov/reports/pdf/R47936/R47936.pdf>.

²² Cancryn, Adam, “Biden admin reroutes billions in emergency stockpile, Covid funds to border crunch,” *Politico*, 2021, <https://www.politico.com/news/2021/05/15/hhs-covid-stockpile-money-border-migrants-488427>.

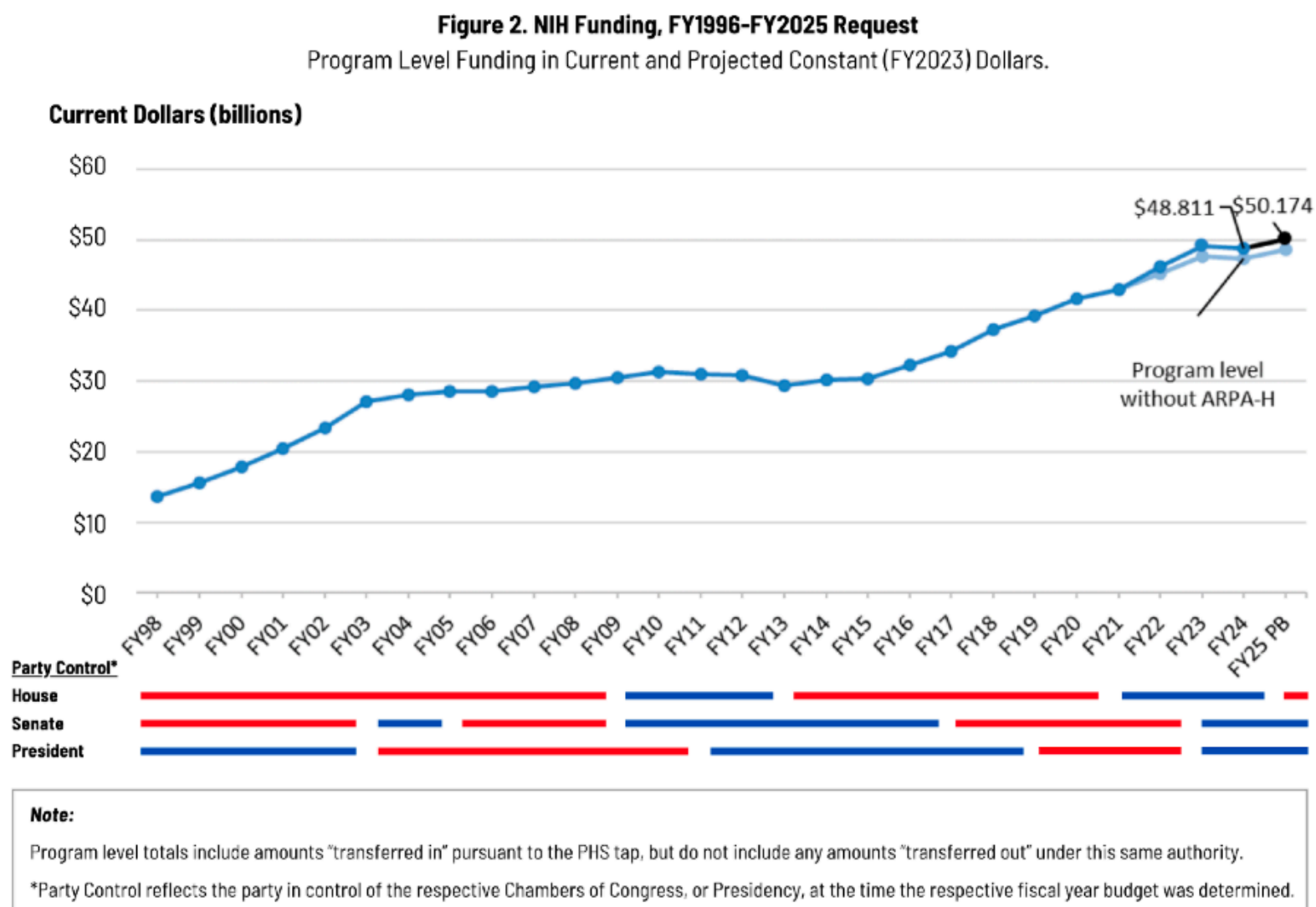
²³ Congressional Research Service, R47936.

²⁴ P.L. 118-47.

²⁵ NIH Office of Management, “Indirect Cost: Definition and Example,” *Division of Financial Advisory Services*, 2020, <https://oamp.od.nih.gov/division-of-financial-advisory-services/indirect-cost-branch/indirect-cost-submission/indirect-cost-definition-and-example>.

indirect cost rates, both the NIH and Congress have set policies capping rates as low as 8 percent in the past.²⁶ It is common for private and nonprofit foundations that fund academic research to also set a maximum indirect cost rate.

Over the past few decades, the NIH has experienced periods of high and low funding growth. Historically, Congress has not specified NIH funding for particular diseases or areas of research, instead allowing the ICs to award funding within their specific mission areas and based on their specific strategic planning and priorities, often using a two-tiered system of peer review. However, in recent years, Congress and the executive branch have both taken on a more direct role by designating funding for specific programs and research areas within specific ICs.



Due to escalating budgetary restraints, increasing demands for funding transparency, and recent accounts of waste, fraud, and abuse, it is imperative the NIH focus on building efficiencies and accountability in its funding mechanisms to ensure federal taxpayer dollars are targeted towards supporting the highest priority research impacting our nation's health.

²⁶ Noll, Roger G. and Rogerson, William P., "The Economics of University Indirect Cost Reimbursement in Federal Research Grants", 1998, *Stanford University Department of Economics WP 97-039*, Available at SSRN: <https://ssrn.com/abstract=78786> or <http://dx.doi.org/10.2139/ssrn.78786>.

Recommendations

- **Restore Congress's Role in Directing Funding** – repeal authorization for the Public Health Service (PHS) Evaluation Set-Aside, also known as the “PHS Evaluation Tap,” under Section 241 of the Public Health Service Act to ensure transparency and accountability in funding decisions.
- **Reexamine Indirect Costs** – consider alternative mechanisms to limit indirect, or F&A, costs, such as tying the indirect cost rate to a specific percentage of the total grant award,²⁷ either universally or for certain designated entities; capping indirect costs at a graduated rate dependent on a recipient's overall NIH funding; or providing incentives or preferences to recipients with established and proven lower indirect costs.
- **Demand Transparency on Indirect Costs** – require any entity receiving grants or awards to report publicly and make searchable their indirect F&A costs, including fixed capital costs, administrative overhead, and labor costs.²⁸
- **Prevent Waste and Fraud** – ensure the NIH is properly accounting for and recovering misused taxpayer dollars.²⁹

Grant Reform: NIH Grant Research Must Protect Against National Security Risks and Threats, and be Independent, Innovative, Responsive, and Transparent

Background

Funding for research project grants and contracts comprise the majority of NIH spending. NIH research projects support the “full continuum” of biomedical and behavioral research, spanning from basic investigations, to translational research, to clinical and community practice. Research projects are largely investigator-initiated and are awarded on a competitive basis as part of a two-tiered system of peer review. The current process has faced criticism for being overly burdensome and biased against innovative, though potentially riskier, proposals. As recipients of taxpayer funding, the research is expected to produce tangible results, which are often more readily achieved through incremental advancements on proven ideas, as opposed to groundbreaking scientific discoveries. This dichotomy often lends itself to grant recipients being more well established, usually at later stages in their careers, with a demonstrated record of success. It is estimated that around 17.5 percent of all grant applications will be funded in FY2024.³⁰

²⁷ See also proposal included in Office of Management and Budget, “Major Savings and Reforms, Budget of the U.S. Government, Fiscal Year 2018,” <https://www.govinfo.gov/content/pkg/BUDGET-2018-MSV/pdf/BUDGET-2018-MSV.pdf>.

²⁸ See also current statutory requirement for ARPA-H grant and cooperative agreement recipients under PHSA Sec. 499A (g)(A).

²⁹ Committee on Energy and Commerce Majority, “E&C Republicans to NIH: Is Agency Recovering All Misused Taxpayer Dollars?”, *Press Release*, 2024, <https://energycommerce.house.gov/posts/e-and-c-republicans-to-nih-is-agency-recovering-all-misused-taxpayer-dollars>.

³⁰ National Institutes of Health, “Overview of FY 2025 President's Budget,” 2024, <https://officeofbudget.od.nih.gov/pdfs/FY25/br/Overview%20of%20FY%202025%20Presidents%20Budget.pdf>.

There has also been historic tension around various funding decisions, how to make these decisions, who should be making them, and what metrics should be utilized during the decision-making process. For example, whether to designate funding for specific diseases and research areas or allow for more flexibility in the peer review process; how to balance proposals related to basic scientific research versus applied research, as well as proposals to support the most pervasive diseases and conditions versus rare diseases; and how to allocate funding among established and successful scientists while enabling new scientists to enter the field.

Recently, there have been several instances of missteps in the NIH's grant review and prioritization processes that have prevented successful research outcomes. For instance, the NIH's RECOVER Initiative, which launched in 2020 with a \$1 billion-plus budget, continues to face criticism from patient advocates, researchers, and lawmakers.³¹ The original goal of the initiative was to understand Long COVID causes, symptoms, and the long-term impact; define the risk factors and impacted populations; and identify possible treatments. However, there have been clear and avoidable mistakes, including initial mistakes to hire scientists more focused on a "big data" approach over experts in post-acute infection syndromes, as well as a misguided focus on observational studies, as opposed to clinical trials focused on identifying tangible treatments. As discussed above, RECOVER also suffered from the longstanding institutional pattern of awarding funding to researchers and institutions with prior established records and funding histories with the NIH, possibly to the detriment of researchers specialized in this space, but who were at an earlier stage in their career. In addition, the number of retractions occurring in academic publishing is rapidly increasing. More than 10,000 scientific papers—a new record—were retracted in 2023.³² As recently as June 2024, a landmark article published on Alzheimer's disease research from 2006 was retracted³³ after a news investigation revealed allegations of manipulated data and images in 2022.³⁴ The Alzheimer's study was supported by multiple NIH grants and has been cited nearly 2500 times over the years, likely leading to millions in wasted and misspent taxpayer funding and related research.

There has also been increased concern about the NIH's approval, management, and oversight of "gain-of-function" and dual-use research, particularly research that involves pathogens with enhanced pandemic potential. Gain-of-function (GOF) research is used as a broad term to encompass scientific inquiries where an organism gains a new property, or an existing property is altered.³⁵ This includes both naturally occurring and experimentally induced changes in organisms to better understand the transmission, infection, and pathogenesis of viruses.³⁶ A subset of GOF research, sometimes called gain-of-function research of concern (GOFROC), often involve "experiments that enhance a pathogen's transmissibility or

³¹ Ladyzhets, Betsy, "NIH documents show how \$1.6 billion long Covid initiative has failed so far to meet its goals," STAT News, 2024, <https://www.statnews.com/2024/05/31/long-covid-nih-recover-initiative-falls-short-on-causes-treatments/>.

³² Noorden, Richard V., "More than 10,000 research papers were retracted in 2023 — a new record," *Nature*, 2023, <https://www.nature.com/articles/d41586-023-03974-8>.

³³ Piller, Charles, "Researchers plan to retract landmark Alzheimer's paper containing doctored images," *Science*, 2024, https://www.science.org/content/article/researchers-plan-retract-landmark-alzheimers-paper-containing-doctored-images?utm_source=substack&utm_medium=email.

³⁴ Piller, Charles, "Blots on a Field: A neuroscience image sleuth finds signs of fabrication in scores of Alzheimer's articles, threatening a reigning theory of the disease," *Science*, 2022, https://www.science.org/content/article/potential-fabrication-research-images-threatens-key-theory-alzheimers-disease?utm_source=substack&utm_medium=email.

³⁵ Kuiken, Todd, "Global Pandemics: Gain-of-Function Research of Concern", *Congressional Research Service*, IF12021, 2022, <https://crsreports.congress.gov/product/pdf/IF/IF12021>.

³⁶ *Id.*

virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security”.³⁷ There have been longstanding concerns that such research and experiments may have the potential to generate pathogens with enhanced pandemic potential (PEPP).³⁸ Such scrutiny has increased since the emergence of the COVID-19 pandemic. Another area of NIH funded research that has faced increased attention is dual use research of concern (DURC). This research is defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”³⁹

The scientific value of such research and how best to safeguard against accidents and deliberate misuse remains an area of active debate. Historically, there has been tension between those in the scientific community who argue GOFROC/DURC is necessary to understand how viruses evolve to be better prepared for new, emerging pathogens, and those who believe the risk of a breach of containment, accident, or deliberate misuse of this research outweighs any speculative benefits. Such concerns led the Obama administration to pause federal funding for certain experiments involving MERS, SARS, and influenza from 2014 to 2017.^{40,41}

Energy and Commerce Committee investigations have revealed the NIH’s inadequate oversight of biomedical taxpayer funded research of risky GOFROC/DURC experiments involving potentially dangerous pathogens.⁴² Ongoing congressional investigations into risky mpox research at the NIH⁴³ and the mismanagement of the EcoHealth Alliance (EcoHealth) grant⁴⁴ have highlighted weaknesses and failures in how NIAID—the NIH Institute that funds and conducts a majority of GOFROC/DURC—reviews

³⁷ See The White House Office of Science and Technology Policy, *U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, Section 3.J (May 6, 2024), <https://www.whitehouse.gov/ostp/news-updates/2024/05/06/united-states-government-policy-for-oversight-of-dual-use-research-of-concern-and-pathogens-with-enhanced-pandemic-potential/>.

³⁸ Kuiken, IF12021.

³⁹ National Institutes of Health, Office of Intramural Research, Dual-Use Research, <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research>.

⁴⁰ National Institutes of Health, “U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses,” *Gain of Function Research*, 2014, <https://osp.od.nih.gov/policies/national-science-advisory-board-for-biosecurity-nsabb/gain-of-function-research/>.

⁴¹ See also The White House of President Barack Obama, “Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research,” *Archives, Blog*, 2014, <https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>.

⁴² Committee on Energy and Commerce Majority, “Chair Rodgers Statement on Gain of Function Research Oversight Policy Update,” *Press Release*, 2024, <https://energycommerce.house.gov/posts/chair-rodgers-statement-on-gain-of-function-research-oversight-policy-update>.

⁴³ Committee on Energy and Commerce Majority, “E&C Republicans Release Interim Staff Report on NIH Misconduct and Inadequate Oversight Involving Taxpayer-Funded Risky MPXV Research that Jeopardizes Public Health Security,” *Press Release*, 2024, <https://energycommerce.house.gov/posts/e-and-c-republicans-release-interim-staff-report-on-nih-misconduct-and-inadequate-oversight-involving-taxpayer-funded-risky-mpxv-research-that-jeopardizes-public-health-security>.

⁴⁴ Committee on Energy and Commerce Majority, “The COVID-19 Origins Investigation: Timeline of Investigation,” *Press Release*, 2024, <https://energycommerce.house.gov/the-covid-19-origins-investigation>.

proposals and conducts oversight of such experiments. NIAID does not have an adequate process in place to weigh the risks and benefits of such research. Moreover, these investigations have identified potential conflicts of interest and misaligned incentives that result in NIAID approving experiments with little debate and no outside, independent oversight.⁴⁵

For several years, Energy and Commerce Committee Republicans have raised concerns about the management of the EcoHealth grant and, specifically, its subaward to the Wuhan Institute of Virology (WIV).⁴⁶ Both EcoHealth and the WIV repeatedly failed to comply with grant requirements and policies, including inadequate accountability for risky experiments at the WIV and subsequent failed responsibilities by EcoHealth to oversee such WIV experiments. These failures were later confirmed by the HHS Office of Inspector General, the Government Accountability Office (GAO), and HHS itself in its actions to suspend and debar EcoHealth, the WIV, and EcoHealth's principal investigator, Peter Daszak.⁴⁷

The Committee is also investigating laboratory safety and accountability for risky research at the NIH, including experiments involving coronaviruses and influenza. This investigation was originally initiated in May 2023,⁴⁸ yet the NIH has been slow and unresponsive to requests for information, refusing to engage or provide even basic information about how risky research proposals are overseen, managed, and adequately safeguarded.

The COVID-19 pandemic also brought attention to the escalating threat of undue and inappropriate foreign influences, as well as direct interference, within U.S. federally funded research. Such threats could manifest through an individual researcher's personal conflict of interest, direct research support or other benefits, outside professional appointments, or prior work experience and relationships. Recent reporting has indicated the NIH may have over 250 instances of potentially problematic research collaborations with Russian entities.⁴⁹ In addition, after recent reports tied NIH funding to research projects using unethically obtained data from minority populations in China, as well as projects linked to the Chinese military and other Chinese research entities, Energy and Commerce Committee Republican leaders wrote to the U.S. Comptroller General, requesting a detailed report regarding the extent to which the NIH adequately safeguards research funds from national security concerns related to China.⁵⁰ Notably, other countries—particularly China—have recently and increasingly bolstered funding and technical assistance in the biomedical research space.

⁴⁵ Congressional Research Service, "Oversight of Gain of Function Research with Pathogens: Issues for Congress," 2022, *R47114*, <https://crsreports.congress.gov/product/pdf/R/R47114>.

⁴⁶ Committee on Energy and Commerce Majority, *The COVID-19 Origins Investigation*.

⁴⁷ See also U.S. HHS Office of Inspector General, A-05-21-00025, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies* (2023); U.S. Gov't Accountability Office, GAO-23-106119, *NIH Could Take Additional Actions to Manage Risks Involving Foreign Subrecipients* (2023).

⁴⁸ Committee on Energy and Commerce Majority, *E&C Republicans Seek Details on Coronavirus Research After NIH Dodges Question About Risky Activities*, Press Release, May 1, 2023, <https://energycommerce.house.gov/posts/e-and-c-republicans-seek-details-on-coronavirus-research-after-nih-dodges-question-about-risky-activities>.

⁴⁹ Data Abyss, *US Funded Russian Research Tracker*, <https://www.dataabyss.ai/platform-resources/us-fed-funded-russian-research-tracker>.

⁵⁰ Committee on Energy and Commerce Majority, *E&C Republicans Ask Government Watchdog to Study Threat of China Exploiting NIH Research for Military Advantage and Unethical Use*, Press Release, 2024, <https://energycommerce.house.gov/posts/e-and-c-republicans-ask-government-watchdog-to-study-threat-of-china-exploiting-nih-research-for-military-advantage-and-unethical-use>.

Instances of research misconduct, including noncompliance and misuse of grant funds, as well as undue and inappropriate foreign influence and interference, have the potential to seriously distort already strained funding decisions and impact the ability of NIH to recover diverted taxpayer dollars. In addition, NIH's failure to appropriately respond or acknowledge such misconduct diminishes the integrity of research the NIH supports and can devastate the public's trust in basic science and the resulting outcomes.

Recommendations

- **Grant Recipients Must Remain Dynamic** – focus on providing grants and awards only to primary investigators that do not have more than three ongoing concurrent NIH engagements.⁵¹
- **Research Must Be Credible, Reliable, and Timely** – consider opportunities to continue to bolster and support early-stage investigators; encourage systematic replication studies across research portfolios and fields; and prevent research and data waste, fraud, and misconduct.
- **Continue Prohibition of Risky Gain-of-Function Research** – prohibit the NIH from conducting or supporting certain risky gain-of-function research occurring in countries that have been designated as foreign adversaries,⁵² and pause any such gain-of-function research of concern until a thorough, comprehensive policy with appropriate guardrails to monitor research that has the potential to pose risks to public health and national security is enacted.⁵³
- **Establish Independent Review Entity for the Proposed National Institute on Infectious Diseases** – remove final review and approval authorities for certain risky gain-of-function research proposals from the proposed National Institute on Infectious Diseases,⁵⁴ and empower a public, independent oversight entity to review, modify, approve or reject as appropriate, and oversee such research and experiments.⁵⁵
- **Demand Accountability from Grantees** – ensure primary grantees are complying with all requirements, including written attestations, to share and provide access to all relevant and supporting information and documentation related to research being conducted by any foreign subgrantee.⁵⁶
- **Support Independent Community Review Oversight Boards** – require grant recipients conducting research involving potentially dangerous agents to establish community oversight boards to review and approve protocols, ensure proper compliance with regulations and guidelines

⁵¹ See also current statutory requirement for ARPA-H Director when prioritizing and awarding grants under PHSA Sec. 499A (n)(1)(D).

⁵² 15 CFR 7.4.

⁵³ See also H.R. 1827, Pausing Enhanced Pandemic Pathogen Research Act of 2023.

⁵⁴ See Table 2, *Proposed NIH Institutes and Centers*.

⁵⁵ See also Select Subcommittee on the Coronavirus Pandemic, Committee on Oversight and Accountability, "An Evaluation of the Evidence Surrounding EcoHealth Alliance, Inc.'s Research Activities," *Interim Staff Report*, 2024, Recommendation II, 1, https://oversight.house.gov/wp-content/uploads/2024/04/2024.05.01-SSCP-Report_FINAL.pdf?source=email.

⁵⁶ See also H.R. 8703, Foreign Research Transparency Act of 2024.

impacting the surrounding community, and create processes for regular community access to information.

- Mandate Foreign Grant Reporting – require each IC to report and publicly post on the IC’s website any grant or subgrant occurring in any foreign country.
- Incorporate a National Security Review – incorporate a specific national security or intelligence community review into the grant and award process for grants that involve research occurring by, or on behalf of, entities or actors that have been designated as foreign adversaries.^{57,58}
- Prevent Conflicts of Interest – ensure the NIH is appropriately updating, communicating, and implementing conflict of interest policies and requiring the disclosure of information that may indicate potential conflicts, including research support and non-financial conflicts of interest involving foreign activities and resources.⁵⁹
- Empower Agencies to Suspend Grants – provide the HHS Secretary, in consultation with the Office of the Director of National Intelligence, permanent authority to immediately suspend, pending investigation, a grant determined to be a threat to national security.⁶⁰
- Ensure Appropriate Oversight of Animal Research – require ethical and judicious standards of care, including appropriate transparency measures, for research involving animals both domestically and abroad.

⁵⁷ 15 CFR 7.4.

⁵⁸ See also Select Subcommittee on the Coronavirus Pandemic, Committee on Oversight and Accountability, “An Evaluation of the Evidence Surrounding EcoHealth Alliance, Inc.’s Research Activities,” *Interim Staff Report*, 2024, Recommendation II, 8, https://oversight.house.gov/wp-content/uploads/2024/04/2024.05.01-SSCP-Report_FINAL.pdf?source=email.

⁵⁹ See also U.S. Government Accountability Office, “NIH Should Take Further Action to Address Foreign Influence,” 2021, *GAO 21-523T*, <https://www.gao.gov/products/gao-21-523t>.

⁶⁰ See also Select Subcommittee on the Coronavirus Pandemic, Committee on Oversight and Accountability, “An Evaluation of the Evidence Surrounding EcoHealth Alliance, Inc.’s Research Activities,” *Interim Staff Report*, 2024, Recommendation II, 7, https://oversight.house.gov/wp-content/uploads/2024/04/2024.05.01-SSCP-Report_FINAL.pdf?source=email.

CONCLUSION & NEXT STEPS

The federal government has a key role to play in supporting basic research, particularly in instances where the return on investment is too distant, or uncertain for initial private sector involvement. Such research has the power to unlock and unleash American private sector innovation to improve the lives of all Americans, especially those living in hope of a cure, treatment, or medical breakthrough—giving them the ability to live their lives to the fullest potential and maximize time with loved ones.

Reform is long overdue. The NIH needs to regain the public's trust by showing it can be transparent, accountable, and responsive, proving it is worthy of public and Congressional support, before it can reestablish itself as the nation's preeminent medical research institute. In light of the lessons learned during and since the COVID-19 pandemic, a renewed focus on tightening federal budgets, and threats of rising foreign influence on our biomedical research enterprise, we must have a reset. We must take action to ensure America remains at the forefront of innovation for our future generations.

The time is NOW to build a stronger NIH for the FUTURE.

The ideas and challenges presented in this framework are intended as a starting point and foundation to foster further discussion to keep America at the forefront of biomedical innovation. Please submit any feedback and additional thoughts, ideas, and suggestions for reform, in writing, to NIHReform@mail.house.gov by August 16, 2024. The Committee looks forward to working with interested stakeholders as we identify opportunities for reform NOW to build a stronger NIH for the FUTURE.