



# Beyond 2020: A Vision and Pathway for NIH



Recommendations for  
a Healthier Future

November 2020



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# Beyond 2020: **A Vision and Pathway for NIH**

Recommendations for  
a Healthier Future

Report Brief  
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# Preface

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We are pleased to convey this report, *Beyond 2020: A Vision and Pathway for NIH*, which presents recommendations for your administration that would further enhance the world's premier biomedical research and health agency, the National Institutes of Health (NIH), by better aligning its organization and policies with present and future strategies for achieving the highest impact in research and training, and for improving health and combatting disease.

The report was created by an august *ad hoc* working group, some with direct experience as director of the agency or an institute within it, many with distinguished and revered research achievements underwritten in part by NIH grants and training mechanisms, and all with deep insight borne of years, often decades, of service as volunteers to enable and advance NIH activities and governance, and as leaders of research institutions or policy/advocacy organizations. Collectively, the group recognizes the challenges and opportunities of a remarkably dynamic research and health enterprise that has produced stunning advances, while at the same time appreciating the ways that large bureaucracies can both enable and inhibit progress.

Of course, NIH itself resides within the massive superstructure that is the federal government. In addition to the important responsibility of the President to appoint the NIH Director, myriad federal regulations and policies far outside of NIH's immediate domain affect the effectiveness and efficiency of the agency, its capacity to achieve its mission, and the role and influence of science in general in government and society. The group provides some examples of existing policies that should be revisited and reconsidered by your administration, where you could rapidly effect change that will positively impact NIH.

Achieving the vision and pathway envisioned here will require wise and bold leadership from a Director determined to alter certain policies and practices extending across the spectrum of NIH activity, from research to training, from intramural to extramural programs, all of them dependent upon the organization and administration of the agency itself. The group frames the characteristics of such a leader and proposes an approach to identifying that individual. Indeed, the group readily identified numerous individuals within the community who could lead NIH with distinction, and urges the President to place special consideration on selecting a woman and/or an underrepresented-minority candidate from among the outstanding candidates.

While the matters highlighted in this report are not intended to be all inclusive, addressing them would have broad impact. The great majority of the group's recommendations are actionable without substantial new costs; indeed, some could reduce costs, while markedly enriching public benefit and addressing national priorities.



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# Executive Summary

## Beyond 2020: A Vision and Pathway for NIH Recommendations for a Healthier Future



**If you think research is expensive, try disease”**

*-Philanthropist and Advocate Mary Lasker (1984)*

**A 2020 version: “If you think science preparedness  
is expensive, try a pandemic.”**

In a report requested by President Franklin D. Roosevelt, Vannevar Bush wrote: “The pioneer spirit is still vigorous within this nation. Science offers a largely unexplored hinterland for the pioneer who has the tools for his task. The rewards of such exploration both for the Nation and the individual are great. Scientific progress is one essential key to our security as a nation, to our better health, to more jobs, to a higher standard of living, and to our cultural progress.”

This statement is as true today as it was in 1945. The Vannevar Bush report led to an unprecedented federal commitment to fundamental biomedical research. The experience of the past 75 years strongly confirms Bush’s prediction that basic research leads to improved health for Americans, economic growth, and preeminence on the international stage. The NIH has made the U.S. the world leader in biomedical research and a magnet for global scientific talent that has strengthened our universities and industries, the engines of discovery, innovation, and development. [See Box, *Guiding Principles*]

To sustain and strengthen our leadership, to continue our advances in understanding, preventing, treating, and curing human diseases, and to address immediate and future health threats, the NIH must adopt bold new approaches to training and supporting a research community that has been transformed by 75 years of changes in technology and society.

## Guiding Principles

The most effective ecosystem to advance discovery and accelerate the translation of new knowledge into benefits for human health embraces the following principles:

1. Fundamental discovery – Transformational advances in human health arise from basic studies of biological processes undertaken without knowing the future utility of this research.
2. Risk-taking - Making breakthrough discoveries and transformative advances require that scientists and funders be willing to take calculated risks and be tolerant of failure.
3. Open science – Science progresses fastest when data and publications are openly shared among scientists and with the public.
4. Integrity and Accountability – The ethical, responsible conduct of science is required to build public trust and to respond to societal concerns.
5. Diversity and Inclusion – Scientists with different perspectives and life experiences broaden the questions being explored and improve team decision-making, as well as the potential impact.
6. Global collaboration - The complexity of science requires bringing together expertise from different disciplines, both within our country and across national borders.
7. Sustainability – Ongoing, stable funding is essential for longterm planning, bold initiatives, infrastructure needs and workforce development.

The advent of fast communication has enormously facilitated collaboration. Computing power and access to big data and large banks of biological samples have made new areas of inquiry possible. Advances in genetics have opened previously unimaginable new avenues of research and novel medical interventions. Biomedical discoveries are increasingly powered by intersecting approaches from physics, chemistry, computer science and engineering, and they are accelerated by a highly networked and interdisciplinary research culture.

The challenge of responding to SARS-CoV-2 has led to unprecedented levels of cooperation and communication among scientists, and across sectors of industry, academia, philanthropy and government. The result is better science working toward vaccines and treatments

at an unprecedented pace. We have also seen unprecedented political pressure and interference, which threatens to undermine the credibility and capabilities of the scientific enterprise, and hampers the ability to effectively develop and deliver safe and effective means to control disease. We must learn from this experience to safeguard, strengthen, and speed medical progress, and ensure evidence-based decision-making for challenges of emerging infectious agents, cancer, cardiovascular disease, mental illness, Alzheimer disease and more.

Only the federal government can simultaneously motivate, organize, manage, and fund the actions needed. This means ending “boom & bust” and “just in time” attention to science. It is time to support NIH and other public health agencies at levels that empowers them to deliver on scientific potential and public expectations. It means taking deliberate measures to unleash more creative power; enable risk-taking; diversify the scientific workforce; promote equity in research and health care; and commit to improving lives everywhere. And it requires strong and principled leadership.

To maintain preeminence in biomedical science in the 21st century, and to ensure that Americans continue to receive exceptional benefits from their longstanding support of science, this report presents a vision for research and health, looking forward from the remarkable past and current achievements of NIH, and a pathway to achieving that vision. The vision and pathway compel certain changes in policies and practices across three components of NIH activity: its research enterprise, its training mandate, and its overall administration and operations.

Our recommendations, summarized below and detailed in the body of the report, frame immediate actions by the President in the first 100 days (see Box), and subsequently by the Administration, particularly the NIH Director, that would enhance the impact of NIH research and the development of the research community. They tap core strengths of NIH and our nation: creativity, innovation, and resilience. They invest in our most important natural resource: our people and their talent.

The goals set out here are ambitious and will be transformational for the biomedical research enterprise, and their realization will be transformative for the health of the nation. We can meet the moment of today's challenges and we can ensure a science-strong future. When science thrives, the public will receive a many-fold return on its investment, in the form of prosperity, security and better health.

## Presidential Action for First 100 Days

There are several visible and high-impact opportunities for the Administration in its first 100 days to drive progress and build upon NIH's successes through transformative policymaking:

1. Appoint a NIH Director who will provide leadership and action on the goals and approaches set forth herein.
2. Review current Executive Orders, regulations and policies, and repeal, reverse, or modify those that appear detrimental to scientific progress, credibility, integrity, innovation, and productive collaboration. *(see examples, Appendix A.)*
3. Ensure that emergency supplementary funding provided by Congress supports recovery from the extended shut-down of all non-pandemic-related biomedical research and training.
4. Increase the Common Fund appropriation to 5% of the NIH research budget with a mandate to motivate and enable multi-institute and trans-NIH research programs.
5. Mandate submission, from NIH to Congress, of annual, rolling, five-year budget forecasts to provide appropriators with clear perspective on prospective gains from sustained funding.
6. Establish and convene a Strength in Science Task Force, comprising stakeholders from government, industry, academia, philanthropy and the public/patient community, charged with identifying initiatives that ensure continued U.S. success and preeminence in biomedical research and innovation.

## 1. Research

- An NIH that focuses on its most important job - supporting fundamental discovery.
  - Ensure that the NIH research portfolio prioritizes funding fundamental investigation.
  - Develop mechanisms and policies that require, within three years, that biomedical data are findable, accessible, interoperable and reusable (FAIR). <https://www.nature.com/articles/sdata201618><sup>1</sup>
  - Require that targeted projects or areas of emphasis originating in particular NIH Institutes or Centers are developed and evaluated by ad hoc external working groups.
- Grant mechanisms that motivate and support scientific creativity, innovation and diversity, and share salary support for principal investigators jointly with awardee institutions.

- Pilot grant mechanisms that emphasize novel ideas and concepts, and seek highly creative scientists; adopt those deemed successful.
- Evaluate the consequences of requiring that principal investigators who draw salary support from NIH should receive part of their salary from their employing institutions.
- Peer-review processes that identify and reward bold ideas, creative risk, innovation and foundational approaches.
  - Limit study section meetings to chartered members, selected as highly respected generalists in each designated area of study.
  - Ad hoc reviewers should provide requested technical expertise by email, and should not participate directly in study section meetings.
  - Grant applications should more commonly be assigned to study sections across disciplinary, organ or disease boundaries.
- Interagency and industrial partnerships that fund data science and platform technology development.
  - Partner with other federal agencies to fund development of complex technologies that benefit biomedical research.
  - Review and enhance interactions between NIH-funded academic research and R&D programs in industry.

## **2. Training and Workforce**

- A diverse biomedical workforce that enables science and society to meet existential challenges of the 21st Century.
  - Establish a comprehensive strategy to expand the participation of under-represented groups in biomedical sciences at every career stage.
- Scientists and physician researchers who are trained and prepared to lead 21st century science.
  - Establish a closed-end grant mechanism to invite new graduate education strategies that promote team research, quantitative analysis, and open, responsible science.
- Graduate and postdoctoral trainees who are supported predominantly by individual fellowships and training grants.
  - Shift the funding for trainees from individual research awards to individual trainee fellowships and training grants.

- PhD scientists that assume expanded roles in academic research, and in the general workforce.
  - Provide career exploration tools to all trainees, adopting or adapting elements of the Broadening Experiences in Scientific Training (BEST) programs.
  - Establish a Scientific Director career track for highly trained and well compensated experts who manage technology platforms.
  - Develop a Lab Research Scientist career track for those who help lead research, training and communication of discoveries in departments or individual labs.
  - Consider funding, together with the private sector, Master's programs that effectively prepare trainees who are committed to careers in industry.
- An NIH-trained workforce that is fluent in the public context of science.
  - Require training in the public context of science, so trainees understand and can effectively communicate the significance and importance of science.

### **3. Administration, Operations, and Policy**

- An agency that is optimally organized and functioning to align with, inspire, and better enable the best 21st Century biomedical research.
  - Engage the Strategic Management Review Board of the agency to perform its mandated assessment of the NIH organizational structure.
  - Build upon the success of inter-institute collaborative programs.
- NIH Administrative policies that ensure a diverse, equitable, and inclusive scientific workforce trained for 21st Century biomedical research.
  - Evaluate existing diversity and inclusion programs and establish explicit quantitative metrics to enable assessment of progress
  - Collect data and examine the impact of COVID-19 on the productivity, satisfaction, and retention of scientists, particularly under-represented minorities and women in biomedicine.
  - Establish a comprehensive talent management and tracking system for all scientists, including those under-represented.
  - The NIH Director should promote necessary changes in diversity, equity, and inclusion policies across all agencies of the government.



- Scientists who are liberated from undue administrative burden.
  - Measure, manage and limit administrative burden to a “not to exceed” cap.
  - Harmonize Institutes and Centers-specific grant mechanisms, adopting standardized applications, funding policies and guidelines across the Institutes.
  - Adjust grant mechanisms with fixed budgets for inflation every three years.
  - Evaluate justification and the impact of unfunded mandates on grantees and institutions; develop infrastructure and platforms necessary for those justified.
  - Build on PubMed and PubMed Central to support a publishing environment that disseminates NIH research outputs more swiftly and openly.
  
- An Intramural Research Program that is an incubator of talent and breakthrough research.
  - Reconfigure the IRP as an incubator for exceptional early stage investigators.
  - Revise personnel, travel and contracting policies to align with research universities and medical schools, and provide compensation parity with academic institutions.
  
- NIH Clinical Center that operates at its full potential as a unique national resource.
  - Establish a new governance structure advised by external experts in administration of clinical research and delivery.
  - Evaluate and change the clinical center's funding model to reflect its unique status as a national clinical research resource.
  - Improve recruitment of clinical scientists; offer loan repayments and other incentives including grants for re-entry into the extramural community.
  - Increase clinical activity by partnering with area academic health centers and promoting intramural and extramural collaborations.
  
- Partnerships and collaborative programs that accelerate development of complex enabling technologies, diagnostics, therapeutics and preventions.
  - Negotiate shared programs with other federal agencies and industry to accelerate establishment of emerging technologies critical for biomedical research.

- Evaluate and promote new models of technology transfer mechanisms.
- Expand SBIR/STTR program to provide pre-company pre-clinical support that could enable NIH investigators to navigate the Valley of Death.

#### **4. Appointment of the NIH Director**

In accord with historical tradition and good institutional practice, we urge the Administration to initiate a systematic search for a highly qualified NIH Director as early as possible following the election, recognizing the essential role of the director in motivating the recommended pathways above, and the complexities of identifying and appointing the best possible person. We suggest that the Administration assess the views of its NIH Director candidates on the matters and issues that are the basis of the recommendations presented here, describe characteristics and qualities embodied in such individuals, and offer examples of topics and questions that might inform a search committee.

#### **5. Why It Matters**

Now is the time to act decisively to lay the groundwork for an NIH that serves the US public and US national interests, in crisis or stability, over the coming decades. To prepare for future health needs, known and unknown, NIH must be primed for future success. Biomedical research is changing profoundly, and NIH must optimize accordingly its policies and practices for incentivizing and supporting the best research and training. The COVID-19 pandemic has highlighted health disparities, and the social justice movement has underscored the lack of diversity in the scientific and healthcare workforce and research agendas, providing additional momentum and urgency for change.

##### ***A look to the future***

If NIH adopts this vision, a bold, risk-tolerant, open, diverse, inclusive and collaborative research ecosystem will emerge that broadens and strengthens the scientific community, accelerates scientific discovery, defines biological processes in sufficient detail to understand, prevent, treat and cure disease, and improves the health and well-being of all of us.

# 1. Research: Driving Innovation and Discovery

**“Progress in the war against disease results from discoveries in remote and unexpected fields of medicine and the underlying sciences.”**  
-Vannevar Bush, *Science the Endless Frontier* (July 1945)

*The NIH's greatest success has been, and should continue to be, unleashing the power of fundamental discovery science in the USA.*

*To do so, the NIH should streamline its grant mechanisms and peer review system, making them more responsive to those with the most creative and bold ideas, drawn from a broad and diverse spectrum of scientists.*

## **Vision 1.1. An NIH that focuses on its most important job-supporting fundamental discovery.**

Prevention and cure of disease are some of the most significant products of scientific advances, as Vannevar Bush noted in his 1945 report requested by President Franklin D. Roosevelt. At the time, Dr. Bush focused on the discovery of penicillin and its importance in saving the lives of many American servicemen in World War II. Today the coronavirus pandemic carries symbolic significance similar to that of wound infections in WW II. While we have not yet solved the pandemic, it will eventually be overcome by basic research, i.e., fundamental scientific discoveries concerning the structure and genetics of viruses and their cellular receptors and the nature of the immune response, as well as technological innovations to detect, generate, and modify genes or their expression. Clinical progress with COVID-19 will emerge from advances in areas seemingly unconnected, and not targeted to any disease or practical therapy, but rather to understanding fundamental biology.

One unanticipated outcome of the pandemic has been the remarkable pivot of newly assembled teams of researchers to studies relevant to COVID-19 and the SARS CoV-2 virus. This was

followed by an unprecedented volume and rate of release of research findings, which in turn enabled other research teams to make and report follow-on discoveries. This was a dramatic demonstration of internet-driven acceleration of scientific discovery. By removing the constraints of a publishing system that was designed for print distribution, open digital sharing of scientific data and knowledge invites investigators globally to contribute to complex, difficult research problems. NIH should further advance policies and infrastructure that support open digital sharing of scientific data and knowledge in a manner that maximizes subsequent use and new knowledge generation.

The systematic generation of a novel therapeutic becomes a reality only when scientists uncover the molecular basis of health and disease. The precise nature of the relevant science cannot be anticipated ahead of time and thus the path from biological discovery to novel drug or diagnostic is typically indirect, and can take decades to be realized. For example, the discovery of genes that drive development of a fruit fly and a nematode worm ultimately led to new drugs for the treatment of cancer.

The opportunities to understand the fundamental molecular pathways of the human body in health and disease have never been greater. The traditional approach of relying on a carefully honed hypothesis is now complemented by tools that empower exploratory programs, such as unbiased whole genome screens, that can interrogate the role of all genes, not just a few specific candidates, in a biological process. Today, in principle, we can dissect all genetic pathways activated in all cells of an organism. Moreover, the ability to garner data from direct observations in humans, in both health and diseased states, can motivate fundamental work directly relevant to medicine. The biology of individuals with rare single-gene diseases can lead to understanding of pathways critical to more common disorders. For example, the molecular understanding of a rare inherited predisposition to very high cholesterol and premature heart disease led to fundamental understanding of how cells internalize molecules from their environment, and clinically to the discovery of mechanisms underlying atherosclerosis and the development of cholesterol-lowering statin drugs that have dramatically reduced the incidence of heart disease. Given the striking evolutionary conservation of genes and gene pathways, such approaches can

include complementary studies of species as distant from each other as humans and single-celled yeast.

It is the mission of NIH to support basic science and mechanistic understanding of health. In some cases, these open-ended goals have been complemented by targeted well-conceived, broadly scoped “Grand Challenge”-type initiatives, such as for sequencing the human genome or achieving precision medicine, which can create or expand fields, invite and promote novel approaches for fundamental discovery, and inspire transformative technologies to advance knowledge. Unfortunately, we are also observing an increased frequency of narrowly scoped projects, occasionally inserted as “earmarks” by Congress, and others developed, reviewed, and funded by individual NIH institutes. This approach runs the risk of eroding support for unscripted basic research and well-conceived broad-based targeted work, and threatens the ability of NIH to achieve its human health imperative.

Fundamental NIH-supported work identifies specific molecular targets and cellular and biochemical pathways associated with both normal biological processes and disease. These targets and pathways are foundational for biotechnology and pharmaceutical companies with specialized pharmacological, toxicological, chemical, and clinical expertise. Companies have neither the resources nor the business rationale to spend decades unravelling the underlying biology that supports their work. No business plan can support the untargeted research that will lead to important discoveries in unanticipated spheres. Such research is the province of investigators in academia and private research institutes who rely primarily on NIH for funding. Without such fundamental discoveries, we will not generate novel medicines.

Biotechnology companies thrive in the U.S. because investors and scientific entrepreneurs recognize the potential of fundamental discoveries. Gene editing by CRISPR-Cas 9, discovered in microorganisms (see Box 1-A), and the field of this year’s Nobel Prize in Chemistry, quickly became the foundation of numerous companies testing its power to cure genetic disorders.

Thus, as Vannevar Bush envisioned, we have established a model in which academia focuses on NIH-funded basic research, and industry on privately funded practical translation opportunities.

We are concerned that NIH appears to be leaning increasingly toward supporting practical applications, even including drug development, to the detriment of more fundamental discovery. Continued progress in understanding, preventing, treating and curing disease depends on a continuous influx of new knowledge from fundamental discoveries. In short, because industry cannot support a robust discovery endeavor, public funds from the federal government must support it.

We strongly endorse the historical commitment of NIH to basic research, with the goal of revealing the molecular definitions of health and disease, to enable practical translation in the labs of biotechnology and pharmaceutical companies.

### **Box 1A: Path to Genome Engineering by CRISPR-Cas technology**

Clinical trials are underway using the CRISPR-Cas technology to repair errors in the genome, hopefully to cure inherited disorders such as sickle cell disease and beta-thalassemia. Early experiments suggest that there is hope for success across a wide range of formerly lethal and crippling genetic disorders. The decades of discovery that led to CRISPR began with a variety of seemingly unconnected research projects driven by desire to understand strange vagaries of evolutionary adaptation, meandered through side-branches of yogurt manufacturing, and coalesced around understanding of the immune system of bacteria, all before recognition of the power to modify the human genome.

In the late 1980s scientists discovered repeating DNA sequences of completely unknown function in microbes living in water of unusually high salt concentrations and subsequently in bacteria that cause plague. These DNA sequences came to be termed 'clustered regularly interspaced short palindromic repeats' (CRISPR). As more sequencing information became available, scientists realized that pieces of viral genomes interrupted the bacterial CRISPR repeats. Studies in yogurt-producing bacteria confirmed suspicions that that the system is designed to protect bacteria from viral invasion, doing so by cutting the viral DNA as it enters the bacterium. Key elements came into view – a Cas enzyme to cut DNA, and RNA to target the region to be cut – which scientists then showed could be reconstituted outside of cells. Further technical manipulation allowed the transfer of the editing mechanism into mouse and human cells, where they accurately cut at specific sites among the three billion base pairs that comprise the human genome. Using components designed to target disease genes, scientists then showed this system could potentially repair disease-causing genes.

## **Pathways:**

**1.1.1.** The NIH Director should ensure that the NIH research portfolio prioritizes funding fundamental investigation. The Director must be the standard-bearer, both within NIH and to policy makers and the public, for the importance and imperative of public funding of basic research to understand biology at scales from atoms to populations, with tools from molecular genetics and biophysics to clinical observation, and incorporating concepts and technologies of biology, chemistry, physics, computer science, mathematics, and engineering.

**1.1.2.** NIH should develop mechanisms and policies (see Pathway 3.3.5) to require that biomedical data are findable, accessible, interoperable and reusable ([FAIR](#))<sup>1</sup> by the publication date, that primary research articles of all NIH-sponsored research be freely and immediately accessible to the public, and that data from [clinical trials be shared](#)<sup>2</sup>. These requirements, which should be met within three years, together with strong encouragement that NIH investigators and trainees embrace a range of open science practices, (e.g., posting manuscripts on preprint servers such as bioRxiv), will speed the pace of research, expand the range of investigators that contribute to a given investigation, and help diversify the research enterprise.

**1.1.3.** The NIH Director, in concert with Institute Directors and Program Managers, should require that targeted projects or areas of emphasis designated by congressional earmarks or originating in particular NIH Institutes or Centers are developed in consultation with, and rigorously evaluated by, ad hoc external working groups consisting not only of scientists expert in the field but also of scientists with broad-based general knowledge and perspective. The Director should put in place mechanisms to evaluate the impact of such funds on the NIH portfolio and on the health of the nation, appropriately use these evaluations when judging the value of subsequent targeted projects or areas of emphasis, and ensure that curiosity-driven basic science is not compromised by end-point focused targeted research.



**Vision 1.2. Grant mechanisms that motivate and support scientific creativity, innovation and diversity, and share salary support for principal investigators jointly with with awardee institutions.**

NIH grant mechanisms should encourage and reward pursuit of bold ideas by creative investigators. The mechanisms should emphasize the value and potential impact of scientists' ideas and track records rather than description of experimental methods. They should invite and recognize research programs that tap concepts and technologies of two or more disciplines, or that describe exploratory and observational investigations that will drive emergence of subsequent hypotheses, despite themselves lacking a hypothesis-driven foundation.

The Research Project (R01) grant is the original and predominant mechanism used by NIH, meant "to support a discrete, specified, circumscribed project" to be performed or led over a 3-to-5 year period by an individual investigator. Successful applications provide extensive preliminary data and appear highly feasible. Thus, the R01 mechanism favors incremental impact over transformational advances. Consideration should be given to new mechanisms, and/or shifting criteria for the R01, to strengthen focus more on the scientist relative to the project, based on creativity and track record. Notably, all researchers, including trainees, have track records, which can and should be compared with those at similar career stages. In addition, certain grants should be longer term and larger than standard R01 grants. Certain NIH Institutes and Centers, e.g., National Cancer Institute and National Institute for General Medical Sciences, have implemented mechanisms, Outstanding Investigator and MIRA, respectively, that embrace some of these criteria and goals.

Scientific breakthroughs are increasingly the product of interdisciplinary work, which enables contributions from different scientific disciplines. In much the same way, diversity in the biomedical workforce also positively impacts research scope, productivity, and creativity to enable discovery (as discussed in the Training and Workforce and Administration chapters).

A substantial portion of research grant budget expenditure is typically devoted to investigator salaries. Current policy permits institutions to compel Principal Investigators (PIs) to recover all or a



great majority of their salaries from NIH grants. The outcomes of this policy are undesirable. First, a large proportion of NIH grant funding is devoted to PIs salary. Second, institutions can operate with little or no financial commitment to their employee investigators, placing all the risk on individual PIs, rather than a demonstration of support for their PIs, inviting and motivating risk-taking. Clearly, any change in policy would require adjustment of institutional business plans and therefore must be respectful of institution-specific differences in revenue and endowment resources, and in any case would need to occur very gradually, e.g., over a ~20 year period. Even gradual recalibration of this policy would liberate funding for additional research grants, as well as free up more resources for research on each grant.

### **Pathways:**

**1.2.1.** The NIH Director should establish an NIH-wide task force to pilot a series of grant mechanisms that emphasize novel ideas and concepts, and seek highly creative scientists; after careful evaluation, adopt those deemed successful. Examples of such approaches could include:

- Increase proportion of grants based on investigator track record and proposed project creativity and risk-taking, with extended (8-10 year) support for transformative directions.
- Reduce Research Strategy page limits for all grant applications (e.g., from 12 pages to 7 for the current R01 mechanism) to focus on the central idea and its potential impact rather than on details of methodology and preliminary results.
- Encourage transdisciplinary work and development of novel technologies that enable detection and analysis on shorter time scales, or increased breadth or depth.

**1.2.2.** NIH should develop a plan, and weigh the consequences, of requiring that all Principal Investigators who draw salary support from NIH should also receive a portion of their salary from their employing institution. One strategy might establish an individual institution re-negotiation cycle, perhaps every 3-4 years as is currently the practice for institutional re-negotiation of facilities and administrative costs.

### **Vision 1.3. Peer review processes that identify and reward bold ideas, creative risk, innovation and foundational approaches.**

For NIH to succeed in implementing grant mechanisms that not only better identify scientists with bold, exploratory, and transdisciplinary ideas, but also reward them with funding to pursue those ideas, it will require revision of peer review processes and practices. Today, reviewers are typically chosen for expertise concerning an organ system or a disease, rather than for understanding of biological processes and mechanisms that might cross traditional boundaries. Optimally, participants in the final review process should be broadly knowledgeable and thoughtful across an area of study, and sympathetic to the breadth of subjects and experimental methods that touch that area. Reviews should not dwell on details of methodology or preliminary data but rather on the promise of both the ideas and the investigator to push boundaries and to advance or disrupt concepts or approaches to biology or disease.

#### **Pathways:**

**1.3.1.** The NIH Director should mandate that study section meetings are limited to chartered members, selected as highly respected generalists in each designated area of study. Chartered members should be from all career stages, and together, represent diverse perspectives and experiences. In this setting, such generalists would recognize and reward bold, disruptive proposals that would strongly advance a broad area of study, rather than those that contribute only incrementally to a subspecialty. This reconfiguration would rebuild a peer review culture, perhaps last widely seen in the 1980s (and still the case among prestigious private postdoctoral fellowship review panels), in which the best scientists are incentivized to participate because their views are valued and impactful.

Well in advance of a study section meeting, proposals that include technologies outside the expertise of the chartered membership should be transmitted to two or more content experts, requesting focused advice (one or a few sentences) about the suitability of the technique/hardware/software for the relevant proposed experiments. These comments would be provided to the chartered members to help inform their evaluations. The ad hoc reviewers should not attend study sections, in order to ensure focus upon breadth and creativity of ideas rather than upon methodologic details.

**1.3.2.** The NIH Center for Scientific Review (CSR) Division of Receipt and Referral should more commonly cross disciplinary, organ or disease boundaries when assigning applications to study sections for review. In addition, the CSR Advisory Council, or a working group designated by the Council, should consider a re-scoped and broadened roster of study section topics to better align peer review with the transdisciplinary, trans-disease, trans-tissue approaches that advance the pace, quality and impact of research. In practice, these changes would shift study section foci toward biological processes, machineries and mechanisms, toward the description, analysis, manipulation and prediction of those processes, and toward the creation of new technologies that empower such work.

**Vision 1.4. Interagency and industrial partnerships that fund data science and platform technology development.**

Biomedical research in the 21st century will increasingly be enabled by concepts and technologies traditionally viewed as “non-biological”, including physics, chemistry, computation, and engineering. Research tools and facilities that drive these disciplines are typically funded by federal agencies and departments other than NIH, including National Science Foundation (NSF), Department of Energy (DOE), Centers for Disease Control and Prevention (CDC), and National Institute for Science and Technology (NIST). The [DOE Secretary's advisory board in 2016](#) described a plan<sup>3</sup> for expanded DOE-NIH intersections and collaborations; some of the recommendations of that group have been followed by the NCI and other NIH Institutes.

Robust funding partnerships, collaborative programs, and joint funding mechanisms that cross bureaucratic boundaries will greatly enhance the NIH research endeavor. For example, they can provide the underpinnings of technological advancements, as occurred with the Human Genome Project; access to clinical, population health, and epidemiological data, as was needed during the [Covid-19 pandemic](#)<sup>4,5</sup>; and bioethical and standard setting expertise, as has occurred for studies in genome editing, clinical trials, and access to genomic information. New mathematical and statistical approaches are in demand as biomedical research has transitioned from a predominantly

descriptive and often qualitative endeavor to a highly quantitative one. Moreover, there is great potential and growing capacity to aggregate and analyze vast amounts of data and integrate many different data types into machine learning- and AI-driven knowledge networks, using core expertise and facilities residing in DOE and NSF, that will contribute to our understanding of disease risk and progression, mechanisms of social and environmental determinants, and relationships of genetics to complex behavioral patterns and diseases.

To maximize innovation, it is also important to lower boundaries that separate fundamental discovery, the province primarily of academia, and diagnosis, prevention, and therapeutic embodiments, undertaken generally in the private sector. This sectarianism is both inefficient and expensive. In part, this a consequence of different philosophies and justifications for work, of cultural differences, and of practical impediments that burden technology transfer.

## **Pathways:**

**1.4.1.** In concert with other federal agencies, NIH should establish funding mechanisms specifically dedicated to building and providing ongoing support of technologies that benefit biomedical and behavioral research. Such multi-agency grants might, for example, be dedicated to generation of platform technologies, as occurred during the Human Genome Project with the DOE National Laboratories; to acquisition and analysis of long-term epidemiological data and social determinants of health in partnership with the CDC; to monitoring and evaluating the impact of environmental factors on health with the Environmental Protection Agency (EPA); or to developing technology centers with NSF. Grants for such projects should support teams of scientists, including staff scientists, and commonly, engineers. Such longer-term employees can provide institutional memory independent of graduate students or postdoctoral fellows, whose presence in laboratories is relatively transient. Among other contributions, their roles can be to develop and keep current complex technologies such as crystallographic analysis and cryo-electron microscopy, or to develop mathematical and statistical tools for machine learning and AI.

**1.4.2.** Build joint programs with DOE, NSF and NIST that aggregate, integrate and analyze the myriad distinct data types across the three classes of NIH research — basic, clinical and population studies. These computational tools will produce a continuum of research that will link social and behavioral determinants of health to objective measures such as omics, imaging and drug resistance.

**1.4.3.** Review and enhance interactions between NIH-funded academic research and R&D programs in industry. The Bayh-Dole Act of 1980, which encouraged academic institutions to patent discoveries made using NIH funding, has improved the utilization of such funding for practical purposes and facilitated the birth and growth of the biotechnology industry. However, negotiations for technology transfer between academia and industry or between academic centers are often unduly protracted, and even the faint hint of potential financial remuneration increases tendencies to secrecy both by institutions and researchers. The power of the alternative—the rapid sharing of information, both in academia and industry—has been demonstrated by the cascade of information during the COVID-19 pandemic. Mechanisms to encourage such openness should be developed and employed. In addition, mechanisms to support open alliances between academic and industrial research and development should be created, so that each part does what it is best suited for in the chain from discovery to therapeutic. This includes, as occur today, academic-industrial partnerships for specific projects, and also sabbaticals between academia and industry, on-site review by representatives of venture or biotechnology communities of academic programs to highlight those ready to transition, and co-location of personnel in joint laboratories dedicated to open science.

## 2. Training and Workforce: Preparing the Next Generation

*Prepare and enable a diverse workforce to foster innovation and bold approaches, empowered for 21st century science.*

### **Vision 2.1. A diverse biomedical workforce that enables science and society to meet existential challenges of the 21st Century.**

Many of the most pressing problems facing humanity are biological at their core: disease, food insecurity, and the destruction of the environment. New global threats to human health, including expanding antibiotic resistance and new and recurring infectious agents, most obviously SARS-CoV-2, emphasize the critical importance of training scientists to combat these threats effectively. If these global challenges are to be overcome, the United States needs more scientists trained at every level of discovery – from those uncovering the fundamental properties of organisms to those translating that knowledge into prevention, treatments, and cures. The U.S. rightfully celebrates its historic leadership in training future scientists, who then spread and disperse their knowledge across the country and the rest of the world. What it cannot claim, however, is success at diversifying its ranks – for example, women and men of color are significantly and pervasively under-represented in the biomedical workforce.

This is problematic from a number of perspectives. Whenever a group is excluded from a talent pool – intentionally or unintentionally – the overall quality of that pool is diminished. Moreover, a positive correlation has been documented between diverse teams and high levels of productivity in various employment settings, suggesting that greater inclusion would boost the excellence and impact of biomedical research. Finally, just as happened when women entered the profession in larger numbers, expanding the diversity of the workforce will broaden the range of research areas pursued by identifying new questions and approaches, and shaping priorities <sup>6</sup>. See Box 2-A.

To maximize our remarkable intellectual resources and realize the full potential of the U.S. investment in biomedical research, we must enhance creativity, innovation, and productivity in biomedical science by cultivating diversity in the biomedical workforce. There is an urgent need for a more diverse biomedical workforce that matches the U.S. population – one that will bring diverse perspectives to identifying and solving our most pressing problems. To meet these needs, we must reimagine NIH recruitment and training mechanisms aimed at increasing and retaining talent for a diverse workforce.

### **Box 2-A. Challenges in retaining talent remain—and are exacerbated by the pandemic**

Despite efforts over the last decades, women remain under represented in the STEM fields. Recruitment is not the primary issue: women, particularly white women, are well represented in undergraduate, graduate and post-graduate biomedical training programs. Rather, attrition reflects a failure to retain and promote women to independent research and leadership positions.

The current pathway to an academic career in science, which involves graduate study in one's 20s and post-docs in one's 20s and 30s and then untenured professor positions in one's 30s and even 40s, poses a particular challenge for women, many of whom will be having children throughout precisely these same years, and who disproportionately provide personal care for aging parents. Despite considerable changes in cultural norms over the past 50 years, women still assume the bulk of these responsibilities. The need to temporarily leave or reduce the time devoted to their studies or positions has lifelong effects, ranging from permanent setbacks on career ladders to complete abandonment of career paths, particularly in academia.

This inequity, like many others, has been highlighted and exacerbated by the pandemic, for example, through the significant increase in childcare needs due to the closure of schools and daycare centers. The toll this has taken on women scientists is already apparent in the output of scientific manuscripts, which indicate that early career women scientists in particular are submitting fewer manuscripts than their male counterparts. Immediate action is essential to avoid reversing recent gender equality gains.

## Pathway:

**2.1.1.** The NIH Director should establish a comprehensive strategy to better attract and retain under-represented groups in biomedical sciences at every career stage, from undergraduate to independent scientists. Current mechanisms have not achieved this goal, and thus need to be replaced with bold programs that are monitored closely for appropriate metrics of success. Examples of potential approaches:

- Comprehensively analyze the handful of programs that have successfully inspired undergraduates from under-represented groups to enter and succeed in careers in biomedical science (e.g., the [Meyerhoff Scholars Program](#) at the University of Maryland Baltimore County, which uses a cohort strategy<sup>7</sup>), and develop training grants that incorporate best practices from those programs (e.g., multi-year summer research opportunities), while encouraging universities to experiment with new ways to achieve the goal of expanding the number of their minority graduates going on to post-graduate study in biomedical sciences.
- Fund post-baccalaureate programs for talented Black, Latinx, and Indigenous college graduates who need additional rigorous quantitative training to be competitive for entry into graduate programs.
- Create a grant program that explicitly provides support for promising under-represented scientists and physicians at a particularly vulnerable stage in their careers – the transition from trainee to independent scientist. One model for such a program is the [Hanna H. Gray Fellows Program](#) of the Howard Hughes Medical Institute.
- Create a grant program to support under-represented M.D.s who wish to pursue a Ph.D. following their medical training. One successful program, which may serve as a model, is the [STAR Program](#) at UCLA School of Medicine<sup>8</sup>.
- Ensure that training grants specifically designed to redress the lack of diversity in biomedical sciences include faculty advisors and mentors who understand the barriers that have stood in the way of women and under-represented minority scientists, and who have received training in effective mentorship practices.



- Modify existing funding mechanisms, and create new ones, to better retain and promote women throughout their careers, including those years with competing duties toward dependents. Mechanisms such as deadline flexibility, grant extensions, salary and research supplements to hire assistants, technicians and lab managers, and new grant mechanisms to accommodate major life events, should be implemented and made available to all scientists, to improve recruitment, productivity, and retention of talent in the biomedical workforce overall.

## **Vision 2.2. Scientists and physician researchers who are trained and prepared to lead 21st century science.**

Critical thinking is an essential ingredient of biomedical training: students must learn to identify and clearly define a worthwhile question, design experiments that have the capacity to address the question, collect and analyze data impartially and rigorously. Over the past 20 years, the demands on biomedical training have changed because of the complexity of the questions that can now be asked and the quantity of data that can be generated. These changes have occurred largely through the development of “omics” and other data-rich platforms, such as ultra-high resolution imaging, and structure determination, and they have driven biomedical science to become increasingly quantitative and cross-disciplinary. Biologists increasingly rely on the expertise of physicists, chemists, engineers, mathematicians and computer scientists to maximize the yield of discovery from data. This quantitative cross-disciplinary approach is now both essential and transformative for solving the most challenging biomedical questions. NIH must respond accordingly and mandate modernization of education in the biomedical sciences.

While training in the ethical conduct of science has been an essential part of NIH graduate training grants for some time, the increased complexity of 21st century science has also raised novel issues that future scientists will need to address. For example, to ensure rigor and replicability, it is important to develop a culture of open science (see Pathways 1.1.2 and 3.2.4) — sharing of data and reagents — as well as training in how to manage these demands within the resources of one’s laboratory. The use of large databases and the many applications of machine learning have complicated issues surrounding privacy. As the country grows ever more diverse, the imperative

for proper inclusion of women and ethnic/racial minorities and vulnerable populations in research studies has become clear and urgent. The dramatic increase in multi-authored papers, especially common in transdisciplinary work, has complicated the task of assigning responsibility for the fidelity of the data and analyses. And the increased sensitivity to the effects of ethnic, racial, gender-based stereotyping, harassment and discrimination has created an urgent need for training in responsible management of one's laboratory, staff, and mentees.

### **Pathway:**

**2.2.1.** The NIH Director should establish a competitive “closed-end” (5-year nonrenewable awards to 15-20 institutions) grant mechanism to support the development of [new strategies for graduate education](#) that will prepare and motivate trainees to work in cross-disciplinary teams, to utilize quantitative tools, and to conduct and communicate their research in an open, transparent, responsible and ethical manner. As with the successful BEST Career Exploration grant mechanism (see Vision 2.4), the outcomes of these awards will yield lessons and some best practices, perhaps differing in different types and locations of institutions, for effective 21st century graduate education. This knowledge can then be adopted or adapted at NIH training grant awardee institutions nationwide.

### **Vision 2.3. Graduate and postdoctoral trainees who are supported predominantly by individual fellowships and training grants.**

Over the past thirty years, NIH support of graduate and postdoctoral trainees has dramatically shifted from training grants and individual fellowships to indirect support of stipends and tuition on the research grants of their advisors. In this system, trainees have become de facto employees of their advisors. Advisors must balance their interest in getting the research done with training and mentoring responsibilities to their trainees and their future prospects. This balance is not always achieved. Furthermore, in such a system, NIH can assess neither the quality of the training they are investing in, nor the number and demographics of those being trained. One reason the shift has occurred is the ever-growing number of international students and fellows, who by law cannot be supported on NIH training grants and fellowships. These individuals, who make up a significant fraction of the workforce, contribute enormously to the success and productivity

of U.S. biomedical science.

Every NIH task force and National Academies of Sciences, Engineering, and Medicine (NASEM) committee that has studied biomedical training over the last 30 years has recommended that NIH restore training grants and fellowships as the primary method of supporting students and fellows<sup>9</sup>. The arguments have focused on the salutary effects of training grants on graduate programs. By holding programs accountable for required foundational course work, ethical conduct of science training, and diversity and inclusion, training grants provide NIH with a much more comprehensive and rigorous way for trainees to acquire research skills; develop scientific communication skills; understand the elements of the ethical conduct of research; learn about the range of available career options (see Vision 2.4); and complete the training period efficiently. In addition, training grants enable NIH to assess the impact of its training dollars. Individual fellowships directly awarded to trainees are also beneficial, as they give trainees greater independence in their choice of advisors and scientific directions to pursue, simultaneously shifting the power dynamic and rewarding advisors who provide strong scientific and career mentorship. Finally, a transition primarily to training grants and fellowships would give NIH stronger and more appropriate control over the size and make-up of the trainee population.

An additional and urgent rationale for supporting training grants and direct fellowships is the imperative to increase diversity in the biomedical workforce. Unlike the indirect support on R01 grants, where NIH has no control over who is being trained, these mechanisms can set standards, and hold institutions accountable for their progress toward greater diversity in the workforce. In this moment when the nation is confronting the impact of racism and [gender harassment](#) <sup>10</sup> in all spheres, now is the time for NIH to play a critical role in making this transition to new training strategies.

One reason this recommendation has been ignored for so long is that it constitutes a seismic shift in the allocation of research funds from R01 grants to training grants and fellowships. By so doing, it creates an apparent “loss of control” that principal investigators have over their research programs. These changes have been, and will continue to be, resisted by a significant fraction of the grantee population. Accordingly, this transition should be embarked upon only after careful consideration of potential unintended consequences, including the increased review burden for NIH, a

skewed distribution of training support among research universities and a loss of innovative and experimental training approaches through over-standardization. This transition should also include termination of the current prohibition of support of international students on training grants and fellowships, which hampers the success of NIH's global outreach, and simplification and facilitation of the current indefensible level of administrative complexity and bureaucracy associated with training grant applications and review. Although challenging, making this transition will substantially broaden the availability of training; help recruit and retain talent to diversify the workforce; build strong conceptual foundations for critical thinking; expand skill-building; and enhance career opportunities.

## **Pathway**

**2.3.1.** Within the first six months of the Administration, the NIH Director should empanel a task force to devise a phased plan, with metrics of success and a mandate for evaluation, that over time substantially shifts the funding for trainees from individual research awards to individual trainee fellowships and training grants while mitigating potential negative effects.

## **Vision 2.4. PhD scientists who assume expanded roles in academic research, and in the general workforce.**

The career prospects of graduates of Ph.D. programs in the U.S. have changed dramatically over the last 20-30 years. In the past, a majority of graduates transitioned to careers in academia. Today, less than 18% of trainees are projected to assume independent faculty positions in academia. Despite this trend, most biomedical training programs are still geared towards an academic path, and trainers too often convey a lack of interest in assisting students to explore other opportunities. The reality is that there are many careers available to the scientific workforce, and which would benefit from science expertise, including in fields of education, industry, policy, and communication, to name some of the most common. NIH recognized the need to familiarize trainees with the range of available career opportunities by creating in 2013 a 5-year closed-end grant program, Broadening Experiences in Scientific Training (BEST), which funded 17 institutions to devise mechanisms to motivate students to learn about and explore career opportunities in sufficient depth to select a career path with confidence upon completion of PhD training. Those programs have now been evaluated and their various features [described](#).

Changes in the nature of the biological sciences have also created changes in the essential roles of the biomedical workforce. With the advent of new and costly technologies, such as cryo-electron microscopy, advanced imaging technologies, and diverse “omics”, and the high demand for expertise in bioinformatics and biostatistics, individual investigators increasingly rely on core facilities or technology platforms to conduct their research. These bring with them the benefit of reducing the demand for labor in individual labs and typically, better quality control and standardization of results as well as access to cutting edge technologies that can more readily be incorporated into the work flow of large platforms than of individual labs. The key ingredient to any successful platform is a highly trained Scientific Director (currently commonly denoted as staff scientists), whose role is to bring specialized expertise to collaborations, including the ability to advise users in optimal designs and data analysis, to advance the technology, and to oversee the effective operation of the platform. Such computational and technology platforms have become an essential aspect of 21st century science, yet a majority of institutions struggle to appoint expert scientific directors or to support them financially, in large part due to difficulties in finding revenue sources to sustainably recruit and retain these critical colleagues.

There is also a growing need for PhD scientists stably associated with individual labs, who provide cutting-edge technical expertise, mentoring and training, key strategic and tactical insights, and institutional memory and stability in otherwise dynamic research environments. Such non-faculty investigators who currently serve these roles (also commonly denoted as staff scientists) can make enormous contributions in academic research settings, at least in part because they are free of traditional faculty responsibilities that lie outside research per se, such as leadership of training programs and didactic course development, service on institutional committees, and primary responsibility for research funding. However, these individuals lack positions with the deserved level of career structure and esteem. They hold neither standardized titles (perhaps consider Lab Research Scientist) and salary ranges commensurate with their contributions and value, nor opportunities for career development and advancement.

Major impediments to establishment of the Scientific Director

and Lab Research Scientist career tracks to manage powerful technology platforms and help to direct lab research and training efforts are driven by institutional and often faculty resistance to a new class of independent scientists who do not carry the responsibilities of faculty (such as teaching), even though “staff scientists” are often accountable for developing and maintaining effective research pipelines. Where successful, fostering programs that identify and support these individuals results in the establishment of high-performing technology and computational capacities that increase the opportunities and competitiveness of investigators and labs within the host institutions. Elements of success include giving staff scientists the status and independence to advance the technologies on which they work, a path to career advancement, treatment as collaborators rather than subservient technical staff, institutional status to apply for grants when appropriate, and recognition as intellectual contributors and coauthors on papers.

In 2015, NCI established a grant program directed at staff scientists who lead technology platforms or who take leadership roles in individual laboratories to give these individuals greater independence and status. Its success is currently being evaluated.

### **Pathways:**

**2.4.1.** Institutions holding training grants should be required to provide career exploration tools in their curricula by adopting or adapting elements of the BEST programs.

**2.4.2.** Using the NCI program as guidance, a new NIH-wide program should be created to establish a Scientific Director career track, for highly trained and well compensated experts who manage technology platforms.

**2.4.3.** NIH should work with academia to create and support a Lab Research Scientist career track, with standardized titles, career trajectories and compensation. These individuals will partner with lab PIs, helping to define and advance the lab’s research program, educate and mentor trainees, and oversee lab governance and maintenance.

**2.4.4.** NIH should consider funding, jointly with the private sector, effective Master’s programs. These programs could, for instance, prepare trainees who are committed to a career in industry. The

PhD degree has become the only de facto path into a career in biomedical sciences. Industry leaders have repeatedly called for a greater number of graduates trained in biomedical sciences at the Master's level. Several institutions have instituted Master's programs in biotechnology to be awarded concurrently with an MBA, in order to prepare leaders in industry who are versed in both business and science. Master's programs can provide the type of background that drive leaders to place proper emphasis on science, medicine, and ethics when making business decisions.

### **Vision 2.5. NIH-trained workforce that is fluent in the public context of science.**

While training in the biomedical sciences has been primarily focused on teaching trainees how to conduct research in an ethically responsible manner, little attention has been given to the importance of understanding and sharing the nature, importance and potential impact of the work. Given the complexity of recent biomedical advances and the profound impact they are likely to have on human health, it is essential that those who are creating scientific knowledge be well-versed in the context and the potential consequences of their work, and also be prepared to engage with and communicate to the public.

To bridge this gap in understanding and shared engagement, future biomedical and physician scientists must be introduced to key events and public reactions to scientific advances, appreciate the interplay among science, government, economics, and intellectual or spiritual culture; understand how their work fits within this larger arc of science and society interactions, and be trained to articulate to the public and its elected representatives the immediate and potential future impact of their work. To be optimally effective, researchers should engage patients and communities to understand their concerns and to partner with them in finding solutions. Training in science communication (including the role of media), as well as understanding the roles that various stakeholders (legislators, regulators, patient and disease advocacy groups, industry and government agencies) play in the biomedical ecosystem will prepare future scientists to be aware of the hopes and concerns of the public, and to convey the immediate and potential future impact of their work. A shift in support of trainees away from research grants and onto training grants and fellowships will help ensure that they receive appropriate mentoring in understanding the public context of science, and are effective in science communication and outreach.



**Pathway:**

**2.5.1.** The NIH Director should extend the current requirement that all students and postdoctoral fellows at institutions holding NIH training grants receive instruction in the ethical conduct of science to include training in the public context of science; ensure that trainees understand the context and implications, and are prepared to effectively engage with the public in communicating the nature, importance and potential impact of their work.



# 3. Administration, Operations, and Policies:

## Maximizing Opportunities

*NIH is considered one of the best managed agencies in the federal government. Recognizing the dynamics of 21st Century biomedical research, NIH should review its structures, functions, policies and operating principles, to further enhance its performance and adapt to a constantly changing environment.*

**Vision 3.1 An agency that is optimally organized and functioning to align with, inspire, and better enable the best 21st century biomedical research.**

Biomedical research is increasingly a transdisciplinary, quantitative endeavor inclusive of physical, biological sciences, computer science, and engineering. The complexity of biological systems in health and disease requires novel approaches that integrate and analyze massive sets of diverse data, finding and linking patterns and correlations from biological molecules, experimental organisms, individuals and human populations to achieve the central vision of precision medicine. Large growing cohorts of patients as well as healthy people are collecting and contributing data and seeking to engage actively in the research process. Biological mechanisms and processes discovered in one disease are commonly found to be relevant for others.

Contrary to these dynamic integrative forces, NIH has long been composed of over two dozen Institutes and Centers focused on a set of diseases and/or research areas that were relevant at the time of their creation. While the contributions of each are justifiably recognized and respected by patients, advocates and scientists, there is a decreasing alignment between the legacy structure of NIH and the emerging continuum spanning mechanisms, diseases, technologies and disciplines, making reassessment of isolated organ- and disease-focused institutes an urgent imperative.

## Pathways:

**3.1.1.** The NIH Director should engage the Strategic Management Review Board of the agency to perform its mandated assessment of the organizational structure of NIH. The [NIH Reform Act of 2006](#) created a Scientific Management Review Board (SMRB) for “periodic organizational assessments and review of the research portfolio in order to determine progress and effectiveness and value of the portfolio, not less than once each 7 years” <sup>12</sup>. The NIH Director should activate the SMRB in compliance with this congressional mandate, and name a working group that includes basic, clinical and population scientists, as well as patient advocates, to complete a formal analysis within the next two years to consider how NIH should be structured and organized to better reflect and enable modern biomedical science.

**3.1.2.** The NIH Director should build upon the success of inter-institute collaborative programs. We recommend that a dedicated increase in the Common Fund budget to five percent or greater of the NIH budget as authorized by Congress (see also Pathway 1.3.2) be advocated with Congress to expand inter-institute initiatives more broadly across biological mechanisms, research disciplines and diseases, and adopt Pathway 1.2.3 to reconfigure the CSR study section roster, placing greater focus on biological mechanisms and processes, as well as new technologies. Key to further progress in such agency-wide common fund programs will be an objective review and evaluation, with revision of the current approach for selecting proposed projects to one that requires agency-wide buy-in, with active input from ICs prior to adoption.

## **Vision 3.2. NIH Administrative policies that ensure a diverse, equitable and inclusive scientific workforce trained for 21st century biological research.**

A major component of the mission of NIH is to train and develop the scientific workforce of the future. Thus, a critical component of the mission of NIH is to achieve diversity and inclusion in the scientific workforce at levels that mirror to the extent possible the growing diversity of the entire population of the country, and ultimately benefit from under-represented talent pools. While many programs have been created at NIH, current statistics and analyses, including a U.S. Government

Accountability Office (GAO) [report in 2018](#) (see Box 3.A) and [recent work from NASEM 2020](#) <sup>13</sup>, still show persistent disparity and lower participation of under-represented minorities and women. For example, approximately 1.8 percent of NIH grantees are African-Americans, far below their percentage in the population. Notably, the success rate of these grantees remains at about 17% whereas the success rate of majority candidates is around 27%. An in-depth assessment and the consideration of new administrative strategies, policies and operational principles should be piloted across the agency.

**BOX 3.A: Section of GAO REPORT 18-545 , AUGUST 2018  
NIH RESEARCH: Action Needed to Ensure Workforce Diversity Strategic Goals Are Achieved.**

"NIH implemented recommendations made by internal advisory bodies to support investigators from racial and ethnic groups considered by NIH to be under-represented in biomedical research. GAO's analysis shows disparities for under-represented racial and ethnic groups, and for female investigators, from 2013 through 2017. For example, in 2017, about 17 percent of investigators from under-represented racial groups — African Americans, American Indians/Alaska Natives, and Native Hawaiian/Pacific Islanders combined—who applied for large grants received them. In contrast, about 24 percent of Hispanic or Latino applicants, an under-represented ethnic group, received such grants. Asians and whites — well represented groups — were successful in receiving large grants about 24 and 27 percent of the time, respectively. Although women represent about half of all doctorates in biological science, GAO found that women investigators employed by NIH in its intramural program comprised about one quarter of tenured investigators. NIH has taken positive steps such as establishing the position of Chief Officer of Scientific Workforce Diversity, who in turn created a strategic workforce diversity plan, which applies to both extramural and intramural investigators. The plan includes five broad goals for expanding and supporting these investigators. However, NIH has not developed quantitative metrics, evaluation details, or specific time frames by which it could measure the agency's progress against these goals."

**Pathways:**

**3.2.1.** NIH should evaluate its numerous diversity, equity, and inclusion programs and establish explicit quantitative metrics to enable assessment of progress. Despite recent progress, the lack of quantitative metrics or time frames prevent regular assessments and tracking of the agency's progress and should be addressed.

**3.2.2.** NIH should collect data on the impact of COVID on the productivity, satisfaction, and retention of scientists, particularly under-represented minority and women scientists, and coordinate with [other entities, such as the National Academies of Sciences, Engineering, and Medicine \(NASEM\)](#)<sup>14</sup> to examine this issue.

**3.2.3.** The NIH Director should establish a comprehensive and centralized talent management and tracking system for all scientists. This system, should be used to evaluate programs and support career progression of all scientists and, perhaps within the office of the Chief Officer of Scientific Diversity, should also improve coordination and quantitative improvements in diversity and inclusion across NIH to monitor the progress of all under-represented minority scientists from end to end across the agency.

**3.2.4.** The NIH Director and its leadership should participate and promote necessary changes in diversity, equity, and inclusion policies across all agencies of the government. Under-represented minority students often face both objective and subjective barriers not encountered by non-minority students. Inadequate STEM education; lack of special programs for research training for under-represented minority students; lack of institutional commitment, support, and mentoring; and financial and economic considerations all compromise the career development of minority scientists. Some of these factors are beyond the scope of any single agency but are the responsibility of all, hence the need for the NIH Director to be actively engaged in addressing these matters across the federal government. For example, the NIH and NSF directors, as co-chairs of the Committee on Science of the National Science and Technology Council, managed by the Office of Science and Technology Policy in the White House, should advocate for expansion and increased support for the under-represented minority scientific workforce as a coordinated government wide priority.

### **Vision 3.3. Scientists are liberated from undue administrative burden.**

Grantees and their institutions are increasingly frustrated with the amount of time they have to devote to writing and rewriting grant proposals and comply with a growing number of onerous rules, bureaucratic minutia of debatable value, regulations and unfunded mandates that detract from their focus on advancing their ideas and

investigations. While certain levels of time and costs unrelated to the performance of research or training are unavoidable, these have mushroomed over the years, eroding the efficacy and efficiency of the NIH budget. For example, important requirements for data sharing, documentation of compliance, animal care rules, clinical trials reporting and other mandates lack critical support mechanisms or infrastructure.

## **Pathways:**

**3.3.1.** NIH should limit the total administrative burden imposed on grantees to a specified “not to be exceeded” cap. NIH should lead with relevant stakeholders a thorough and continuous quantitative review of all sources of burden on grantees as well as NIH personnel outside of the direct conduct of research or training. Whenever a new regulation or process is proposed, it should be the subject of a formal impact study on the total administrative burden to remain under the committed cap by eliminating or streamlining other sources of burden.

As one possible starting point, the new NIH Administration should consider relevant recommendations from the NASEM Committee on Federal Research Regulations and Reporting Requirements report, *“Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century”*<sup>15</sup> to reduce administrative burden on investigators, grantee institutions and NIH itself.

**3.3.2.** The NIH Director should move toward harmonizing all ICs grant mechanisms, adopting standardized applications, and coordinating funding policies and guidelines across the Institutes whenever possible.

**3.3.3.** The NIH Director should regularly review and adjust every three years fixed budget grant mechanisms to reflect the impact of biomedical research inflation.

**3.3.4.** NIH should address unfunded mandates. NIH should evaluate their justification, and the impact of their fulfillment on grantees and their institutions. The infrastructure and platforms necessary for effectual fulfillment of justified mandates should then be developed, at scale, by NIH. For example, the important goal of data sharing and archiving could be addressed by NIH in a manner analogous to what the National Library of Medicine did for many biotechnology information and publications resources such as PubMed and PubChem, which have proven extremely valuable.

**3.3.5.** NIH should build on PubMed and PubMed Central to support a publishing environment that disseminates NIH research outputs more swiftly and openly. This includes open access sharing through preprint servers and traditional journals. NIH could take three steps: (1) require that NIH funded research is shared through PubMedCentral by open access means immediately upon publication (2) encourage that NIH-funded research is first posted on preprint servers; and (3) include preprints in PubMed/PubMedCentral.

**Vision 3.4. An Intramural Research Program that is an incubator of talent and breakthrough research.**

The NIH Intramural Research Program (IRP) supports research, training and career development, functioning as a distinctive ecosystem in which investigators can undertake innovative research projects with long-term stable funding. The IRP provides a compelling example of NIH research inside the Beltway, readily visible to Congress and policy makers, and serves as a special research site and a national resource. The IRP, especially during its early days, has been the crucible for an entire generation of scientists, many of whom have gone on to achieve the highest honors in science. Currently, however, the common perception is that the IRP is no longer differentiated from many academic programs around the country; rather, it should be a center for ground-breaking research that would be difficult to accomplish elsewhere, and/or a sought-after destination for the most promising early-stage investigators that form the core of the next generation of exceptional scientific leaders.

**Pathways:**

**3.4.1.** The NIH Director should reconfigure the IRP to ensure a continuously creative, vibrant and impactful research environment, and establish IRP policies that promote scientific and personnel flexibility and healthy turnover. New policies should be implemented to make the IRP nimble and at the cutting edge, and to provide greater career fluidity for those who join or depart the program, such as:

- The IRP could be converted into a premier “incubator” for exceptional early stage investigators, during or after which they could launch bold research programs with ~7 years of unrestricted funding, free of non-research academic responsibilities (analogous to current Stadtman Fellows). At the end of this initial period, they would be expected to depart to extramural positions (similarly to premier science centers such as the European Molecular Biology Laboratory

and the Max Planck Institutes). Of course, the IRP would continue to host a proportion of selected tenured established investigators, recruited from intramural and extramural ranks. This scheme would provide a larger and continuous influx and efflux of well-trained creative investigators.

- IRP investigators in good standing who depart to extramural institutions should be provided with three years of transitional support, consistent with policies for NIH Lasker fellows and HHMI Janelia Farm group leaders. These grants should, if at all possible, be issued from the extramural funding pool as the research is intended to be performed in the extramural community.
- Federal restrictions affecting personnel, compensation, contracting and travel should be addressed, as they impede scientific progress, limit IRP efficiency and effectiveness, and reduce its competitiveness for attracting and retaining outstanding investigators.
- The 23 intramural programs should be consolidated into a smaller number with coherent scientific themes that may not be IC-specific to better reflect the interdisciplinary conduct of modern science. The Porter Neuroscience Center housing investigators from eight ICs provides a good precedent for assigning space by research foci rather than institute affiliation. Program integration would be further advanced if control over budget, appointments and/or review were delegated to the consolidated units. More emphasis on fundamental mechanisms rather than organ or disease-based approaches could be achieved by pooling resources from different institutes. This is especially relevant to the research and development of novel scientific technologies that would benefit many or all ICs.

**3.4.2.** The NIH Director and the Department of Health and Human Services should work with Congress and the Administration to revise a range of policies affecting NIH personnel, travel and contracting to more closely align with research universities and medical schools, and to create an NIH-specific special pay statute that would provide compensation parity with academic institutions.



### **Vision 3.5. An NIH Clinical Center that operates at its full potential as a unique national resource.**

The Clinical Center has been a centerpiece of the IRP for decades, supporting exemplary clinical research and training. However, despite recent reorganizations, its future is seriously threatened on several fronts. First, the Clinical Center budget resides within the overall IRP budget, with no provision to keep pace with the fast-rising costs of health care and clinical research; sustainable funding for the Clinical Center as a unique national resource should be a priority for NIH. Second, recruitment of outstanding clinical trainees and tenure-track investigators has been compromised by federal bureaucratic burdens and by difficulties in creating a path for return to academia. Third, several institutes have reduced their clinical center activities because of the impact of clinical research costs on the rest of their nonclinical programs. Fourth, the volume of activity in the Clinical Center has declined, reflecting the national trend toward conducting clinical research in outpatient settings, the greater cost of clinical research relative to laboratory research and difficulty in recruiting new investigators (which could be addressed by reviewing current terms and conditions, and considering linkage with specific extramural training programs). Finally, the organizational structure of the Clinical Center should reflect and enable its central role in the IRP, and its expected national leadership in infectious diseases, vaccine development, cancer immunotherapy, and other critical areas.

#### **Pathways:**

**3.5.1.** The NIH Director should expeditiously establish a new governance structure advised by external experts in administration of clinical research and delivery.

**3.5.2.** The NIH Director should evaluate and change the Clinical Center's funding model to reflect the unique nature of the clinical center as a national clinical research resource. We recommend that the clinical center should receive a direct appropriation from Congress as an authorized center similar to other ICs.

**3.5.3.** The NIH Director should develop a strategy to improve recruitment of clinical scientists, highlighting advantages and importance of that career track, and offering loan repayments and other incentives including re-entry grants in the extramural community and possible inclusion in specific extramural training grants for clinical research.



**3.5.4.** The NIH Director should increase clinical activity by partnering with area academic health centers and promoting intramural and extramural collaborations.

**Vision 3.6. Partnerships and collaborative programs that accelerate development of complex enabling technologies, diagnostics, therapeutics and preventions.**

Modern research is increasingly dependent on the development of novel technologies such as molecular imaging or advanced computing. NIH lacks sufficient expertise, funding mechanisms, and workforce configurations for the efficient development of such enabling technologies and should adopt a “culture of partnering” with other federal agencies and with the private sector to accomplish these important goals.

In a related way, NIH should not try to assume the private sector’s role, to capitalize on discoveries to create tangible products and services. The product of NIH is knowledge; the product of industry is products. Except when market forces preclude industry investments, NIH is unlikely to identify therapeutic solutions faster or better than the private sector (which spends more than four times the budget of NIH) and should avoid duplicating those efforts.

However, NIH may be able to work with the Small Business Administration to develop revisions in the SBIR program to help investigators bridge the so-called Valley of Death - the gap between early discoveries and initial translational studies that could justify funding from the private sector for out-licensing or company formation.

**Pathways:**

**3.6.1.** NIH should develop joint programs with other federal agencies and with the private sector to accelerate creation and establishment of platform technologies critical for biomedical research. Previous collaborations of this type, such as the creation of biology-specialized x-ray crystallography resources with the Department of Energy have been fruitful. Looking ahead, cryo-electron tomography is an example that could benefit from a similar approach, as well as large scale computing for AI-driven analyses of biological complexity in support of precision medicine.

**3.6.2.** NIH should evaluate and encourage new models of technology transfer mechanisms. In the U.S., the obligation for grantee institutions to establish full-fledged technology transfer offices to fulfill legislative mandates has led to a fragmentation of the intellectual property generated in the country. Most of these technology transfer offices do not cover their costs through licensing revenues at most institutions. Licensing and business development sections of U.S. companies commonly point to the fact that most potential products today require multiple licenses owned by different parties and often decry the complexity of negotiating IP with most universities due to differing policies and viewpoints specific to each institution. This transactional friction and inefficient market slows translation of potentially valuable discoveries. In certain applications, such as infectious diseases, patent pools have been useful. These patent pools are common in the information technology industry. A more efficient IP market in the U.S. could accelerate translation of discoveries and increase revenues to universities. We recommend that NIH collaborate with other agencies to evaluate different models such as universities pooling related IP portfolios to lower these transactional barriers.

**3.6.3.** NIH should propose to the Small Business Administration an expansion of the SBIR/STTR program's remit to provide pre-company pre-clinical support that could enable NIH investigators to navigate the Valley of Death. NIH is currently required to commit a significant fraction of its budget to the support of small companies, but cannot address the all-important steps of early experimental demonstrations of feasibility – validation needed by incubation stage proto-companies yet to be formed. NIH should negotiate creation of a specific competitive process within the SBIR/STTR allocation, perhaps with industry participation, to overcome the Valley of Death problem.

# 4. Appointment of the NIH Director

In accord with historical tradition and good institutional practice, we urge the Administration to initiate well before Inauguration Day a systematic search for a highly qualified NIH Director, recognizing the essential role of the NIH Director in motivating the recommended pathways above, and the complexities of identifying and appointing the best possible person. We suggest that the Administration assess the views of its Director candidates on the matters and issues that are the basis of the recommendations presented here, describe characteristics and qualities embodied in such individuals, and offer examples of topics and questions that might inform a search committee.

**Characteristics of candidates.** The essential criteria for an NIH Director have never been clearly articulated, but we offer the following characteristics as qualifications for the position: an outstanding record of scientific accomplishment in one or multiple areas of biomedical research (likely to be accompanied by election to one or more of the National Academies of Sciences, Engineering, and Medicine, high ranking positions at respected institutions, and/or the award of major prizes); an appreciation of the importance of other areas of medical research; a strong reputation for integrity and good character; a history of professional or public service; excellent knowledge of the NIH and its activities, usually based on participation in the affairs of the NIH as a grantee, reviewer, consultant, or employee; an ability to represent the NIH with clarity and conviction to other members of the U.S. government, the scientific community, and the public; and a high level of interest in leading the NIH in a fashion that will enhance the agency's performance. Traditionally, all NIH Directors have held an MD degree, and it is essential that the Director has wide knowledge about medicine. However, we do not view the MD degree as an essential attribute.

Queries for candidates. Many of the qualities sought in candidates for NIH Director can be ascertained and assessed from search committee questions that measure a candidate's knowledge and attitudes about the agency. We offer below a list of topics and questions that members of a search committee might pursue during the interview process:

**Motivations.** Why would you want to become the Director of the NIH? What are your aspirations and major plans for it? Views of the agency overall. What are the two or three strongest and weakest aspects of the NIH as it currently operates? The NIH budget. What do you think are the best arguments to present to leaders of the new Administration or to Congressional appropriators for enhancing the NIH budget? What are your goals for its budgetary future?

**The Common Fund.** The NIH Reauthorization bill of 2006 created the Common Fund to provide the NIH Director with a greater hand in guiding program development across the Institutes and Centers. How well do you think the Common Fund mechanism has worked? What would you do, if anything, to improve it?

**Grant mechanisms.** Some view the predominant NIH grant mechanisms to be quite conservative, focused on circumscribed projects carried out by individual investigators, using only well-validated concepts and approaches. Do you agree, and if so, how would you change this crucial NIH activity.

**Scientific initiatives.** In addition to CSR-managed grant mechanisms, specific RFAs are initiated by IC Directors, the Administration, or Congress. What is your view of those other approaches to NIH-supported science? Is the balance among them right? Current legislation supports initiatives on Precision Medicine, Alzheimer's Disease, cancer (Cancer Moonshot), and), neuroscience (BRAIN). Should any of these be adjusted?

**Peer review.** NIH-based systems for review of grant applications are a persistent target for concern, especially when success rates for applicants are low. What do you think are the major deficiencies in the review process, as practiced by the Center for Scientific Review or by individual Institutes? How would you go about repairing them?

**Open science.** In recent years, there has been increasing interest in sharing the results of publicly funded science through the creation of shared data repositories, public digital libraries, open access journals, and pre-print servers. What is your view of these developments? How would you grow such efforts?

**COVID-19 and NIH research.** How well have NIH and the scientists it supports responded to the pandemic? If you were working on a COVID-19 Commission, what would you recommend as a role for NIH in future pandemics? What problems did NIH-funded investigators who work on topics other than COVID-19 experience, and how should damages be addressed?

**Workforce demographics.** What do you think of the demographics of the scientific workforce? At issue are disparities among racial and ethnic groups and gender, and the increasing average age at which scientists receive their first independent grant. What are your views? What policy changes would you recommend?

**The Intramural Program.** About 11 percent of the NIH budget supports the intramural research program. What are your views about the size, direction, function, and quality of the IRP? What kinds of changes do you think are desirable?

**The Clinical Center.** The Clinical Research Center on the NIH campus has been a major feature of the IRP for several decades and is housed in an impressive new facility, but it is confronting several problems: fiscal shortfalls, declining patient census, inefficient recruitment of new clinical investigators, and procedural deficiencies. What is your view of these problems and what do you think should be done?

**General directions of biomedical research.** As the world's largest funder of biomedical research, NIH is widely emulated, and its practices are intensively debated. What are your views of the current distribution of NIH's resources for fundamental, translational, and clinical research? Or of the need for additional resources for studies of prevention, behavior, public health, global health, implementation science, complementary medical practices, and other topics judged by some to be under-supported? Do other portions of the NIH research portfolio need more or less support in the next five to ten years?

**Recruitment of NIH leaders.** A major responsibility of the NIH Director is the hiring of individuals to occupy major positions in the Director's Office and to serve as Directors of Institutes and Centers. What kinds of approaches do you favor for these recruitments? What qualities do you look for in such searches? What do you see as the advantages and disadvantages of such positions and how would you try to overcome the shortcomings?

**Research integrity and reproducibility.** NIH-sponsored research has been criticized frequently in the past few years for lapses in accuracy and even integrity. How do you view these criticisms? What do you think are the underlying causes? What kinds of remedies do you envision?

**Ethics and Public Context of Science.** Do any of the current norms and funding conditions for ethical research using human subjects (including data and tissue samples) and animal subjects need revision? In light of vigorous public debate about effects on social structures, morality, and culture of emerging areas of science, what role should NIH play in training scientists or sponsoring research on ethics of such things as genome editing, synthetic biology, neurological enhancements, chimeric organisms and organoids?

**Training.** Several profound questions have been raised about the way in which biomedical scientists are trained in the U.S. Are we training too many people for too few academic positions? Why are trainees becoming independent scientists at such an advanced age? Do trainees get an accurate picture of the available employment opportunities? Why do so few trainees come from the under-represented minority sectors of our increasingly diverse population? Which of these do you see as central issues? What are your responses to them? What steps do you think might be taken to improve the situation?

**Multiagency cooperation to advance science.** Biomedical sciences increasingly depend on disciplinary strategies, including physical and computation sciences, that are outside the primary remit of NIH and instead are principle foci in other federal agencies. NIH has not traditionally formed cooperative partnerships or jointly funded interagency programs to address these needs. Would you encourage and enable such agreements? If not, why not?

**Science in federal policy making.** Science and evidence have not held a trusted place in consideration of matters of health (and in general) in the current Administration. For some in the public, this has eroded trust in science carried out or sponsored by federal agencies, including NIH. What do you see as your role in combatting this problem? As a member of the Executive Branch, what would you do to try to prevent or reverse it?

**Miscellany.** The NIH Directorship is a complex job, with deep responsibilities. Are there aspects of the position that worry you? Are there parts of the job that we haven't asked about that you would like to discuss? Are there reasons that you might not want to accept the position if asked?

# 5. Why it Matters

Now is the time to act decisively to lay the groundwork for an NIH that serves the U.S. public and U.S. national interests in moments of crisis and over the coming decades.

To prepare for future health needs, known and unknown, the NIH must be primed for future success. Biomedical research is changing profoundly, and the NIH must adapt its policies and practices for incentivizing and supporting the best research and training. The COVID-19 pandemic has highlighted health disparities, and the social justice movement has underscored the lack of diversity in the scientific and healthcare workforce and research agendas, providing additional momentum and urgency for change.

The rapidly paced evolution of the biomedical research enterprise is defining the vectors of change needed for NIH. Increasingly, research questions and approaches are not primarily defined and executed within traditional disciplines. Instead, discoveries increasingly emerge from analyses of large data sets generated using a combination of technologies and approaches from physics, chemistry, computer science, engineering and the social sciences. A highly networked, transdisciplinary research culture will accelerate the generation of scientific knowledge and deepen our understanding of complex biological processes in health and disease. Collaborative teams with broad expertise more comfortably tolerate big risks in hypothesis formulation and research methodologies. Thus, while single discipline work will remain important and unquestionably drive new discoveries and innovation, NIH must adjust its funding and training modalities, and foster public-private partnerships, to facilitate breakthroughs at the fertile interfaces of research fields and to enable more collaborative and interconnected open science. Recognizing the increased inclusion of humans as research subjects, NIH must also manage large clinical datasets and tissue banks, integrate data



from social determinants of health, and reinvent approaches and training for ethical research with human subjects.

### **A look to the future**

The SARS-CoV-2 pandemic has driven innovations in funding, data sharing, collaborative research, and public-private partnership financing. The Administration, together with a determined NIH Director, have a unique opportunity to combine the lessons of a changing research enterprise and a public health crisis to create an NIH that reflects a more interconnected world.

The NIH we envision would support a diverse, inclusive and collaborative research ecosystem. Just as natural ecosystems are defined by interactions of organisms with each other and their physical environment, a future research ecosystem would be defined by synergistic interactions among scientists from different backgrounds and disciplines, and between scientists and an open data infrastructure. Scientists would tackle fundamental questions in biomedicine using a “by all means necessary” strategy that incorporates tools, concepts and expertise from all relevant disciplines, and helps research fields refine their approaches and even their fundamental assumptions.

The future NIH ecosystem would be resilient and responsive. Multi-disciplinary literacy and team-based investigation would enable scientists to change research direction when desired or to focus on a new, urgent, emergent investigation when needed. The SARS-CoV-2 pandemic made this need evident. Physicists could partner with virologists and behavioral scientists to develop better models for aerosolization to test the efficacy of distancing and masking in limiting spread; genomics could cross-fertilize with epidemiology to produce new ways to measure and predict spread of COVID-19; and computer scientists could build AI-based data-mining and search tools to help biologists extract new correlations and hypotheses from an explosively growing COVID-19 literature. Clearly, isolated disciplines and siloed NIH Institutes, and a workforce that undervalues contributions from large segments of the U.S. population, are inadequate to develop the science needed to fight this disease, and other complex diseases. The resilient NIH ecosystem will feature activities, structures and policies — from training and research grant mechanisms, to intramural and extramural administrative structures, to partnerships with other

federal agencies and industry — that incentivize and reward creativity, openness, cooperation, and shared expertise. If NIH adopts this vision, a bold, risk-tolerant, diverse, inclusive and collaborative research ecosystem will emerge that broadens and strengthens the scientific community, accelerates scientific discovery, defines biological processes in sufficient detail to understand, treat and cure disease, and improves the health and well-being of all. Change is rarely easy. Some of the proposed pathways will be difficult. Some will take time. But it is undoubtedly worth the effort. Consider the following:

***1. Science will thrive in a research culture that values inclusion, openness, cross-disciplinarity and greatly increased tolerance of risk.***

- New NIH granting mechanisms and coordination across Institutes will incentivize cross-disciplinary and risk-tolerant research programs. Scientists will be supported to build diverse research teams that can seamlessly harness skills and knowledge from various fields and backgrounds.
- NIH diversity and inclusion efforts will attract more people to the sciences. Diversity in the workforce promises a broader sampling of innovative ideas emerging from different experiences and perspectives, while an inclusive environment will give every scientist the opportunity to thrive. International scientists would greatly benefit from such an environment as well.
- A shared data infrastructure, access to expert-supported cutting-edge instrumentation and platforms, and incentives for open science will empower scientists to generate essential data that are immediately and openly shared. With full and open access, scientists across all disciplines will fully harvest data using Artificial Intelligence algorithms to interpret complex information and generate further knowledge.
- Re-envisioned NIH training and fellowship programs will prepare the next generation to work and collaborate comfortably in a data-rich and cross-disciplinary environment and will act as levers to increase and reward diversity and inclusion in the scientific workforce. The dividend will be broadened and accelerated innovation.

## **2. When science thrives, the nation is healthier and more prosperous.**

The public can expect greater health and economic returns on its investments.

- A more diverse, inclusive and collaborative research community will produce research that is better targeted to addressing health needs of the entire U.S. population, better focused on overcoming health disparities. Public trust in science will increase when a diverse and publicly-engaged workforce can better explain how science is done and how it affects all of our lives.
- An inclusive, diverse and collaborative research ecosystem will yield better diagnostics, disease prevention and novel treatments. Personalized genomics already has changed cancer diagnosis and therapy, but such examples are still the exception. As new technologies are applied to medicine – including new imaging modalities, sensitive molecular biomarker detection, therapeutic delivery systems and health IT data integration – precision medicine will complement public health strategies to revolutionize health care. Interdisciplinary collaborations across federal agencies will strengthen NIH's integrated focus on both genetic and molecular determinants, and social, behavioral and environmental determinants of health and disease. We will need these combined insights to make inroads on common diseases, such as obesity, heart disease and addiction, as well as rare ones.

## **3. When science thrives, the U.S. capitalizes on its global leadership role.**

Since World War II, the U.S. has been the global leader in science. But other parts of the world are catching up, largely by following the path forged by the U.S. and investing in biomedical research.

- The U.S. can protect national security and intellectual property more effectively if it motivates and engages in global alliances, rather acting unilaterally, to enforce the rules of a global research ecosystem.
- Through global alliances, the U.S. can remain an attractive destination for international scientists, who are essential to U.S. success in science, job creation, and entrepreneurship.

- The U.S. can directly benefit, as global problems like pandemics and environmental crises are solved more effectively with global approaches.

Biomedical research in the U.S. faces persistent and mounting barriers - barriers to participation of racial and ethnic groups historically excluded from science, barriers to the pursuit of bold discovery science, barriers to collaboration between disciplines, agencies and countries, and barriers to full and equitable access to scientific knowledge. The pathways offered in this report will help the NIH overcome these barriers, accelerating the pace and societal impact of future scientific discoveries for the benefit of all of us.

# Acknowledgments

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**The analysis and recommendations of this report are the authors' alone and do not necessarily represent the views of sponsors and those acknowledged here:**

**The Coalition for the Life Sciences (CLS)** is an alliance of [eight professional organizations](#), working together to foster public policies that advance basic biological research and its applications in medicine and other fields. The issues addressed by the CLS include science education, professional training, and the funding, management, and oversight of scientific work, especially by the federal government.

**The Chan Zuckerberg Initiative (CZI)** provides support for, and is a partner with, the CLS on this project and other CLS activities. CZI was founded in 2015 to leverage technology, community-driven solutions, and collaboration to help solve some of society's toughest challenges, and a mission to build a more inclusive, just, and healthy future for everyone.

**Howard Hughes Medical Institute (HHMI)** is the largest private biomedical research institution in the United States. HHMI scientists make discoveries that advance human health and our fundamental understanding of biology. HHMI also invests in transforming science education into a creative, inclusive endeavor that reflects the excitement of research. HHMI's headquarters are located in Chevy Chase, Maryland, just outside Washington, DC.

**Schmidt Futures** is a philanthropic initiative, founded by Eric and Wendy Schmidt that finds exceptional people and helps them do more for others together. Schmidt Futures knits talent into networks, bet on the most promising ideas through diverse forms of competition and support, and equip people to scale through partners and modern tools. To realize this vision, Schmidt Futures uses a broad set of tools — including gifts, grants, investments, and startup activity — for charitable, educational, and commercial efforts with a public purpose.

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# Appendix

## Executive Orders and Relevant Rules and Regulations and Policies

As a visible and high-impact opportunity to drive progress, the committee recommends that the Administration, in its first 100 days, review current Executive Orders, regulations, and policies, and repeal, reverse, or modify those that appear detrimental to scientific progress, credibility, integrity, innovation, and productive collaboration, including but not limited to:

### Executive Orders/Presidential Proclamations

**On October 21, 2020, President Trump signed the Executive Order on Creating Schedule F in the Excepted Service.** The order establishes a new classification within the Federal workforce titled "Schedule F" for employees serving in confidential, policy-determining, policy-making, or policy-advocating positions that are not normally subject to change as the result of a presidential transition and will be employed "at-will" with none of the civil service qualification requirements or protections that insure expert, independent and apolitical advice to the Administration and Congress. The EO directs agencies to reclassify federal civil service employees in the competitive service who serve in policy-related roles as members of the excepted service by January 19, 2021. This order is likely to apply to all Institute Directors and all policy-related positions at NIH, including grant reviews and funding decision policies. This EO may profoundly change the nature of policy making at NIH toward a more politically driven appointment process for key NIH leadership positions beyond that of the Directors of NIH and NCI. This will negatively impact the necessary stability, experience and independence of the leadership of the agency.

**On September 22, 2020, President Trump signed the Combating Race and Sex Stereotyping Executive Order.** The EO has implications for federal agencies, grantees, and contractors and is a follow-up to a September 4 executive memorandum, M-20-34, which directed executive branch agencies to end trainings on topics such as "critical race theory," and "white privilege." The purpose of the September 22 executive action is to "combat offensive and anti-American race and sex stereotyping and scapegoating," and "divisive concepts." The EO charges that workplace diversity trainings and efforts to address bias and privilege are not to be supported with Federal funding.

**On May 29, 2020 President Trump signed a proclamation that bans the entry of certain Chinese nationals on F or J visas**, including graduate students, and postdoctoral and other researchers. Please note that the ban applies to graduate students, postdoctoral fellows and other researchers who have been funded by, studied at, been employed by or conducted research at or on behalf of an entity in the People's Republic of China that supports the Chinese government's "military-civil fusion" (MCF) strategy.

**On May 29, 2020, President Trump announced the U.S. withdrawal from the World Health Organization.** During the President's announcement, he added that the organization's more than \$400 million annual U.S. contribution will be diverted to other health groups. The full US withdrawal from WHO becomes effective on July 6, 2021.

**In January, 2017 President Trump took down the President's Council of Advisors on Science and Technology (PCAST) website and all its reports.** Included in the reports was a pandemic response playbook called, "Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents." The document is a 69-page National Security Council guidebook developed in 2016 with the goal of assisting leaders "in coordinating a complex U.S. Government response to a high-consequence emerging disease threat anywhere in the world." It outlined questions to ask, who should be asked to get the answers and what key decisions should be made.

### **Department of Health and Human Services' Rules and Regulations and Policies**

**In June 2019, HHS announced the Administration's policy with respect to the use of human fetal tissue from elective abortions in HHS-conducted or -funded research:** Intramural NIH research involving human fetal tissue from elective abortions has been discontinued. New extramural grant applications, or current research grants in the competitive renewal process, must be reviewed by an ethics advisory board which would recommend whether, in light of ethical considerations, NIH can fund the research project.

**On April 22, 2020, the U.S. government abruptly cancelled a recently competitively renewed National Institutes of Health (NIH) grant held by the New York research institute EcoHealth Alliance.** The grant was restored in principle after the legality of the cancellation was challenged, but funding will not be permitted by NIH until the grantee meets numerous inappropriate and difficult requirements. The defunding of the grant after more than a decade of work in this important field

seems to be tied to EcoHealth Alliance's occasional collaboration with the Wuhan Institute of Virology and to a question raised during a Presidential press conference.

**On July 10, 2020, HHS directed hospitals to immediately shift submission of their COVID-19 data to an office in HHS**, bypassing the CDC's National Healthcare Safety Network, the traditional repository of such data. The new reporting would preclude ready access to data by the public, researchers, and media, including the numbers and age ranges of COVID-19 patients treated in each facility, available beds and ventilators. All hospitals were immediately ordered to submit data to a system developed by private contractors.

### **Department of Homeland Security Rules and Regulations and Policies**

**On July 28, 2020, Department of Homeland Security announced that it would reject all initial requests for Deferred Action for Childhood Arrivals (DACA)** and related requests for employment authorization, grant requests for advance parole for international travel only in exceptional circumstances, and limit grants of deferred action and work authorization to one year rather than two years.

**On October 6, 2020, Department of Homeland Security issued the Strengthening the H-1B Nonimmigrant Visa Classification** Program Interim Final Rule revising the definition of "Specialty Occupation" and DOL issued the Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States Interim Final Rule, amending the regulations governing permanent labor certifications and Labor Condition Applications to incorporate changes to the computation of prevailing wage levels. Together, these rules significantly change decades of requirements for the H-1B program.

**On September 24, 2020, Department of Homeland Security proposed a rule to require a fixed period of stay** for international students, exchange visitors and foreign information media representatives to encourage program compliance, reduce fraud and enhance national security. The Notice of Proposed Rulemaking, Establishing a Fixed Time Period of Admission and an Extension of Stay Procedure for Nonimmigrant Academic Students, Exchange Visitors and Representatives of Foreign Information Media, proposes to remove the duration of status framework that currently allows aliens in F, J, and I classifications to remain in the United States for as long as they maintain compliance with the terms of admission.



# Footnotes

- <sup>1</sup> The FAIR Guiding Principles for scientific data management and stewardship <https://www.nature.com/articles/sdata201618>
- <sup>2</sup> Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk (2015), NASEM
- <sup>3</sup> Secretary of Energy Advisory Board Report of the Task Force on Biomedical Sciences, September 22, 2016 [https://www.energy.gov/sites/prod/files/2016/10/f33/9-22-16\\_Report%20of%20the%20SEAB%20TF%20on%20Biomedical%20Sciences%20with%20transmittal.pdf](https://www.energy.gov/sites/prod/files/2016/10/f33/9-22-16_Report%20of%20the%20SEAB%20TF%20on%20Biomedical%20Sciences%20with%20transmittal.pdf)
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- <sup>5</sup> Epidemiological Modeling Needs New, Coherent, Federal Support for the Post-COVID-19 Era, OPCAST, Sept 28, 2020 [http://opcast.org/OPCAST\\_Epidemiological\\_Modeling\\_Report\\_09-28-20.pdf](http://opcast.org/OPCAST_Epidemiological_Modeling_Report_09-28-20.pdf)
- <sup>6</sup> Diversity Matters McKinsey & Company, February 2, 2015; Cultural Diversity, Innovation and Entrepreneurship: Firm-Level Evidence from London.; The business case for diversity in the workplace is now overwhelming.
- <sup>7</sup> [Replicating Meyerhoff for inclusive excellence in STEM](#) , Science 26 Apr 2019 : 335-337
- <sup>8</sup> MD Wong et al Journal of Graduate Medical Education, February 1, 2016
- <sup>9</sup> For example: Biomedical Research Workforce Working Group Report. June 14, 2012. [https://acd.od.nih.gov/documents/reports/Biomedical\\_research\\_wgreport.pdf](https://acd.od.nih.gov/documents/reports/Biomedical_research_wgreport.pdf) and Trends in the Early Careers of Life Scientists (1998) <https://www.nap.edu/read/6244/chapter/1>
- <sup>10</sup> Sexual Harassment of Women Climate, Culture, and Consequences in Academic Sciences, Engineering, and Medicine (2018)
- <sup>11</sup> [Graduate STEM Education for the 21st Century](#), NASEM (2018)
- <sup>12</sup> H.R.6164 - National Institutes of Health Reform Act of 2006 <https://www.congress.gov/bill/109th-congress/house-bill/6164>
- <sup>13</sup> [Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine: Opening Doors](#) <https://www.nap.edu/catalog/25785/promising-practices-for-addressing-the-underrepresentation-of-women-in-science-engineering-and-medicine-opening-doors>
- <sup>14</sup> NASEM, Investigating the Potential Impact of COVID-19 on the Careers of Women in Academic Science, Engineering, and Medicine - <https://www.nationalacademies.org/our-work/investigating-the-potential-impact-of-covid-19-on-the-careers-of-women-in-academic-science-engineering-and-medicine>
- <sup>15</sup> <https://www.nap.edu/read/21824/chapter/3>

From Box 2A:

[https://web.archive.org/web/20200421205441/https://ideas.repec.org/p/bon/boncrc/crcr224\\_2020\\_163.html](https://web.archive.org/web/20200421205441/https://ideas.repec.org/p/bon/boncrc/crcr224_2020_163.html)

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