Sustaining Discovery in Biological and Medical Sciences

A Framework for Discussion

FASEB

Federation of American Societies for Experimental Biology

www.faseb.org/sustainingdiscovery

FASEB
Federation of American Societies for Experimental Biology

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FASEB Mission

A federation of 27 scientific societies, FASEB's mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences through service to our member societies and collaborative advocacy.

FASEB Constituent Societies

The American Physiological Society (APS)

American Society for Biochemistry and Molecular Biology (ASBMB)

American Society for Pharmacology and Experimental Therapeutics (ASPET)

American Society for Investigative Pathology (ASIP)

American Society for Nutrition (ASN)

The American Association of Immunologists (AAI)

American Association of Anatomists (AAA)

The Protein Society (PS)

Society for Developmental Biology (SDB)

American Peptide Society (APEPS)

The Association of Biomolecular Resource Facilities (ABRF)

American Society for Bone and Mineral Research (ASBMR)

The American Society for Clinical Investigation (ASCI)

Society for the Study of Reproduction (SSR)

The Teratology Society (TS)

Endocrine Society (ES)

The American Society of Human Genetics (ASHG)

International Society for Computational Biology (ISCB)

American College of Sports Medicine (ACSM)

Biomedical Engineering Society (BMES)

Genetics Society of America (GSA)

American Federation for Medical Research (AFMR)

The Histochemical Society (HCS)

Society for Pediatric Research (SPR)

Society for Glycobiology (SfG)

Association for Molecular Pathology (AMP)

Society for Free Radical Biology and Medicine (SFRBM)

Executive Summary

The Federation of American Societies for Experimental Biology (FASEB), the nation's largest and oldest coalition of biological and medical researchers composed of 27 member societies and representing over 120,000 scientists and engineers, is concerned about the future of biological and medical research. Inconsistent investment policies, growing demands for research funding, and outdated policies are jeopardizing current and future progress in this important area of research. This is a serious problem for the nation, and requires immediate attention and action. In this report, FASEB presents its analysis of the problems and proposes options for mitigating them.

Investment in biological and medical research has paid enormous dividends, and it has made the United States the world leader in this critical area of science. Publicly sponsored biomedical research produced discoveries that lowered death and disability from polio, heart disease, cancer, and other diseases, and new scientific breakthroughs have given us the opportunity to dramatically accelerate desperately needed progress on therapies for thousands of other diseases and conditions. In addition to improving health and enhancing quality of life, bioscience research has created vibrant new industries. Biotechnology, with its applications to health, agriculture, and environmental remediation, has become a critical component of economic progress.

Unfortunately, the research enterprise that has yielded so much in the past and that offers so much promise for the future is now under tremendous strain. Research budgets have not kept pace with expanding opportunities and rising costs. After adjusting for inflation, the federal investment in the life science has declined by more than 20 percent since 2003. Insufficient funding—along with increased regulatory burden and budgetary uncertainty—is a growing obstacle to future advancement. Rapid growth of the research enterprise fueled increased dependence on external research support, and the demand for research funding has skyrocketed. Consequently, the fraction of submitted proposals that are ultimately funded (the funding rate) are at an all-time low. There are more highly meritorious requests for research funding than the system can accommodate.

Change is taking place throughout the research enterprise as agencies, institutions, and individuals are forced to adapt to new funding and regulatory environments. To ensure that new arrangements and policies are made in a proactive, deliberative manner and will be most conducive to progress, FASEB undertook an examination of the major challenges facing the biological and medical research enterprise and methods to alleviate them. FASEB's Science Policy Committee conducted analyses, developed recommendations, and prepared a discussion framework. After a series of roundtable discussions with representatives of FASEB societies, funding agencies officials, representatives of research organizations, and other stakeholder groups, the document was revised. This final report summarizes key themes that emerged from the analyses and discussions and offers recommendations to maximize the amount and efficient use of research funding, optimize the composition of the research workforce, and improve the funding mechanisms used to support research.

The following sections of this Executive Summary outline the major steps that FASEB believes are critical to sustaining biological and medical research in the United States in the coming decades. The points outlined here and their historical backgrounds are expanded upon in the main body of this report.

1. Maximize research funding

Despite decades of path-breaking discoveries leading to new treatments, diagnostics, and dramatic improvements in health and quality of life, the federal investment in biological and medical research has not kept pace with rising costs, and the research enterprise in the United States is contracting. The National Institutes of Health, the largest federal source of biomedical and life science research funding in the U.S., has lost more than 20 percent of its capacity to support research in the past decade. Other federal research budgets are also declining and impeding scientific progress.

Sustain funding

Stable, predictable increases in federal funding for the biomedical and life sciences are desperately needed to restore lost capacity, maximize discovery, and capitalize on the unprecedented opportunities before us. The size and scope of the federal investment in research make it impossible for other sources of research support to fully replace the decline in federal research dollars. Furthermore, many other sources of research support are contracting as well.

1.1 Congress and the Administration should restore the lost purchasing power of agency research budgets

1.2 Congress and the Administration should provide sustainable and predictable funding for biological and medical research

1.3 Funding agencies should expand mechanisms to facilitate financial support from stakeholders, such as industry, patient groups, and foundations

1.4 The research community should expand its efforts to communicate more broadly the value of biological research and the importance of federal funding

Optimize the use of resources

While more funding is desperately needed, there are ways to partially offset some of the lost capacity for scientific discovery. Over-regulation and other inefficient practices waste scarce research resources. Simplification and harmonization of federal regulations would lessen the financial burden on institutions responsible for compliance. Policies promoting more shared use of research resources and reducing incentives for over-expansion of research facilities are also needed.

Reduce regulatory burden

Compliance with a growing number of regulations has lowered researcher productivity and increased the cost of conducting research. Researchers are spending exorbitant amounts of time on regulatory compliance and reporting, reducing time for research. Research institutions are devoting more resources to regulatory activities, expanding administrative staff, and developing new monitoring systems.

Simplification and harmonization of federal regulations would enable scientists and engineers to expend more effort on research and also lessen the financial burden on institutions responsible for monitoring regulatory compliance. Incentives to implement more efficient oversight practices could also reduce costs, while careful scrutiny of proposed new regulations would help minimize future growth of compliance costs.

1.5 The research community should vigorously and collectively oppose the addition of unnecessary or duplicative regulations

1.6 The federal government should eliminate duplicative or unnecessary regulations, and it should streamline or harmonize those that serve important functions

1.7 The federal government and research institutions should eliminate duplicative or unnecessary training and certification requirements

1.8 Investigators and administrators must take steps to promote efficient regulatory compliance practices at their institution

1.9 The research community should encourage regulatory changes that permit efficient practices, such as multi-site Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs), whenever possible

Enhance deployment and use of resources

More efficient use of existing resources is essential; however, many policies and practices are in conflict with this goal. Timely passage of appropriations bills would help improve resource allocation and planning. More efficient use of infrastructure resources would expand access and leave more funding available for research projects. Research sponsors should provide greater flexibility in shared instrumentation and core facility programs to ensure that equipment is available to the widest possible range of users. Removing incentives for expansionary construction could restore some stability in the research enterprise and reduce long-term financial liabilities for both the federal government and institutions.

1.10 Because of the breakdown in the appropriations process, federal research agencies should be allowed to carry funding over into the following fiscal year

1.11 Research sponsors should provide greater flexibility in shared instrumentation and core facility programs to ensure that equipment is available to the widest possible range of users

1.12 Research sponsors should encourage greater resource sharing when funding infrastructure

1.13 The research community should examine the effect of reducing incentives for debt-financing of new facility construction

1.14 Stakeholders should create a broader range of institutional ranking metrics (including indicators of a stable and sustainable research system) to reduce the likelihood of wasteful overcapacity

2. Optimize funding mechanisms

While increased funding is essential for progress in biological and medical research, research sponsors can expedite progress by improving the ways that researchers are funded. We need to reduce the time spent preparing and reviewing applications. Funding agencies need to increase the evaluation of their portfolios and continue to explore improved mechanisms for investigator-initiated research funding. Grant mechanisms that worked well in the past may no longer be the most effective way to fund biological and medical science in the 21st century.

2.1 Research sponsors should make greater use of just-in-time components in grant applications

2.2 Research sponsors should standardize grant application forms and materials to the greatest extent possible

2.3 Research sponsors should explore the use of merit reviewed pre-proposals

2.4 Research sponsors should consider extending the duration of some investigator-initiated grant awards to decrease the amount of effort spent competing for funding

2.5 Research sponsors should undertake regular evaluations of funding mechanisms and share findings with the broader community

2.6 Advisory councils and boards of research sponsors should review portfolio allocations and prioritize investigator-initiated research

2.7 Research sponsors should explore the impact of funding scientists or research programs instead of proposals for specific projects

2.8 Research sponsors should monitor the amount of funding going to a single individual or research group to ensure a broader distribution of research funding

2.9 Research sponsors should examine the feasibility of awarding partial funding to grants based on their priority score

2.10 Research sponsors should consider creating a transition award for senior investigators

3. Improve workforce utilization and training

The U.S. system of laboratory staffing and research training has been extraordinarily successful. Created in an era of growth, the system is highly productive but dependent on expanding budgets. With resources becoming increasingly scarce, there is a need to find new, yet equally successful ways to employ and train research scientists and engineers. Dependence on external funding and the consequent pressure to produce results quickly must be reduced. Education and training strategies should be regularly evaluated to ensure effective and efficient production of investigators in needed fields and areas of research, and that they are equipped with essential transferable skills.

3.1 Research sponsors should take steps to reduce principal investigator dependence on external salary support

3.2 Institutions should communicate information about career prospects to incoming graduate students and provide information about career paths to current trainees

3.3 The research community should take additional actions to ensure quality training of graduate students and postdocs

3.4 The research community as a whole should continue to monitor graduate and postdoctoral education to ensure that changes do not undermine efforts to diversify the workforce

3.5 NIH should create new funding mechanisms and modify current vehicles to increase the number of physicians and other clinicians entering research careers

3.6 Congress should increase the NIH salary cap contingent upon a reduced F&A cost recovery at higher salary levels

3.7 The research community should employ more staff scientists and consider more extensive use of career technicians

Acknowledgments

This project was chaired by FASEB President-Elect Parker B. Antin, PhD. Bethany Drehman, PhD of FASEB's Office of Public Affairs served as the staff liaison with guidance from Howard Garrison, PhD and Yvette Seger, PhD. FASEB President Joseph R. Haywood, PhD took an active role in the effort and co-chaired discussions of major issues.

Several members of FASEB's Science Policy Committee and FASEB's elected leadership made substantial contributions to the analyses and recommendations (see Appendix B). Representatives from FASEB member societies and other research organizations provided additional perspectives in a series of roundtable discussions convened by FASEB (see Appendix C). We are also grateful for the suggestions made by reviewers from the FASEB Board and member societies.

The FASEB Board and representatives from member societies provided important comments and insights during the review process.

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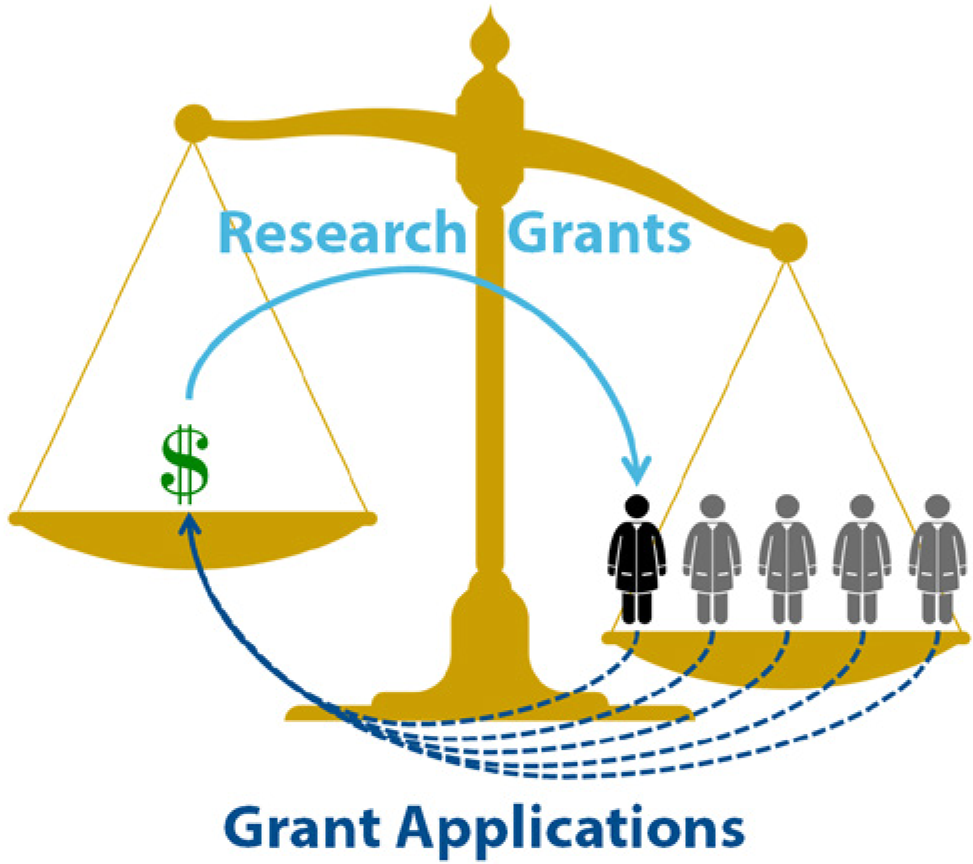


Our national investment in biological and medical research has paid enormous dividends, creating new knowledge, improving health, enhancing quality of life, and launching new industries. It has made the United States the world leader in biological and medical science. Publicly sponsored bioscience research produced the discoveries that lowered death and disability from polio, heart disease, cancer, HIV, and other diseases, and has also led to unprecedented improvements in the world's food supply. Our pharmaceutical industry has grown and prospered by developing new therapeutics from basic research funded by federal agencies, and the multi-billion dollar biotechnology industry emerged from discoveries made by researchers funded by federal agencies. Federally supported research programs across the biosciences have and continue to play a critical role in training the next generation of scientists. Today, students, scientists, patients, and entrepreneurs are attracted to the United States from across the globe by the outstanding scientists and engineers in our research institutions.

Sustained support of the biomedical sciences has dramatically reduced the burden of illness, but thousands of diseases and conditions remain in desperate need of solutions. Challenges brought on by the emergence of Ebola and other infectious diseases are a reminder of how much remains to be done. Fortunately, new scientific breakthroughs provide opportunities to dramatically accelerate progress. For example, new discoveries about the structure of signaling proteins will help develop new and more effective drugs. Scientists have recently identified components of blood (biomarkers) that can be used to diagnose and track the progress of some of our most devastating diseases, and new experimental "organs-on-a-chip" technology may expedite the development and approval of new therapeutics.

In the words of the Director of the National Institutes of Health, Francis Collins, MD, PhD, "Biomedical research is at a critical juncture – a moment of exceptional opportunities that demand exceptional attention." Yet in the face of so much opportunity, the research enterprise that has yielded so much in the past is now under tremendous strain. Biomedical research funding has not grown in over a decade while costs have continued to rise, leading to a drop of more than 20 percent in the capacity to support research and a corresponding drop in the number of research grants awarded (see Figure 1). Funding shortfalls at the National Science Foundation and the United States Department of Agriculture have led to similar constraints in other fields of bioscience research. These losses are a critical obstacle to future advances in biological and medical research, but the research community also faces other challenges. Growing regulatory burdens drain scarce resources, and the educational and grant funding mechanisms of the past may no longer be appropriate for current and future needs. Together, the challenges posed by insufficient budgets, over-regulation, increased demand for research grants, and uneven, unpredictable growth are threatening to constrain our progress in biological and medical research.

Introduction

To address these challenges, FASEB initiated a dialog to identify the major challenges facing the bioscience enterprise and to propose methods to alleviate them. Analyses were conducted under the auspices of FASEB's Science Policy Committee, and the results of this process were summarized in a draft discussion framework that was reviewed by the FASEB Board and the member societies. To further review and extend the analyses and proposals, a series of three roundtable meetings were convened. In addition to representatives of FASEB and its constituent societies, participants included officials from funding agencies, subject matter experts from other fields, representatives from organizations of research institutions, and other stakeholder groups. This document is a summary of key themes that emerged.

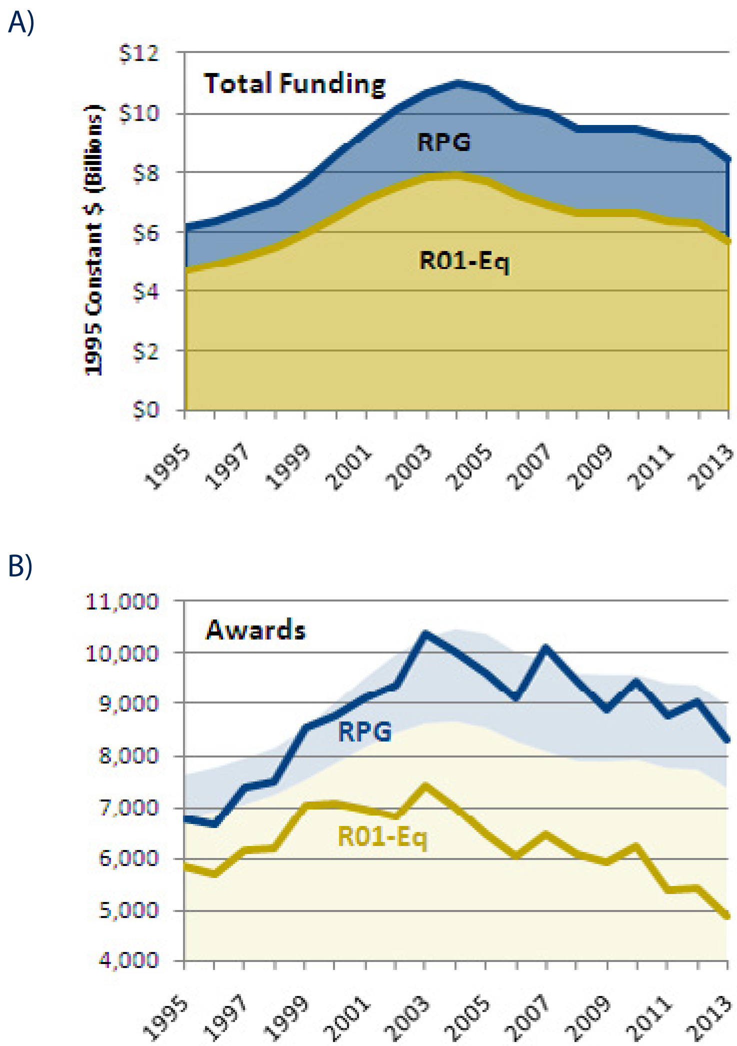


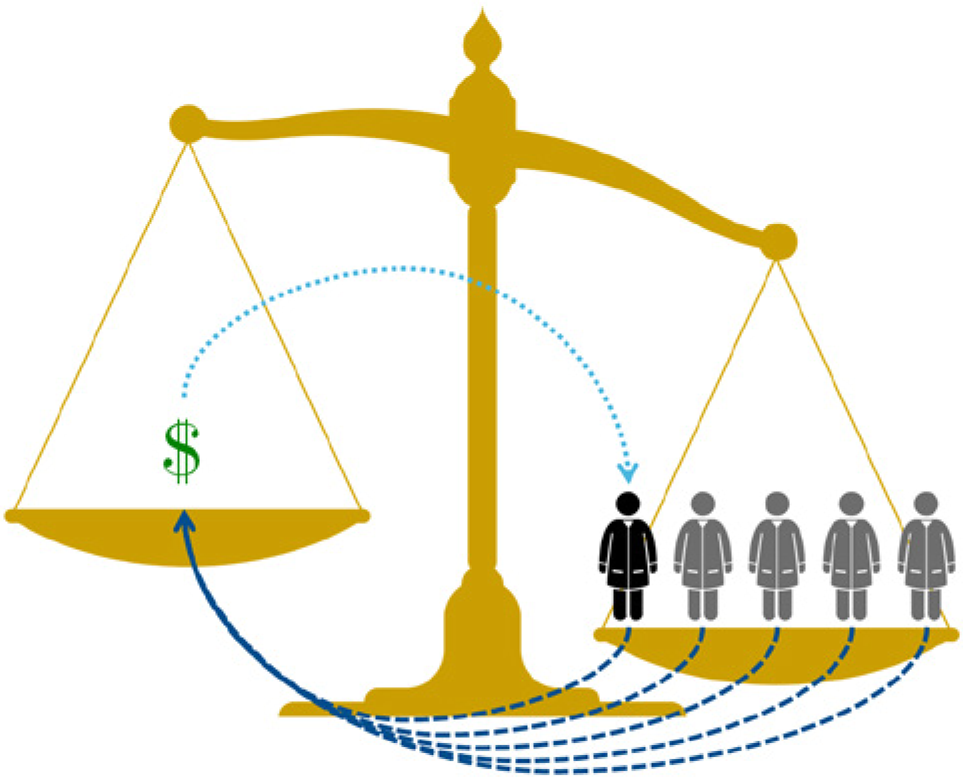
Figure 1: **The decline in NIH funding has resulted in fewer grant awards.** The following trends for NIH Research Project Grant (RPG) (blue) and R01-Equivalent (R01-Eq) (gold) grants, a subset of RPGs, from FY 1995 to 2013 are shown: A) Total funding for all grants (competing and continuing) in billions of 1995 constant dollars; B) Number of awards (new and competing renewals). In panel B, total funding is shown in the background for comparison. Since 2003, the number of RPG and R01-Eq grants awarded has fallen by 20 and 34 percent, respectively.

Source: National Institutes of Health. NIH Data Book and associated success rate tables. *NIH website*.

Technical notes: Constant dollars were calculated using the Biomedical Research and Development Price Index (BRDPI).

Section 1: Insufficient Funding

In the United States (U.S.), the federal government is the single largest source of support for basic and applied biological and medical research. Unfortunately, when adjusting for inflation, the federal investment in life science research has declined by more than 20 percent in the past decade, disrupting ongoing efforts and preventing us from taking full advantage of dramatically expanding research opportunities. There are no substitutes for the scale and scope of the federal investment in research. Moreover, most of the other sources of funding are contracting as well. Potential cost savings exist, such as mitigating regulatory burden, counteracting inefficiencies associated with delayed federal budgets, and optimizing physical infrastructure. However, savings from these measures are insufficient to replace the budgetary losses. Stable and predictable increases in federal funding for the biological and medical sciences are necessary to maintain the preeminence of the U.S. in bioscience research, improve our health and quality of life, and protect us from new and emerging diseases.



Declining federal funding and rising cost of research

1.1: The U.S. federal investment in biological and medical research is decreasing

Approximately 80 percent of federal life science funding is provided through the National Institutes of Health (NIH). The National Science Foundation (NSF) is the engine for scientific discovery in many other areas of the life sciences. In recent years, the budgets of NIH and other research funding agencies have not kept pace with rising costs. The decline in federal support has reduced the number of research projects. This will slow the generation of discoveries essential for new therapies, disease prevention strategies, and other improvements to our health and standard of living.

NIH is the primary source of federal funding for biomedical research: The mission of NIH is to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability." Nearly 85 percent of the NIH budget is awarded as competitive grants to scientists working at universities and other research sites throughout the United States (extramural). Another 10 percent supports research conducted by NIH staff scientists (intramural) with the remaining funds used to support the peer review of grant applications, other administrative services, and physical infrastructure.

See Recommendation 1.1

See Recommendation 1.2

NIH budgets have not kept pace with inflation: Since fiscal year (FY) 2003, the annual growth rate of the NIH budget has reached a historical low of 0.8 percent (see Figure 2, panel A), and budgets decreased in FY 2006, FY 2011, FY 2012, and FY 2013. Adjusting the NIH budget for inflation using the Biomedical Research and Development Price Index (BRDPI) presents an even starker picture (see Figure 2, panel B), with an annual rate of -2.2 percent. Over the FY 2003-2015 time frame, NIH's capacity to support research declined by 22.9 percent.

Biological research budgets of other federal agencies have also declined: In addition to NIH, other federal departments and agencies support life science research (see Table 1 for select examples), comprising 18.6 percent of the 2012 federal investment in these fields.[1] Shortfalls in life science research funding at these agencies are even greater than those at NIH (see Figure 3).

1 Due to the slightly lower growth rates among other agencies, the share of federally funded research supported through NIH has grown over the past few decades, reaching 81.4 percent in FY 2012.

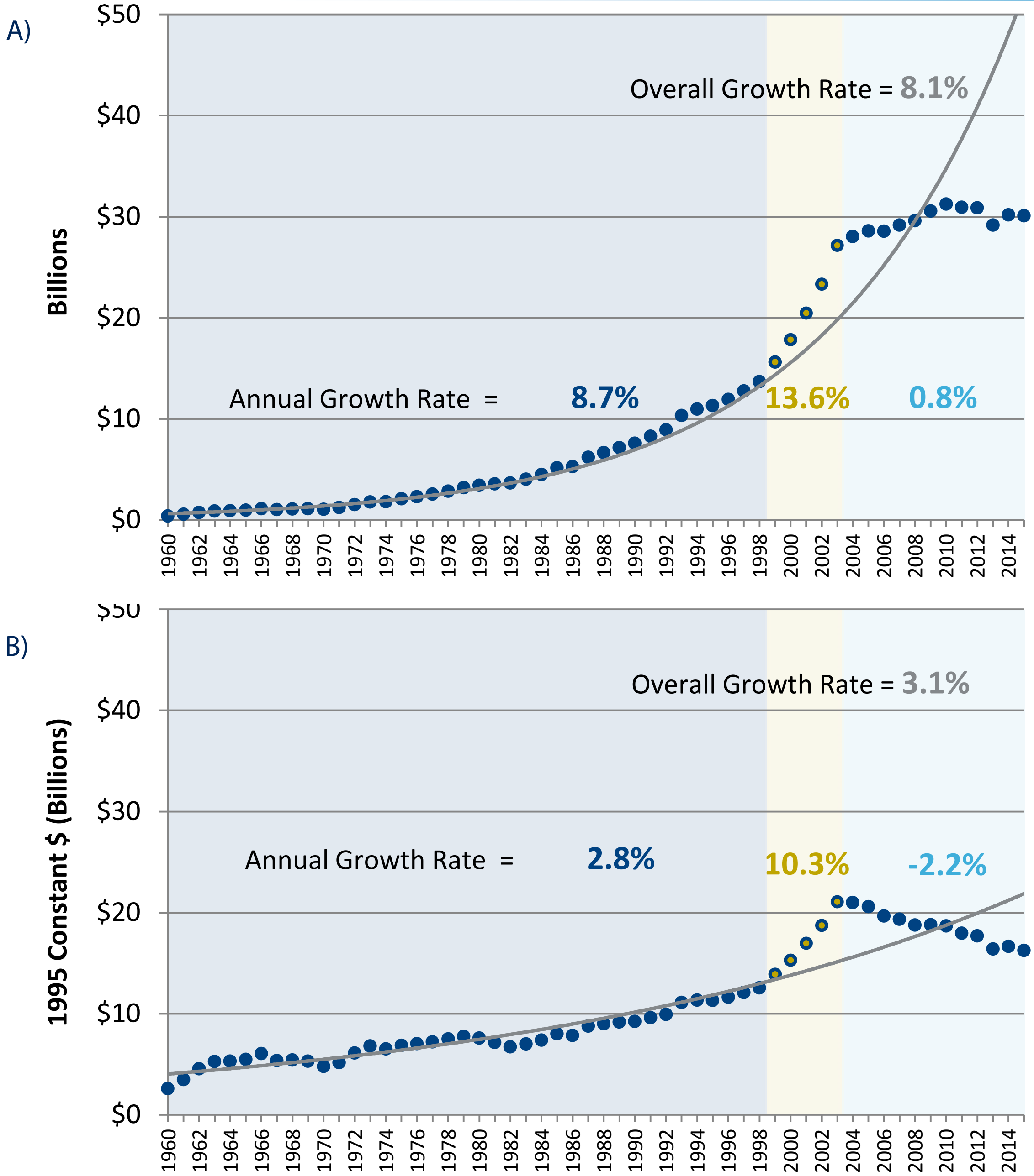


Figure 2: NIH total appropriations and calculated annual growth rates demonstrate that federal support has fallen in the past decade. This the only period in which inflation-adjusted funding fell in nearly every year and marks a departure from previous trends. Funding is presented in A) actual and B) 1995 constant dollars. Annual growth rates for the early growth (FY 1960-1998, dark blue), doubling (FY 1999-2003, gold, data points with gold fill), and post-doubling (FY 2004-2014, turquoise) eras, as well as for combined time period (FY 1960-2014, grey) are shown.

Source: NIH Office of the Budget. Current Mechanism Table and Appropriations History by Institute/Center. *NIH website.*

Technical notes: Data reflect the NIH total budget authority, including Superfunds and budget transfers. Funding from the American Recovery and Reinvestment Act of 2009 is not shown here as this federal support for research was considered "supplemental" and accounted for separately from regular, annual appropriations. Constant dollars were calculated using the Biomedical Research and Development Price Index (BRDPI). Continuous growth rates were established by calculating the best fit curve for $f(t)=ae^{kt}+c$

Federal Department/Agency/ Program	Types of Life Science Research Supported	FY 2014 Appropriations (Billions)
National Science Foundation (NSF)	Basic biological research, environmental and systems biology, research infrastructure and resource development, multi-disciplinary initiatives and projects, science education	$7.171
Department of Energy (DOE), Office of Science	Biofuel research, biogeochemical systems, basic biological research, bioengineering	$5.066
United States Department of Agriculture (USDA), Agricultural Research Service (ARS) and Agriculture and Food Research Initiative (AFRI)	Agriculture, forestry, aquaculture, human nutrition, food safety, animal husbandry	ARS: $1.122 AFRI: $0.316
Department of Veterans Affairs (VA), Medical and Prosthetic Research Program	Biomedical and clinical research with an emphasis on diseases and injuries affecting veterans	$0.586
Department of Defense (DOD), Congressionally Directed Medical Research Programs	Biomedical and clinical research with an emphasis on diseases and injuries affecting soldiers and their families	$0.581

Table 1: Federal departments and agencies that support biomedical and life science research and their respective bioscience research portfolios.

From FY 2003 to 2013, these agencies experienced inflation-adjusted losses to their bioscience research portfolio of approximately 29 percent. This completely eliminated the increased investment between FY 1998 and 2002, returning to levels typical of the 1970s.[2] Each of these agencies has a unique mission, and each research portfolio differs from one another and from NIH. Clearly, budget shortfalls at these other federal science agencies detrimental to their own unique research programs, and these agencies certainly cannot replace NIH's lost capacity to fund research.

See Recommendation 1.4

See Rec. 1.4.1

See Rec. 1.4.2

Federal funding for biological research remains constrained: Federal support for biological and medical research comes out of the discretionary portion of the federal budget. However, caps on discretionary spending, mandated by Budget Control Act of 2011 (BCA), will greatly constrain any possible growth in funding for scientific research through FY 2021 (see the gray bars in Figure 4). BCA caps are set to increase slightly, but inflationary losses are likely to be larger. Therefore, the overall buying power of federal science agencies will continue to decline for at least the next several years unless something is done fundamentally to change funding levels or priorities.

2 Only data from FY 1973 and subsequent years were used in this analysis due to changes in the survey tool and concerns regarding data consistency.

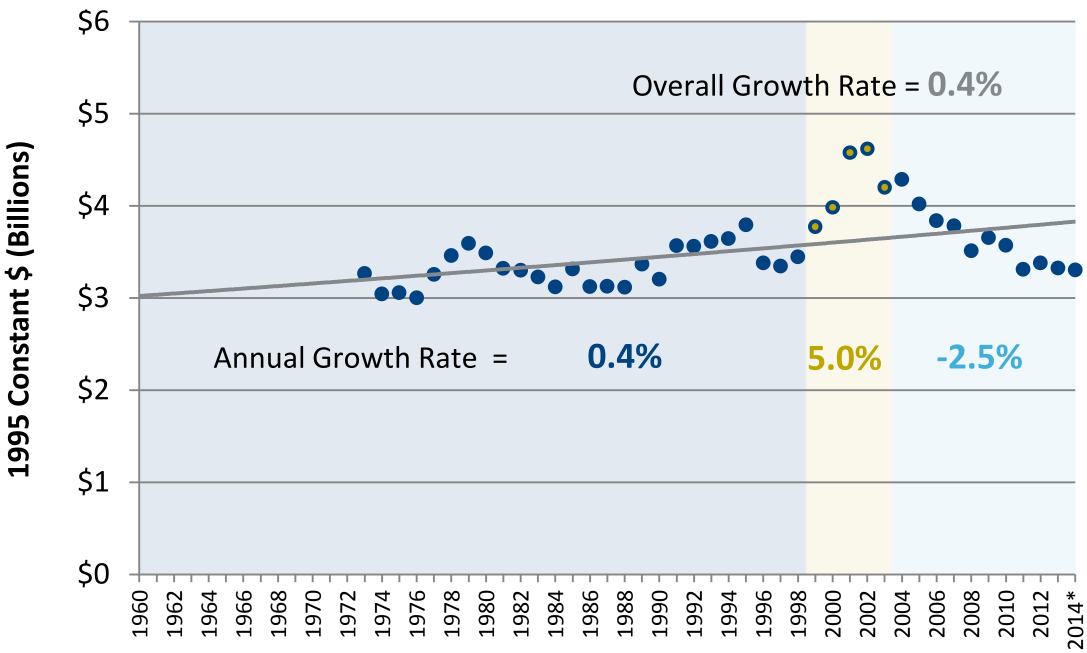


Figure 3: Federal obligations from FY 1973-2012 for basic and applied life science research across all agencies, excluding NIH, also demonstrate declining support in the past decade. The graph presents total obligations for 1995 inflation-adjusted dollars. Federal life science research obligations – excluding NIH – have historically been fairly regular and annual growth rates generally parallel those of NIH appropriations. Just as NIH funding has undergone a precipitous decline in the past decade, so has federal obligations for all other life science research funding.

Source: NSF National Center for Science and Engineering Statistics. Survey of Federal Funds for Research and Development. Data accessed via WebCASPAR.

Technical notes: The survey is conducted annually and collects data from 15 federal departments, their 67 subagencies, and 12 independent agencies. Federal obligations are defined in the survey as "the amounts for orders placed, contracts awarded, services received, and similar transactions during a given period, regardless of when the funds were appropriated." For the time-series data used here, the survey tool has been stable since FY 1973. The survey includes funding from the American Recovery and Reinvestment Act of 2009. Data for FY 2013 and FY 2014 are estimates.

Only obligations assigned as basic or applied research were used in this analysis, and development funding was excluded. We were unable to identify an ideal composite of subcategories to represent research areas substantially supported by NIH, so the broad category "Life Sciences" was used. This category includes agriculture and environmental sciences, but does not include some biomedical engineering research.

Constant dollars were calculated using the Biomedical Research and Development Price Index (BRDPI). Continuous growth rates were established by calculating the best fit curve for $f(t)=ae^{kt}+c$

In addition to the budget caps, BCA also raises the possibility of mandatory cuts, known as sequestration, to nearly all areas of discretionary spending through FY 2021 if Congress and the Administration fail to reduce the deficit (see the light gray part of the bars in Figure 4).[3] As a result of sequestration in FY 2013, NIH funded approximately 640 fewer competitive research project grants (RPGs) than it did in the prior fiscal year, and the budgets of non-competing (multi-year) grants were reduced by an average of 4.7 percent. Sequestration also forced NSF to award 689 fewer grants in FY 2013. Although the Bipartisan Budget Act of 2013 effectively canceled sequestration for FY 2014 and FY 2015,[4] the threat of sequestration remains for FY 2016-2021, and reductions in the number of grant awards similar to those seen in FY 2013 could occur again.

See Recommendation 1.1

Budget cuts result in fewer research grants and projects: Erosion of research budgets, through direct cuts and inflationary losses, limit the number of research grants that can be awarded. For the NIH extramural community, RPGs are the primary source of research funding. R01-equivalent (R01-Eq) grants, an important subset of RPGs, are the most frequently used grant mechanism and provide substantial, multi-year support. R01-Eq grants are the gold standard of research funding. For both RPGs and R01-Eq grants, the number of new awards has decreased as the constant dollar value of the NIH budget has declined (see Figure 1). From FY 2003-13, the inflation-adjusted loss to the NIH budget was -22.4 percent. R01-Eq funding, however, suffered greater losses (-24.7 percent), and the number of R01-Eq awards declined by 34.0 percent over this time period.

See Recommendation 1.2

See Recommendation 1.4

Unpredictable funding hinders the ability of agencies, institutions, and researchers to plan for the future: Basic research discoveries and their subsequent application can take years, even decades, and investigators, their institutions, and funding organizations typically plan multi-year research programs. Uncertain budgets and high annual variability in grant support makes such planning difficult and impedes the optimal use of funding resources.

See Rec. 1.4.1

See Rec. 1.4.2

See Rec. 1.4.3

See Rec. 1.4.4

See Rec. 1.4.5

Instability diminishes the value of the federal investment in research: The past decade has seen very high variability in federal funding. Sequestration, for example, removed $1.7 billion (or 5.5 percent) of the NIH budget and $149 million (or 2.1 percent) from NSF in FY 2013. Abrupt budget cuts force reductions to research grants, closing of laboratories, and halting of research projects. Time, energy and resources invested in prematurely terminated research projects are lost. The often arbitrary nature of the cuts means that the

3 The BCA required Congress to enact $1.2 trillion in deficit reductions across ten years and staring in FY 2012; failing to do so would trigger sequestration, which aimed to achieve these reductions through across-the-board cuts in FY 2013 and lowered spending caps from FY 2014-2021.

4 Under the FY 2014 budget, the Bipartisan Budget Act of 2013 restored only a portion (59 percent in actual dollars for NIH) of the research funding lost in FY 2013 as the budgetary caps (pre-sequestration levels) still remained below FY 2012 levels.

losses are not based on an evaluation of merit or potential, and rather are a function of timing. Even if funding is later restored, the disruptions in funding are costly. Delays necessitate new start-up costs and the recruitment of new staff. Personnel losses, and the consequent loss of expertise, may have long-term consequences as highly trained researchers seek employment in other fields. Budgetary instability is extremely disruptive, costly to research, and contributes to unnecessary delay in the discovery pipeline.

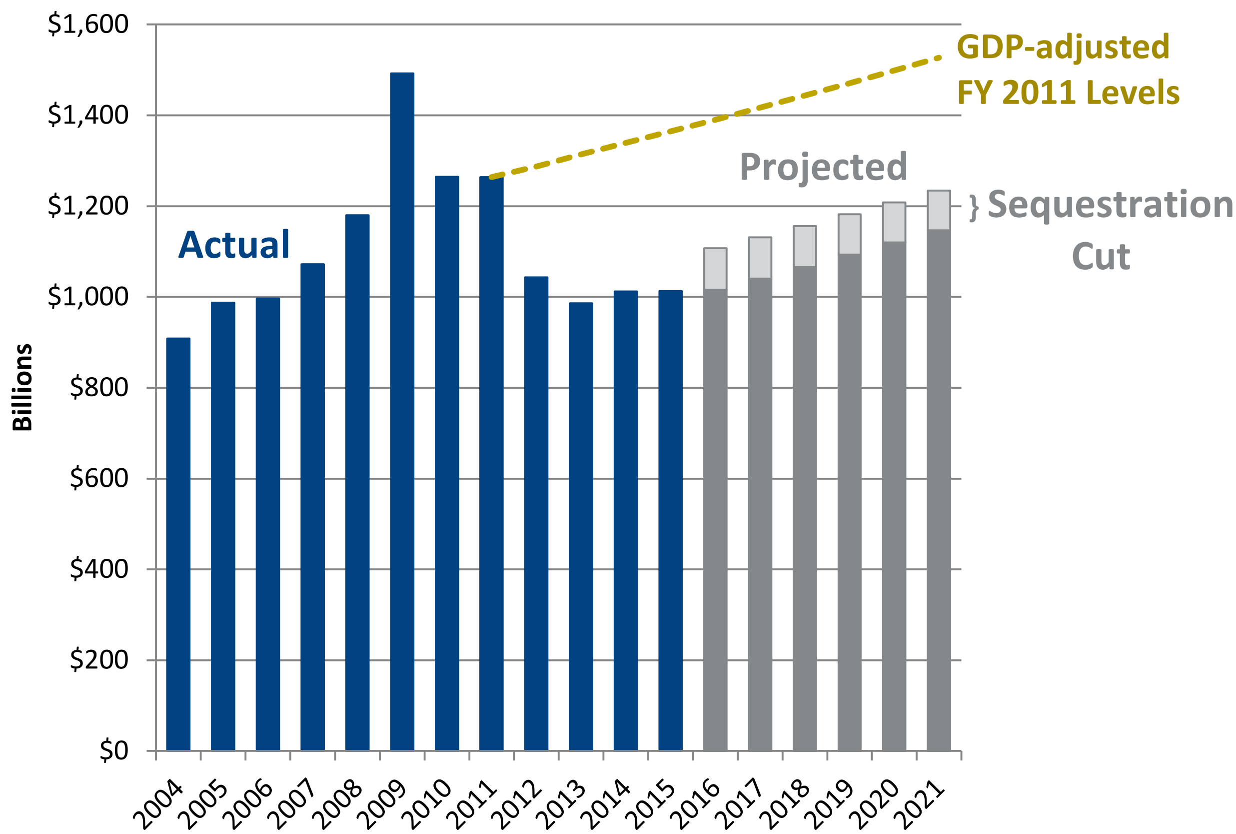


Figure 4: **U.S. federal discretionary spending is highly constrained through FY 2021.** Actual discretionary spending (blue) and caps under current legislation (gray) are indicated. The sequestration cuts mandated by the Budget Control Act (BCA) are shown for out years (pale gray). The BCA greatly limited discretionary spending in subsequent years as illustrated by inflation-adjusted FY 2011 levels (gold, dotted line).

Source: Federal Science Partners LLC

Technical notes: Caps and funding levels were calculated from legislation including appropriations bills, the Budget Control Act of 2011, American Taxpayer Relief Act of 2012, and Bipartisan Budget Act of 2013.

Constant dollars were calculated using the Chain Type Price Index For The Gross Domestic Product (GDP).

1.2: Other research sponsors cannot replace lost Federal support for research

Federal investment in biological and medical research is declining. Universities, medical schools, and other research institutions also receive research funding from state governments, private industry, and philanthropies. These entities, however, are unable to replace the lost federal funds, and their support does not match the breadth and variety of subjects supported by the federal government.

See Recommendation 1.4

See Rec. 1.4.3

State higher education funding has declined: In FY 2012, approximately eight percent of total life science research and development (R&D) expenditures at public universities were financed by state and local governments.[5] This funding is used to provide laboratory equipment and materials, build and maintain research laboratories on university campuses, and employ salaried faculty, students, and other staff who conduct research. State support, however, has declined concurrently with funding losses at federal research agencies and, in some cases, fallen at a much faster pace. In the past five years, total state funding (tax appropriations plus other sources) for higher education institutions has declined in 38 of the 50 U.S. states. In 12 states, losses were greater than 20 percent, and an additional 12 states experienced losses greater than 10 percent (see **Table 2**).[6] These recent reductions in state and local support are a relatively new development but may reflect a permanent shift in state spending priorities.[7]

Philanthropies cannot replace lost federal funding: While an important complement to federal funding, the scale and scope of philanthropic research support makes it an insufficient replacement for lost federal dollars. Grants

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5 **NSF National Center for Science and Engineering Statistics.** Higher Education Research and Development Survey. Data accessed via WebCASPAR in December 2013. Available data range: 2010-2012.

6 **Center for the Study of Education Policy,** Illinois State University. Grapevine. FY 2012-2013 tables. Accessed November 2013.

These figures are not inflation-adjusted. Therefore, the number of states whose funding was effectively lower in 2013 can reasonably be expected to be closer to 46 of 50. Alaska, North Dakota, Wyoming, and Illinois did see substantial growth during this period. However, the first three states rank in the bottom quartile for total funding, and the increase in Illinois was due primarily to the bolstering an underfunded pension program.

7 **Center for the Study of Education Policy,** Illinois State University. Grapevine. Historical reports for 1974-75, 1979-80, 1989-90, 1992-3, 1995-96, 2005-06, 2012-2013.

State	Five-Year Percent Change (FY 2008-13)
Alabama	-28.4 %
Alaska	22.3%
Arizona	-36.6%
Arkansas	3.0%
California	-23.9%
Colorado	-14.3%
Connecticut	-7.5%
Delaware	-11.0%
Florida	-24.9%
Georgia	-6.8%
Hawaii	-7.4%
Idaho	-12.3%
Illinois*	21.0%
Indiana	2.0%
Iowa	-9.9%
Kansas	-8.1%
Kentucky	-10.7%
Louisiana	-31.2%
Maine	-2.6%
Maryland	3.7%
Massachusetts	-22.1%
Michigan	-21.5%
Minnesota	-17.6%
Mississippi	-11.6%
Missouri	-8.9%
Montana	2.9%
Nebraska	0.4%
Nevada	-23.8%
New Hampshire	-35.7%
New Jersey	-7.6%
New Mexico	-21.3%
New York	2.8%
North Carolina	6.6%
North Dakota	35.4%
Ohio	-10.9%
Oklahoma	-10.7%
Oregon	-19.8%
Pennsylvania	-18.3%
Rhode Island	-14.2%
South Carolina	-22.2%
South Dakota	-4.4%
Tennessee	-11.2%
Texas	1.2%
Utah	-7.8%
Vermont	-3.1%
Virginia	-9.7%
Washington	-22.4%
West Virginia	-2.9%
Wisconsin	-4.8%
Wyoming	32.3%

Table 2: Total state support (tax-based appropriations plus other sources) for higher education has fallen from FY 2008 to FY 2013. In 38 of the 50 U.S. states, state government support for higher education declined in actual dollars. Accounting for inflationary losses would raise this number to approximately 46 states.

Source: Center for the Study of Education Policy, Illinois State University. Grapevine. FY 2012-2013 tables. Accessed November 2013. It is produced in cooperation with the State Higher Education Executive Officers.

Technical notes: Other state sources of non-tax appropriations include lottery proceeds and interest from state-funded endowments.

These figures are not inflation-adjusted, and six of the 12 states with increases grew by less than five percent from FY 2008-2013. Therefore, the number of states whose funding was effectively lower in 2013 can reasonably be expected to be greater than 38.

*The recent gains in Illinois are due to increased appropriations to the State Universities Retirement System to rectify under-funded pension programs

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See Recommendation 1.3

See Rec. 1.4.4

from foundations accounted for only a small percentage of the total U.S. biomedical and life science research funding. And while funding from major foundations for life science and medical research increased by approximately 80 percent from 2004 - 2011,[8] this increase was only able to replace 12 percent of NIH's lost buying power during this same time period. (Philanthropic gifts from individuals and other entities appear to provide an equivalent level of funding as foundation grants, although the data are less robust.[9]) Moreover, foundations tend to support research in specific areas and are less likely to support a program of broad, fundamental research.[10] In many cases, foundations – unlike federal agencies – do not contribute to the cost of research infrastructure because they either do not reimburse facility and administrative (F&A) costs or pay far below the negotiated federal rates.[11]

See Recommendation 1.3

See Rec. 1.4.5

Industry R&D is not a substitute for federal support: Industry R&D budgets are also decreasing and unable to offset the lost federal research support. Total biomedical R&D expenditures by U.S. private companies declined over the period of 2007-2012.[12] While important to progress in the biological and medical sciences, the type of research likely to receive industry support is concentrated in specific areas and unable to replace the broad, long-term investments made by public agencies.

Basic research projects, the source of path-breaking insights that ultimately lead to new products and processes, are unlikely to attract industry funding. The return on investment in basic research, while often extraordinary, is unpredictable and materializes over the long term, making it less attractive to profit-oriented firms. Industry research is heavily weighted towards application and development,[13] and industry-funded grants and contracts at universities are likewise concentrated in more applied and translational biological fields.[14]

8 **The Foundation Center.** Foundation Stats, dataset: "Total FC 1000 Grants" Accessed December 2013.

9 **Murray FE.** Evaluating the Role of Science Philanthropy in American Research Universities. National Bureau of Economic Research. Working Paper Series number 18146. June 2012.

10 Ibid.

11 **Reardon S.** Charitable grants found lacking. *Nature* News. 2013; 504(7480): 343.

12 **Chakma J, Sun GH, Steinberg JD, Sammut SM, Jagsi R.** Asia's Ascent – Global Trends in Biomedical R&D Expenditures. *N Engl J Med.* 2014; 370(1):3-6.

13 **NSF National Center for Science and Engineering Statistics.** *National Patterns of R&D Resources: 2011–12 Data Update.* December 2013. NSF 14-304.

In 2011, 78 percent of R&D expenditures funded by industry were for development, 16 percent for applied research, and just under 6 percent for basic research. In contrast, federal R&D expenditures were 46 percent for development, 23 percent for applied research, and 31 percent for basic research.

14 **NSF National Center for Science and Engineering Statistics.** Higher Education Research and Development Survey

Industry support was compared to total funding from all sources to determine proportional support levels.

Through grants to universities and other educational institutions, federally funded research makes a major contribution to the education and training of young scientists and engineers. This is not the case with industry-funded R&D. In 2012, only one percent of business R&D spending was made at universities and colleges, the place where the vast majority of U.S. students gain research experience.[15]

Intellectual property issues are another constraint associated with industry R&D, and industry sponsorship may not promote as much research accessibility and transparency as federal funding. A 2005 study of industry contract norms for clinical trials conducted at U.S. medical schools found large variations in the restrictive provisions that senior administrators deemed acceptable, which sometimes included "gag clauses" and limitations on which party is permitted to write the resulting manuscripts.[16]

Institutions are facing growing financial constraints: Some institutions are able to use endowments, philanthropic gifts, and other internal funds for research. (Licensing revenue from university discoveries can also supplement research funding, but this revenue is quite modest at most institutions.[17]) However, at the vast majority of U.S. research institutions, internal financial support is limited and cannot replace the loss in research funding from federal, state, and other sponsors.

See Rec. 1.4.3

15 **NSF National Center for Science and Engineering Statistics.** NSF 14-304. *This does not include philanthropic gifts and other forms of support beyond contracted research.*

16 **Mello MM, Clarridge BR, Studdert DM.** Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry. *The New England Journal of Medicine*. 2005; 352(21): 2202-2210.

17 **So AD, Sampat BN, Rai AK, Cook-Deegan R, Reichman JH, et al.** Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience. *PLoS Biology.* 2008; 6(10): e262.

1.3: Better resource management can provide some relief

Careful stewardship of the public investment in research is a responsibility of the entire research community. Opportunities to make better use of research resources need to be identified and pursued. Savings generated by reducing bureaucratic excesses, implementing better federal budgeting practices, and increased resource sharing can maximize return on the public investment. While these savings are not large enough to offset the budgetary losses, they should not be ignored.

1.3.1: Over-regulation increases the cost of research for the federal government, institutions, and other research sponsors

The number and range of federal regulations has greatly expanded over the past two decades, increasing the cost of research, reducing the amount of research that can be conducted, and delaying discovery.

See Recommendation 1.6

See Rec. 1.6.3

See Recommendation 1.7

Redundant regulations are wasteful: Federal regulations and policies are designed to ensure that research is conducted safely and ethically and that federal research funds are used as intended. Regulations are established by Congress. Various federal departments and agencies set policies to implement regulations and address other areas of concern. Sometimes regulatory policies are not aligned with each other, resulting in non-identical, overlapping rules. For example, federal agencies have different financial conflict of interest reporting policies for researchers. Compounding this, state and local governments can add another layer of duplicative rules, as in the case of travel regulations. Regulatory redundancy creates an overly complex and confusing regulatory landscape for investigators and research institutions to navigate.

See Recommendation 1.5

The number of federal regulations is rising: In the 1990s, the federal government promulgated approximately 1.5 new or substantially changed federal regulations and policies per year that "directly affect[ed] the conduct and management of research under Federal grants and contracts." In the past

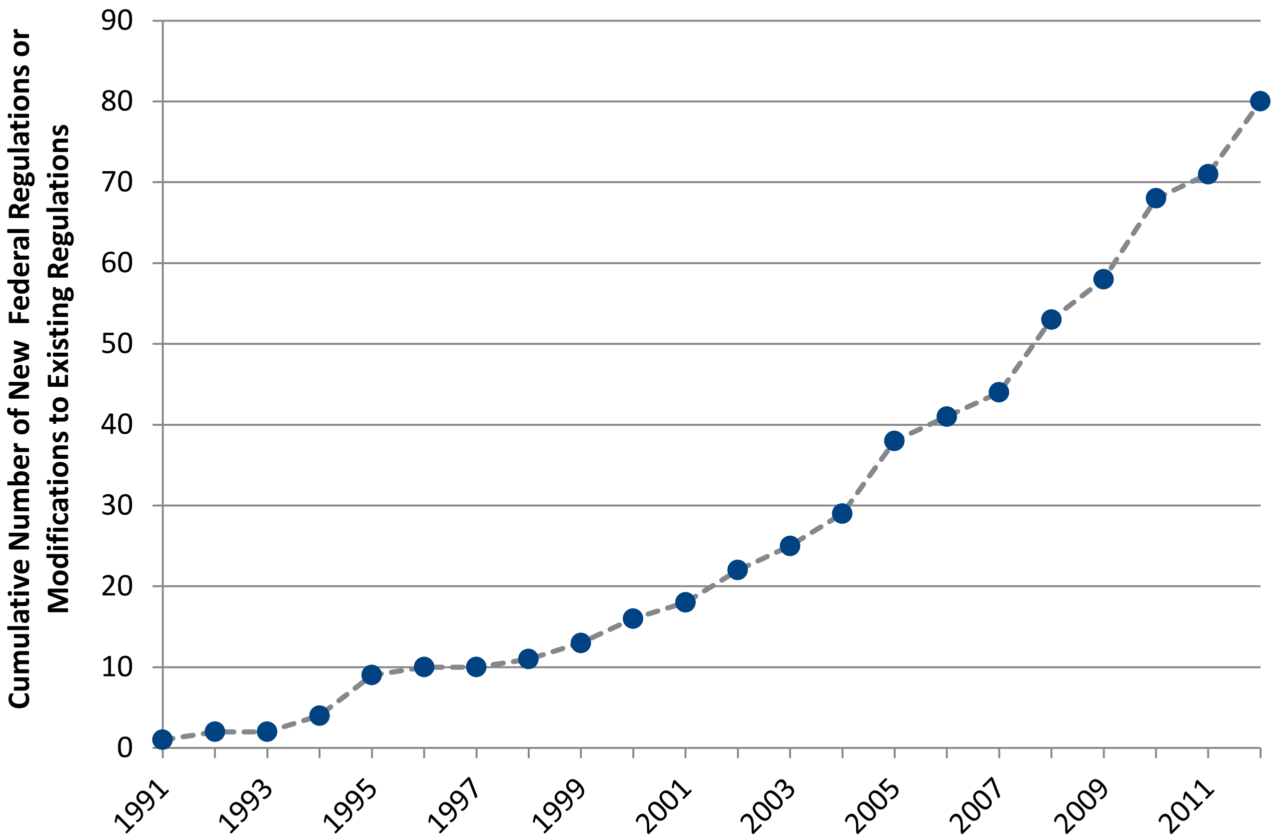

Figure 5: The cumulative number of new federal regulations and modifications to existing regulations has rapidly increased from 1991 to 2012. In addition to these new regulations and regulatory modifications, a further 27 implementation and interpretation changes were identified during this time period. Research institutions receiving federal research funding must maintain compliance with this growing number of regulations.

Source: Council on Government Relations (COGR). *Federal Regulatory Changes Since 1991*. November 15, 2013.

Technical notes: The COGR document lists federal regulatory changes that affect "the conduct and management of research under Federal grants and contracts" in chronological order.

In some instances, regulations were instituted and/or amended more than once; in these cases, all relevant changes were tallied. Also, when legislation required additional agency-based regulation, both the date of the legislation and the date of the agency regulation(s) were used.

Regulations associated with the American Recovery and Reinvestment Act (ARRA) of 2009 are not included.

See Recommendation 1.5

See Rec. 1.5.1

See Rec. 1.5.2

See Rec. 1.5.3

decade (2003-2012), this number has increased to 5.8 per year (see Figure 5). This does not include the 27 significant implementation and interpretation changes since 1991 that affect operations at research institutions; most of which occurred in the last five years.[18]

Federal agencies and offices issue guidance documents, including Frequently Asked Questions (FAQs), to clarify regulations and policies. This guidance has also increased in the past two decades. For example, the October 2013 NIH Grant Policy Statement[19] has more than twice as many words as the April 1994 version[20] (then titled Public Health Service Grants Policy Statement). Commentaries for laboratory animal protocols published in the journal "Lab Animal" by the NIH Office of Laboratory Animal Welfare grew from approximately 1.5 per year from 1996-2005 to approximately 5.0 per year from 2006-2013.[21] To avoid the risks of noncompliance and the resulting penalties, institutions often treat new guidance as additional regulation, transforming something meant to serve as helpful advice into a rigid, time-consuming requirement.

See Recommendation 1.8

See Recommendation 1.7

We have created a culture of over-compliance: Seeking to quickly comply with new regulations and policies and avoid any penalties or liabilities, institutions often adopt inefficient and risk-adverse practices. This results in time-consuming and complex systems that go well beyond legal requirements. Examples of institutional over-compliance include using detailed budgets in cases where simpler modular budgets are required, adding conflict of interest reporting to the review of animal research protocols, and requiring detailed justifications for small purchases (e.g., less than $20).[22] The rapidly changing regulatory landscape hinders efforts to rein in over-compliance.

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18 **Council on Government Relations (COGR).** *Federal Regulatory Changes Since 1991*. November 15, 2013.

19 **NIH Office of Extramural Research.** NIH Grants Policy Statement. *NIH website*. October 1, 2013.

20 **NIH Office of Extramural Research.** PHS Grants Policy Statement. *NIH website*. April 1994.

21 **NIH Office of Laboratory Animal Welfare**. Commentary on Lab Animal Protocol Review Columns. *NIH website*. Last updated April 22, 2014. Accessed July 21, 2014.

22 These examples were taken from individual responses to the FASEB 2013 Survey on Administrative Burden. Similar examples and many other instances of over-compliance were also reported in the following documents:

Decker RS, Wimsatt L, Trice AG, Konstan JA. *A Profile of Federal-Grant Administrative Burden among Federal Demonstration Partnership Faculty: A Report of the Faculty Standing Committee of the Federal Demonstration Partnership.* January, 2007.

Schneider SL, Ness KK, Rockwell S, Shaver K, Brutkiewicz R. *Federal Demonstration Partnership (FDP) 2012 Faculty Workload Survey Research Report*. April 2014.

National Science Board. *Reducing Investigators' Administrative Workload for Federally Funded Research*. March 2014. NSB-14-18.

Administrative burden decreases investigator time spent conducting research, reducing productivity: With the proliferation of federal regulations, reporting requirements, and associated administrative tasks, investigators have less time available to conduct research. This diversion of time and effort impedes progress on research projects. Delays and waste caused by excessive administrative tasks and bureaucracy are frustrating for researchers and also take a toll on their morale.[23]

See Recommendation 1.5

See Recommendation 1.7

See Recommendation 1.9

The increasing regulatory burden facing institutions, combined with the federal cap on the administrative portion of F&A cost reimbursement, contributes to reduced administrative support for faculty. Because administrative expenses above the cap are not recovered, [24] institutions may shift personnel and resources away from individual faculty to the institution's compliance activities, as illustrated in this comment from a major research university:

> *"[T]he institutional administrative support that is available to faculty has eroded as more and more staff time is consumed by addressing new requirements, and as more and more resources are diverted from faculty support to fund new staff to administer systems, programs, reviews, and other duties associated with the ever changing reporting, regulatory, and monitoring requirements."* [25]

Added regulations raise the administrative costs of research: Increased costs stemming from regulatory expansion include: (1) the salaries of the growing number of administrators required for institutions to maintain compliance; (2) the purchase or development of software to fulfill compliance tasks; and (3) the salaries and time of investigators and research personnel spent on administrative activities (see box on FDP surveys of faculty administrative workload). As the number of federal regulations and policies increased, more institutional staff time has been dedicated to compliance, and the number of executive and professional administrative staff at research institutions has grown. Analyses of the Integrated Postsecondary Education Data System collected by the U.S. Department of Education documented this expansion of executive and professional administrative positions, which

See Rec. 1.5.3

See Recommendation 1.8

23 For examples, see the following:

Holleman W, Gritz ER. Biomedical Burnout. *Nature*. 2013; 500(7480): 613-614.

National Science Board. NSB-14-18.

Federation of American Societies for Experimental Biology (FASEB). *Findings of the FASEB Survey on Administrative Burden.* June 07, 2013.

24 Raising the cap would result in fewer and/or smaller awards in this era of constrained federal funding. Also, these caps are the only mechanism in place to constrain the rising costs of administration; unlike research proposals, research administrative activities does not undergo external merit review.

25 **National Science Board.** NSB-14-18.

greatly outpaced growth of full-time faculty positions (see Figure 6).[26, 27] These reports concluded that the increase in government mandates was a major cause of administrative staff growth.

See Recommendation 1.5

See Recommendation 1.6

These additional staff costs are significant. The American Recovery and Reinvestment Act of 2009 (ARRA) mandated quarterly reporting of research progress, financial information, sub-awards, and vendor use, as well as separate management of ARRA funds from other forms of federal support. A Federal Demonstration Partnership (FDP) survey of member universities found that extra administrative staffing costs alone totaled $7,973 per ARRA award beyond the normal administrative costs of federal grants. This figure does not include faculty and research staff time spent on compliance, which would further increase the estimated costs. [28]

Personnel costs are not the only additional expense resulting from new regulations. In 2011, a consortium of university associations reported that software systems for effort reporting cost universities approximately $500,000 each.[29] An informal survey on the costs of compliance with the 2011 amendments to the Public Health Service regulations governing financial conflicts of interest described expenditures of $250,000 - $300,000 to build or purchase and then implement new software.[30]

Growing administrative expenses divert resources from other areas – including funds for research personnel, laboratory equipment, and infrastructure. By draining funds from these areas, regulatory expansion is slowing progress in science and technology.

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26 **Desrochers DM, Kirshstein R.** Labor Intensive or Labor Expensive? Changing Staffing and Compensation Patterns in Higher Education. *Delta Cost Project Issue Brief.* February 2014.

27 **Thornton S, Curtis JW.** Losing Focus: The Annual Report of the Economics Status of the Profession, 2013-14. *American Association of University Professors Academe Magazine.* March-April 2014.

28 **Federal Demonstration Partnership, Research Administration Committee, ARRA Subcommittee.** *The FDP ARRA Administrative Impact Survey Report*. December 5, 2011.

29 **Association of American Universities, Association of Public and Land-grant Universities, Council on Governmental Relations.** *Regulatory and Financial Reform of Federal Research Policy Recommendations to the NRC Committee on Research Universities*. Letter. January 21, 2011.

30 **Blum C.** Capitol View. *NCURA Magazine* October/November 2013; 50(5): 4-5.

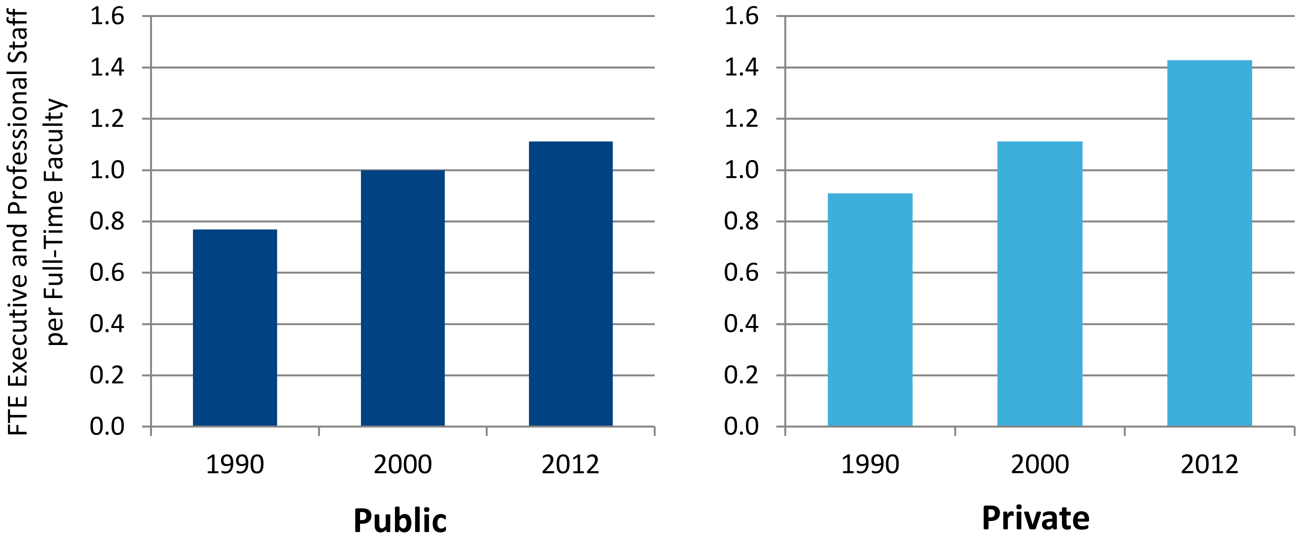

Figure 6: **The number of full-time equivalent (FTE) executive and professional staff has grown faster than the number of full-time faculty** at public (dark blue) and private (turquoise) academic research institutions.

Source: Desrochers DM, Kirshstein R. Labor Intensive or Labor Expensive? Changing Staffing and Compensation Patterns in Higher Education. *Delta Cost Project Issue Brief.* February 2014.

Technical notes: The Delta Cost Project, now based at the American Institutes for Research, has generated a database for 1987-2010, 24-year matched set from the Integrated Postsecondary Education Data System (IPEDS) collected by the U.S. Department of Education National Center for Education Statistics. The Delta Cost Project's database was combined with the 2011 IPEDS Fall Staff Survey dataset. The report used the following definitions for faculty and staffing categories:

> *"Full-time faculty: Staff whose primary responsibility is instruction, research, public service, or a combination of these roles. Faculty may hold the rank of professor, associate professor, assistant professor, instructor, lecturer, or equivalent; faculty may be on tenure track, not on tenure track, or 'without faculty status.'*
>
> *. . . Executive, administrative, and managerial (EAM): Positions where work is directly related to management policies or general business operations of the university. Examples include presidents, vice presidents, managers, provosts, and deans. Assistant and associate positions (e.g., assistant deans, associate department heads) also are included if their principal activity is administration, not instruction. (Deans and department heads whose principal activity is instruction, research, or public service are classified as faculty/instructors.)*
>
> *Professional (support and service): Positions that provide student services, academic, or professional support and generally require a bachelor's degree. Examples include business/financial analysts, human resources staff, computer administrators, counselors, lawyers, librarians, athletic staff, and health workers."*

[See Recommendation 1.6](#)

[See Rec. 1.6.1](#)

[See Rec. 1.6.2](#)

[See Recommendation 1.7](#)

[See Recommendation 1.8](#)

[See Recommendation 2.1](#)

[See Recommendation 2.2](#)

Federal Demonstration Partnership Surveys document investigator time lost to administrative tasks [31, 32]

In the 2005 and 2012 FDP surveys on faculty workload, respondents in the biological, health, and agricultural sciences reported that more than 40 percent of their time spent on federal grants was for pre- and post-award administrative tasks (see Figure 7). Survey participants estimated that between one-quarter and one-third of this time could be reallocated to active research if greater assistance was provided.

Faculty members have reported declining quality and quantity of administrative support at their institution.[33] In the 2005 FDP survey, agriculture, biology, life science, and health science faculty reported receiving limited assistance for most administrative tasks. The increasing complexity of the regulatory landscape certainly makes it more difficult for institutional and agency staff to adequately assist faculty. In the 2012 FDP survey, only 21 percent of faculty agreed with the statement, "[w]hen I have questions about federal regulations related to research, obtaining answers is straightforward." Respondents to the 2012 FDP survey were also more likely to agree than disagree with statements that the resulting workload is "exhausting" and serves as a barrier to productivity. In the 2005 FDP survey report, one investigator clearly articulated this problem:

> *"A major problem with administrative/compliance burdens is not simply the time but also the erosion of creativity and individual initiative. This is hard to address by a survey, but is the most important factor in driving the best students away from scientific careers."*

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31 **Decker.** *A Profile of Federal-Grant Administrative Burden*

32 **Schneider.** *Faculty Workload Survey Research Report*

33 For select examples, refer to the following reports:

National Science Board. NSB-14-18.

FASEB. *Survey on Administrative Burden*

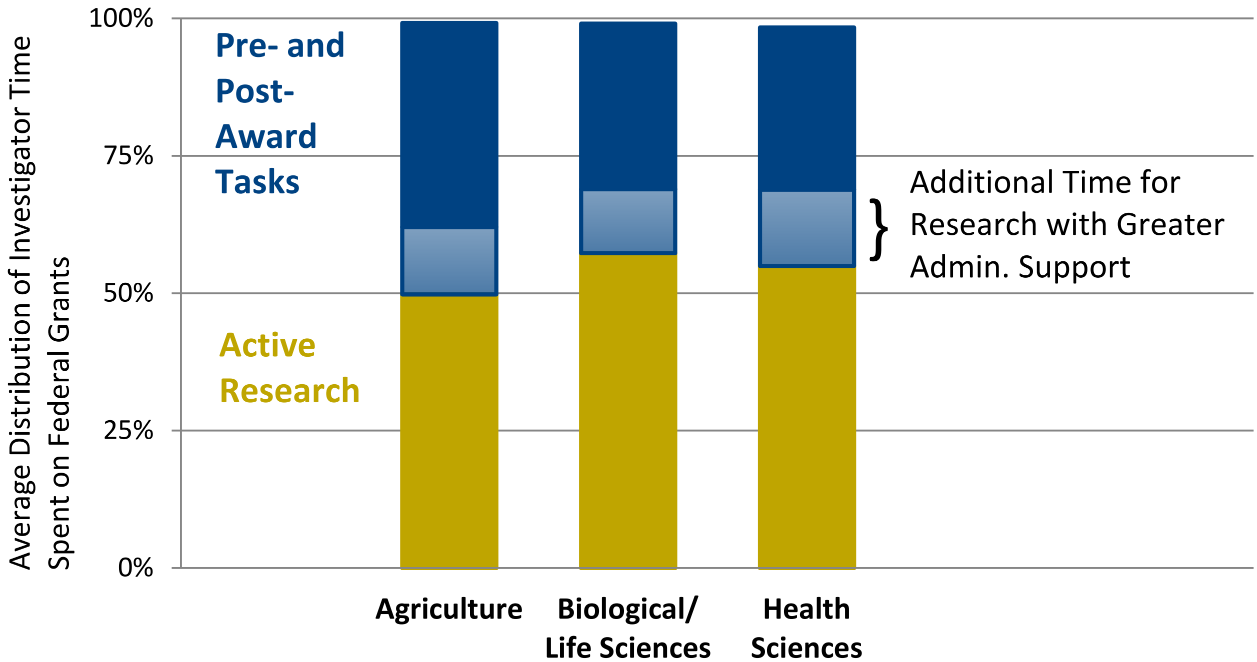

Figure 7: Less than 60 percent of faculty time spent on government agricultural, biological, and biomedical research grants is used to perform active research. Average percent time faculty spent on active research (gold) and grant-related tasks (blue) are indicated by field. In these fields, faculty surveyed estimated that with increased administrative support, approximately one-quarter or more of the time currently spent on grant-related tasks could be used for active research (lighter blue).

Source: Decker RS, Wimsatt L, Trice AG, Konstan JA. *A Profile of Federal-Grant Administrative Burden among Federal Demonstration Partnership Faculty: A Report of the Faculty Standing Committee of the Federal Demonstration Partnership.* January, 2007. Appendix A tables 10 and 39.

Technical notes: The survey categorized time across three categories: (1) Active Research: "reviewing literature, designing studies, running experiments, collecting/analyzing data, writing up findings, publishing and presenting research, etc."; (2) Pre-Award Research Related Activities: "writing/submitting proposals and budgets, applying for approvals, developing protocols, drafting safety/security plans, etc."; and (3) Post-Award Research Related Activities: "purchasing supplies/equipment, supervising budgets, managing personnel, complying with regulations, monitoring safety/security plans, writing reports, etc."

The survey queried what percentage of time spent managing federal grants could be accomplished by administrative staff at the researcher's institute. This value was used to estimate the additional active research time possible with greater administrative support.

Survey values do not total 100 percent due to rounding.

1.3.2: Budgetary uncertainty hinders efficient resource management

When Congress delays passing appropriations bills, agencies have less time to carefully plan and execute their budgets. Budgetary uncertainty results in the postponement of expenditures at agencies during the first part of the fiscal year and then forces accelerated spending at the end of the year.

See Recommendation 1.10

The federal budget process does not operate according to schedule: Congress should pass all twelve appropriations bills, funding all federal agencies, before the new fiscal year begins. The last time it succeeded in doing so, however, was for the FY 1998 budget.[34] In recent years, appropriations for NIH and other research funding agencies have often been passed several months after the fiscal year began. Continuing resolutions, temporary mechanisms used to fund agencies until appropriations bills are passed, are used to fill in the appropriations gap, but only guarantee funding levels for a short time period (typically no more than a few months). Without passage of an appropriations bill, agencies are prohibited from initiating new programs.

Delayed budgets impede efficient management: Federal agencies do not know their annual funding levels until an appropriations bill passes. When funded by a continuing resolution – with no certainty about their ultimate spending authority – federal agencies delay nonessential expenditures, decrease the number of new awards, and reduce the size of ongoing, multi-year awards.[35] Once a funding bill is passed, agency staff must quickly expend their budget in the remaining months of the fiscal year. Alternating cycles of diminished and expedited spending are not conducive to efficient expenditures, resulting in lost opportunities and rushed decisions. The resulting inefficiencies have been documented in other areas of federal expenditures. For example, one analysis of government IT contracts estimates that those made in the last week of the fiscal year were two to six times more likely to have a lower quality rating than those made during the rest of the

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34 **Congressional Research Service.** *The Congressional Appropriations Process: An Introduction*. February 23, 2012. J Tollestrup. R42388.

35 For recent examples, refer to the following NIH notices:

National Institutes of Health. NIH Operates Under a Continuing Resolution. Notice Number: NOT-OD-15-001. *NIH Website*. Issued October 1, 2014.

National Institutes of Health. NIH Operates Under a Continuing Resolution. Notice Number: NOT-OD-14-043. *NIH Website*. Issued January 16, 2014.

National Institutes of Health. NIH Operates Under a Continuing Resolution. Notice Number: NOT-OD-14-012. *NIH Website*. Issued October 25, 2013.

National Institutes of Health. NIH Operates Under a Continuing Resolution. Notice Number: NOT-OD-13-002. *NIH Website*. Issued October 11, 2012.

year.[36] The shortened timeframe due to delayed appropriations certainly exacerbates this problem as more and more spending decisions must be pushed later and later into the fiscal year.

Agencies with "one-year" appropriations face greater challenges when spending bills are delayed: Agencies that operate under an annual budget cycle, such as NIH, forfeit any funds they are unable to expend within the fiscal year. Delayed appropriations compress this timeframe, thus, making it more difficult to efficiently and responsibly allocate the annual budget. Approximately one percent of the NIH budget (about $300 million per annum) is forfeited. The Department of Veteran Affairs Medical and Prosthetic Research program, in contrast, operates under two-year and "available until expended" appropriations, and it leaves only around 0.02 percent of its yearly research budget unspent. If the NIH had similar budgetary flexibility, it could retain approximately $294 million each year.

1.3.3: Coordinated use of research resources could increase the return on the federal research investment

State-of-the-art scientific instrumentation and equipment enable researchers to expand scientific knowledge in areas that were previously inaccessible. New technology also allows them to increase the volume or scale of their efforts. Advances in science, in turn, create new research questions that spur the creation of even more powerful instrumentation. This dynamic relationship between technological innovation, scientific discovery, and cutting-edge research infrastructure has become central to progress in science and engineering. Research institutions, seeking to keep their scientists and engineers at the forefront of their fields, are pressed to provide this environment.

Growing risk of facility overexpansion and underutilization: In the past decade, research facility construction expanded while federal research funding declined. Biological and medical research space at academic institutions has been growing since 1986-87, and this growth accelerated following the doubling of the NIH budget (see **Figure 8**). Planned new construction expenditures also increased immediately after the doubling era (133 percent in constant dollars from 1998-99 to 2002-03) and have not yet returned to pre-doubling levels, suggesting that the amount of research space will continue to rise. These findings are consistent with an analysis of U.S. medical

36 **Liebman JB, Mahoney N.** Do Expiring Budgets Lead to Wasteful Year-End Spending? Evidence from Federal Procurement. National Bureau of Economic Research. Working Paper Series number 19481. September 2013.

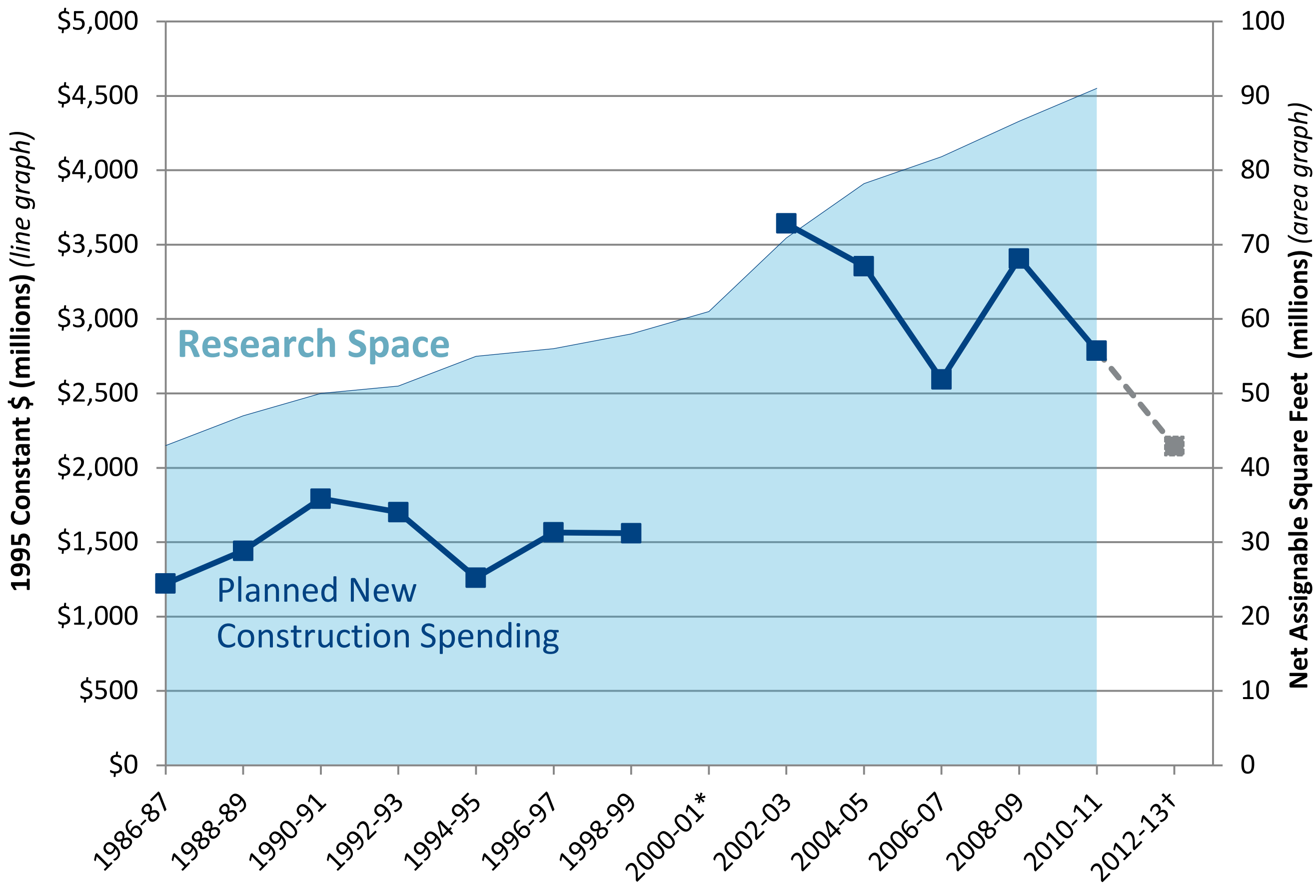


Figure 8: Biological and biomedical research space and construction trends at U.S. academic institutions show substantial growth in the past decade. While research space (light blue area) has consistently increased over time, this growth was accelerated following the doubling of the NIH budget. Planned new construction spending (inflation-adjusted, dark blue line) also grew dramatically following the doubling and remains elevated.

Source: NSF National Center for Science and Engineering Statistics. Science and Engineering Research Facilities Survey. *NCSES website.*

Technical notes: Research space measures only space currently in use or immediately available for use, including facilities rented by an institutions, but not space leased to other parties or being temporarily used for other activities. Planned spending figures reflect the total planned expenditures for projects beginning within the next two years. Thus, for new construction, any new space would not likely be available until several survey cycles later. Estimated figures for 2012-13 are also provided, but are subject to change.

NSF staff utilized weighting systems and a combination of logistic regression models and linear regression models to correct for institutional and question non-response, respectively. Overall survey response rates were generally high. Only academic institutions meeting the minimum required R&D expenditures were surveyed (1986/7-1996/7, $50,000; 1998/9-2000/1, $150,000; 2002/3-present, $1,000,000).

The "Biological and biomedical sciences" and "Health and clinical sciences" survey categories were combined in this analysis. Prior to the 2006-07 survey cycle, these categories were termed "Biological sciences" and "Medical sciences."

The 2000-2001 survey tool was substantially different from prior and subsequent cycles. Planned spending data were not collected.

Constant dollars were calculated using the Chain Type Price Index for the Gross Domestic Product.

school data, which also documents growth in research space and facility expenditures.[37]

The planned new construction expenditures and subsequent facility growth was a reasonable response to the doubling of the NIH budget. Immediately following the doubling, however, budget cuts and inflationary losses eroded federal support. Construction spending, however, remained elevated and the amount of available research space continued to grow. Facility underutilization has already been reported at a few institutions,[38] and, if these trends continue, more institutions will face this problem. Underutilized facilities waste scarce resources and are also a drain on future research budgets. Research facilities must be maintained, regardless of utilization levels. Fixed costs for research facilities, such as maintenance, utilities, and debt servicing, persist and must be paid. These costs, whether incurred as higher F&A rates[39] or taken at the expense of other institutional priorities, delay scientific progress.

Current incentives emphasize size over quality and sustainability: Several aspects of the current research funding system encourage institutional growth at the expense of the long-term viability of the enterprise. [40] Shifting faculty salaries to research grants and the reliance on trainee labor are two examples that are discussed in other sections. Institutional ranking systems that emphasize size over quality are another source of expansionary pressure.

The number of NIH grantees or total federal grant funding are frequently used to judge the performance of institutions and their leadership. Even when broader ranking metrics are used, they typically include absolute measurements of research volume (see Table 3). More research space allows institutions to hire more investigators (including those whose salaries are primarily or completely supported by external research sponsors) to compete for more federal grants. Thus, expansion of facilities is essential for institutions to move up within ranking hierarchies. New facilities are frequently used to attract successful researchers to an institution, and state-of-the-art facilities may be necessary to retain those who may be targets for recruitment by other institutions.

See Recommendation 1.14

Reimbursement systems may also encourage expansion. Infrastructure costs for depreciation/use, maintenance, and debt servicing on loans can be recovered as F&A expenses on federal grants. A recent U.S. Government

See Recommendation 1.13

37 **Heinig SJ, Krakower JY, Dickler HB, Korn D.** Sustaining the Engine of U.S. Biomedical Discovery. *NEJM*. 2007; 357(10):1042-7

38 **Harris R, Benincasa R.** U.S. Science Suffering From Booms And Busts In Funding. National Public Radio broadcast and accompanying online article. September 09, 2014.

39 *The U.S. Government Accountability Office recommended further study of the impact of F&A rates, including uncapped facility costs, on NIH's capacity to fund research.*

U.S. Government Accountability Office. *Biomedical Research: NIH should assess the impact of growth in indirect costs on its mission*. September 2013. GAO-13-760.

40 **Alberts B.** Overbuilding research capacity. *Science*. 2010; 329(5997):1257.

Ranking System	Metrics Used
The Top American Research Universities, *The Center for Measuring University Performance*	Total R&D expenditures; federally sponsored R&D expenditures; number of members of the National Academies among faculty; number of significant faculty awards; number of doctorates awarded; number of postdoctoral appointments; median SAT scores
Best Medical Schools: Research Ranking, *U.S. News and World Report*	Equal weighting of NIH total grant funding awarded and grant funding per faculty member
Academic Ranking of World Universities ("Shanghai ranking"): Life and Agriculture Sciences, and Clinical Medicine and Pharmacy, *The Center for World-Class Universities of Shanghai Jiao Tong University*	Number of alumni and staff Nobel Laureates, weighted by time of award; number of highly cited researchers; number of indexed research articles, percentage of articles in top journals

Table 3: Metrics used among common ranking systems for research universities and medical schools tend to measure operational scale rather than the quality and stability of the research program.

Source: Lombardi JV, Philips ED, Abbey CW, Craig DD. *The Top American Research Universities: 2012 Annual Report.* The Center for Measuring University Performance. 2013; **Flanigan S, Morse R.** Methodology: 2015 Best Medical Schools Rankings. *U.S. News and World Reports Website*. March 10, 2014; **Academic Ranking of World Universities.** *"ARWU - FIELD 2014 Methodology."* ARWU Website. Accessed September 18, 2014.

See Recommendation 1.13

Accountability Office report stated that the lack of a cap on facilities costs could "encourage universities to borrow money to build new facilities, which could lead to the building of more new space than is necessary for research needs."[41]

Present funding mechanisms do not promote optimal resource sharing: To carry out cutting-edge research, investigators require access to scientific equipment ranging widely in price, size, and typical frequency of use. Shared equipment, whether between neighboring laboratories, within departments, or across multiple institutions, can extend the value of research funding. Unfortunately, many research funding mechanisms only promote shared equipment in a narrow range of circumstances.

See Recommendation 1.11

For instance, the current threshold of the NIH Shared Instrumentation Grant (SIG) program is $100,000. Less expensive equipment does not qualify, forcing individual laboratories to purchase separately their own machines even if daily use is low. Other equipment below the SIG threshold, such as 3-D printers, might not be cost effective unless the expense is spread across multiple laboratories; the lack of shared funding mechanisms can delay the adoption of these technologies.

41 **U.S. Government Accountability Office.** GAO-13-760.

Access to new technologies and costly instruments can be provided at the institutional level through core facilities. These shared resources typically specialize in specific research techniques. They are frequently staffed by dedicated personnel, who not only facilitate use of the new technologies, but often also play an important role in their further development. In some circumstances, however, regional core facilities may be more efficient and broaden the number and variety of investigators able to take advantage of the technology. For example, due to the large space requirements and high costs associated with powerful nuclear magnetic resonance (NMR) machines, several multi-institutional cores have already been established. However, there is no longer a standard mechanism for funding regional cores, although support may occasionally be made available for a specific mission.

See Recommendation 1.11

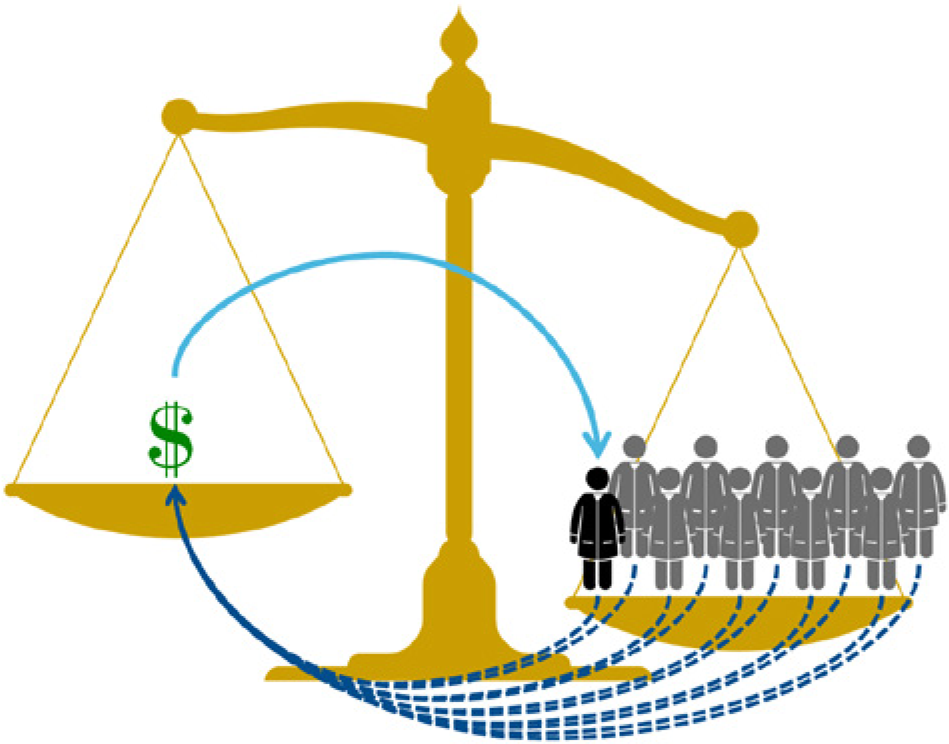
The research community needs a unified approach for the support of resource and IT infrastructure: Some resources can be provided most efficiently through a central service. The centralized structure increases access, standardization, and utilization. Stock centers fulfill this role for biologics, from cell lines to genetic constructs; databases and databanks serve this role for scientific information. Unfortunately, even extensively used non-profit resource centers often struggle to secure sustained federal support.[42]

See Recommendation 1.12

42 **Baker M.** Databases fight funding cuts. *Nature* News. 2012; 489(7414): 19.

Section 2: A Rising Demand for Research Grants

Accelerating progress in the biological and medical sciences has created exciting new opportunities for research, and the U.S. needs a dynamic, growing research enterprise to capitalize on them. Additional resources are necessary to explore these new avenues and their possible applications to human health and other areas of national need. Funding for research, however, has not kept pace. This funding shortfall, in combination with changes in the employment and training of scientists, has placed enormous strain on the system.



Expanding research opportunities and growing number of researchers

2.1: The expansion of opportunities for discovery is generating a rising demand for research funding

Recent research discoveries have given scientists and engineers groundbreaking insights and novel techniques, allowing them to extend the frontiers of knowledge in exciting new directions. The scientific workforce has grown and is poised to make tremendous strides. Entirely new fields such as medical genomics, biomedical engineering and bioinformatics have emerged. We are on the threshold of an unprecedented era of progress, but its realization will require necessary federal investments.

Opportunities in the biological and medical sciences have never been greater: Advances in biological and medical research have opened up many more promising lines of inquiry. For example:

- Researchers are now evaluating the use of biomarkers – chemical components of blood – to distinguish individuals who will develop Alzheimer's disease from those who will not. With an estimated 115 million people projected to be affected by 2050, researchers are seeking methods to provide physicians the ability to identify patients earlier in the disease process and begin treatment before irreversible brain damage occurs.
- A new experimental technology being pioneered by NIH's National Center for Advancing Translational Sciences and other federal agencies, "organs-on-a-chip," uses a series of micro-chambers, fluids, and human cells to simulate a person's internal organs. Researchers anticipate that someday this technology will expedite the development and approval of new therapeutics.

See Recommendation 1.1

As opportunities have increased, so have the number of grant applications: From 1995 to 2013, the number of NIH RPG applications submitted annually nearly doubled. R01-Equivalent (R01-Eq) grant applications have also steadily increased (see Figure 9). Unfortunately, declining federal support means an ever smaller fraction of grant applications can be funded. Since FY 2011, less than 20 percent of RPG and R01-Eq applications were awarded funding, and this percentage continues to fall.

The increase in grant applications is primarily due to a larger number of applicants: An NIH analysis of application and applicant trends found that the increase in grant applications is primarily due to growth in the number of

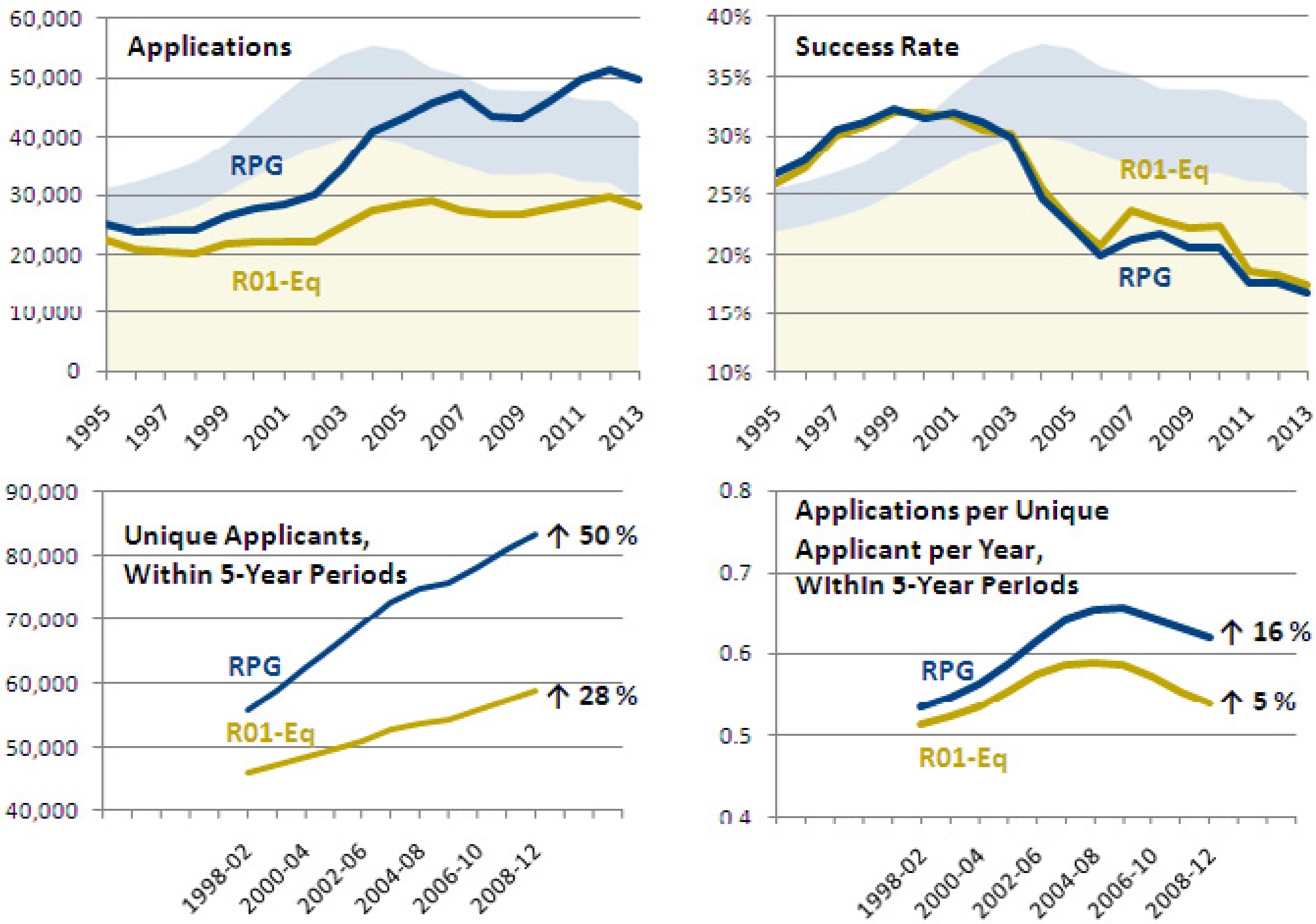


Figure 9: Declines in NIH grant funding coupled with increases in the number of applicants have resulted in lower success rates. Growth in the number of applications was primarily due to the increase in the number of applicants rather than an increase in the number of applications each applicant submitted. The growth in applicants was concomitant to declines in NIH appropriations.

The following trends for NIH Research Project Grant (RPG) (blue) and R01-Equivalent (R01-Eq) (gold) grants are shown: A) Number of grant applications submitted; B) Annual success rates; C) Number of unique grant applicants within the five-year periods FY 1998 - 2002 to FY 2008 - 2012; and D) Average number of applications submitted by unique applicants per year within the same five-year periods. In panels A and B, inflation-adjusted funding is shown in the background for comparison.

Source: National Institutes of Health. NIH Data Book and associated success rate tables. *NIH website*; **Rockey S.** More on More Applicants. *Rock Talk blog*. April 26, 2013.

Technical notes: Because a scientist might not apply for research grants every single year, NIH has assessed the number of unique (i.e., different) individuals who applied for at least one grant in a five-year period. Therefore, an applicant that submitted only one proposal and an applicant that submitted four are each counted as a single applicant. This approach better captures the total applicant pool and reduces noise seen in annual applicant data.

Constant dollars were calculated using the Biomedical Research and Development Price Index (BRDPI).

applicants seeking funds (i.e., investigators) (see Figure 9). The number of RPG and R01-Eq applications per applicant grew only slightly. In contrast, the number of unique applicants has continued to grow, with approximately 50 percent more RPG applicants and 28 percent more R01-Eq applicants in FY 2008-12 than in FY 1998-2002.[43]

Reduced participation of physicians in research

Physician scientists are a critical component of the biomedical research workforce and undergo an extensive and costly period of training. Their levels of participation in research are highly sensitive to changes in the funding climate. After 2003, when the NIH budget growth ended, a smaller percentage of medical students planned on research careers, fewer new medical school graduates undertook postdoctoral research training, the number of NIH grant applications from physicians declined, and a shrinking number of physicians reported research as their primary activity (see Figure 10).[44, 45, 46] Faced with numerous barriers to a research career (lengthy training, costly education, substantial student debt, demanding patient care duties, salary caps on NIH grants, and institutional pressures to generate revenue), the extreme competition for research grants may prove to be an insurmountable obstacle for many physicians considering a research career.

See Recommendation 3.5

See Recommendation 3.6

Without a major change or intervention, a shortage of physician scientists seems likely. Declines in this specialized population will have many long-term consequences for biomedical research. For example, NIH RPGs with MDs as principal investigators are twice as likely to involve human subjects research than those headed by PhD or MD-PhD scientists.[47, 48] If there are fewer physician scientists working on NIH funded research, the amount of human subjects research would most likely decrease.

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43 **Rockey S.** More on More Applicants. *Rock Talk blog*. April 26, 2013.

44 **NIH Advisory Committee to the Director.** *Physician-Scientist Workforce Working Group Report*. June 2014.

45 **Garrison HH, Deschamps AM.** NIH research funding and early career physician scientists: continuing challenges in the 21st century. *FASEB J*. 2014 Mar;28(3):1049-58.

46 **Garrison HH, Deschamps AM.** *Physician Scientists: Assessing the Workforce*. December 11, 2013.

47 Ibid.

48 **Rockey S.** Does your academic training destine your choice of research subject? *Rock Talk blog.* February 1, 2013.

The comparable fraction was 23.3 percent for PhD and 23.6 percent for MD-PhDs.

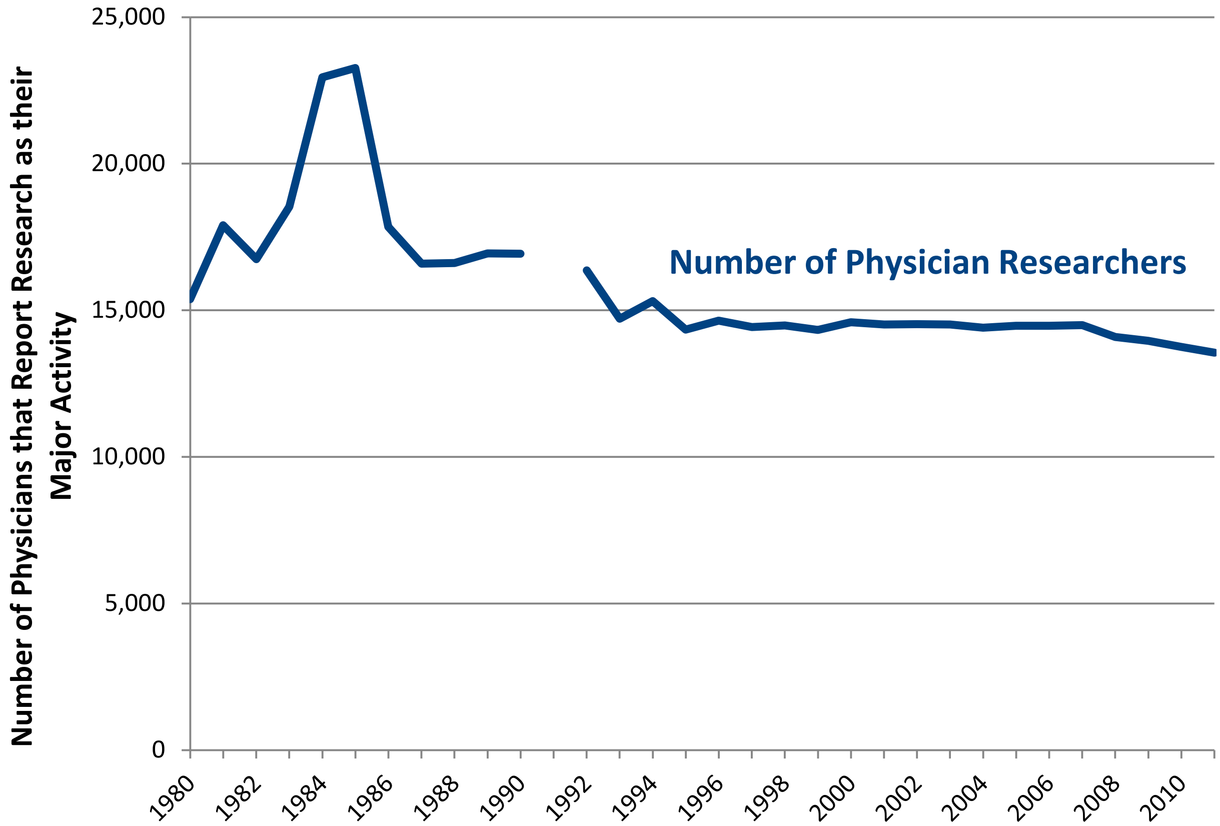


Figure 10: The number of physicians reporting research as their major activity is falling. From 1995 through 2007, the number of physicians in the American Medical Association (AMA) survey citing research as their major professional activity was remarkably constant, ranging from 14,340 to 14,650. After 2007, however, the number of physician researchers dropped, and by 2010, only 13,557 individuals reported research as their primary professional activity, the lowest number in more than three decades.

Source: Garrison HH, Deschamps AM. NIH research funding and early career physician scientists: continuing challenges in the 21st century. *FASEB J*. 2014 Mar;28(3):1049-58.

Garrison HH, Deschamps AM. *Physician Scientists: Assessing the Workforce*. December 11, 2013.

Technical notes: FASEB staff assembled the AMA annual survey of the major professional activity of U.S. physicians from several separate data combinations to generate the full time series. Please refer to "Physician Scientists: Assessing the Workforce" for additional information.

2.2: The demand for research grants is exacerbated by the growing reliance on external salary support

Researchers are becoming more heavily dependent on research grants to cover their salaries. The number of individuals submitting biomedical research grant applications has continued to rise while research funding has not kept pace, and in fact has fallen. This funding shortfall, in combination with changes in way scientists are trained and employed, has placed enormous strain on the system, disrupted promising careers, and delayed progress in critical areas of research.

See Recommendation 3.1

Institutions are requiring researchers to charge a growing proportion of their salary to sponsored research projects: Shifting investigator salary to extramural grants and other external sponsored research funds reduces an institution's payroll expense and long-term financial liabilities. It shifts risks from the institutions to faculty and laboratory workers, thus reducing the downstream consequences of unpredictable funding for institutions and encouraging expansion of faculty positions.[49]

In addition to being spared the salary expense, putting salaries on extramural grants means that institutions can charge the associated fringe benefits as a direct cost to grants and receive F&A reimbursement for both the funded salary and fringe benefits (see Table 4). It also helps shield institutions from the growing costs of providing fringe benefits, which rose by nearly 200 percent from 1994 to 2011, greatly outpacing major inflation indices[50] as well as faculty salary rates.[51]

See Recommendation 1.14

Institutions exert pressure on faculty to obtain salary support from external sources. At many institutions, there is little or no obligation to provide salary for tenured researchers. Tenure agreements at U.S. medical schools are

49 See Section 1.3 for further discussion of incentives for facility expansion.

50 **National Center for Education Statistics of the U.S. Department of Education.** The Integrated Postsecondary Education Data System (IPEDS). *Salaries, Tenure, and Fringe Benefits Survey.* Data accessed via WebCASPAR in February 2014. Available data range: 1994-2011.

51 Data provided to Yale University by the American Association of University Professors from its Annual Report on the Economic Status of the Profession and published on the Yale University website.

Salary and Fringe Benefit Categories	Salary-based Costs Associated with NIH Research Grants	
	25 % Effort	50 % Effort
Individual's institutional base salary	*$120,000*	*$120,000*
Direct salary (percent effort charged to grant)	**$30,000**	**$60,000**
Fringe benefits reimbursement (ex. 44.1%)	**$13,230**	**$26,460**
Subtotal	*$43,230*	*$86,460*
F&A cost recovery (ex. 55%)	**$23,777**	**$47,553**
Total	**$67,007**	**$134,013**

Table 4: Example of fringe benefit and F&A cost rate calculations for faculty salary charged to a grant as a direct cost. Fringe benefit and F&A cost rates are based on the negotiated rates of a major public university system.

Direct salary charges are calculated as the percent effort assigned to the grant multiplied by the individual's salary. (Note that the Congressionally established salary caps establish an upper limit on the salary rate used in this calculation.) Fringe benefit reimbursement is determined by multiplying the direct salary charged by the negotiated fringe benefit rate. Because both the salary and fringe benefits charged to federal grants are categorized as direct charges, they are eligible for F&A cost recovery. This is calculated as total direct costs multiplied by the negotiated F&A cost rate.

increasingly unlikely to provide a guarantee of full or any salary (see Table 5 and Table 6). In 1999, 46 percent of U.S. medical schools offered a total salary guarantee for basic science department faculty, by 2008 only six percent did. Pressure to maximize external salary support is applied through a combination of rewards and penalties, including salary supplementation, salary cuts, non-financial incentives (such as changes in course load or other department responsibilities), and the criteria used in tenure and promotion decisions.[52] For example, the University of Pittsburgh issued a new policy in 2013 stating that the School of Medicine aims to "obtain an overall average of 75 [percent] support of faculty salaries from research grants." Failure of faculty to meet their individual targets could result in as much as a 20 percent salary reduction in the following year.[53] Not obtaining sufficient external funding can

52 For examples, refer to the following:

Zucker IH. *ACDP Salary Supplementation Survey Results*. PowerPoint. July 2005.

University of Pittsburgh School of Medicine. *Faculty Performance and Evaluation Update*. January 30, 2013.

Decker. *A Profile of Federal-Grant Administrative Burden*.

Schneider. *Faculty Workload Survey Research Report*

53 **University of Pittsburgh School of Medicine.** *Faculty Performance*

Basic Science Department Tenure Agreement Contains:	Number and Percentage (%) of U.S. Medical Schools							
	1999		2002		2005		2008	
Specific financial guarantee	**74**	**(62%)**	**59**	**(49%)**	**62**	**(52%)**	**59**	**(50%)**
• *Total salary*	*46*	*(39%)*	*25*	*(21%)*	*8*	*(7%)*	*7*	*(6%)*
• *Other amount*	*28*	*(24%)*	*34*	*(28%)*	*54*	*(45%)*	*52*	*(44%)*
No financial guarantee	**29**	**(24%)**	**37**	**(31%)**	**42**	**(35%)**	**45**	**(38%)**
Unclear financial guarantee	**16**	**(13%)**	**24**	**(20%)**	**12**	**(10%)**	**12**	**(10%)**
Other	-	-	-	-	**3**	**(3%)**	**3**	**(3%)**
Total	**119**	**(100%)**	**120**	**(100%)**	**119**	**(100%)**	**119**	**(100%)**

Table 5: The frequency of an institutional salary guarantee in tenure agreements declined among basic science faculty at U.S. medical schools. Full salary guarantee has nearly completely disappeared, and the presence of any other type of financial guarantee has fallen within the past decade. Likewise, tenure agreements are more likely not to include any type of financial guarantee.

Clinical Department Tenure Agreement Contains:	Number and Percentage (%) of U.S. Medical Schools							
	1999		2002		2005		2008	
Specific financial guarantee	**62**	**(56%)**	-	-	**56**	**(50%)**	**49**	**(44%)**
• *Total salary*	*9*	*(8%)*	-	-	*3*	*(3%)*	*3*	*(3%)*
• *Other amount*	*53*	*(48%)*	-	-	*53*	*(47%)*	*46*	*(41%)*
No financial guarantee	**32**	**(29%)**	-	**(36%)**	**43**	**(38%)**	**46**	**(41%)**
Unclear financial guarantee	**17**	**(15%)**	-	-	**10**	**(9%)**	**9**	**(8%)**
Other	-	-	-	-	**4**	**(4%)**	**7**	**(6%)**
Total	**111**	**(100%)**	-	-	**113**	**(100%)**	**111**	**(100%)**

Table 6: The frequency of an institutional salary guarantee in tenure agreements also declined among clinical faculty at U.S. medical schools. Clinical department faculty trends follow those of basic science department faculty, albeit at lower overall rates of any type of a financial guarantee at all time points.

Source: Jones RF, Gold JS. The present and future of appointment, tenure, and compensation policies for medical school clinical faculty. *Acad Med.* 2001; 76(10):993-1004; **Lui M, Mallon WT.** Tenure in transition: trends in basic science faculty appointment policies at U.S. medical schools. *Acad Med.* 2004; 79(3):205-213; **Bunton SA, Mallon WT.** The continued evolution of faculty appointment and tenure policies at U.S. medical schools. *Acad Med.* 2007; 82(3):281-289; and **Bunton SA.** The relationship between tenure and guaranteed salary for U.S. medical school faculty. *AAMC Analysis in Brief.* 2010; 9(6).

Technical notes: Data was collected by AAMC staff. For the years 1999 and 2002, the category "Other" was not used. The most recent reports note that additional institutions are in the process of reviewing or revising the salary guarantees within their tenure agreements, suggesting that this trend will continue.

also negatively impact tenure and promotion decisions. In both the 2005 and 2012 FDP Faculty Workload surveys, faculty nearly universally reported that "sponsored research activity is a primary factor in my institution's promotion and tenure policies."[54, 55]

Researchers have become more heavily dependent on research grants to cover their salaries: For researchers working throughout academia, there is a dearth of information on sources of salary support. One of the few sources is the Association of Chairs of Departments of Physiology (ACDP) annual survey. From 1989-2003, the ACDP surveys reported a 15 percentage point increase in the average percentage of salary support on research grants among physiology department faculty; subsequently, salary support plateaued as funding became more constrained.[56] The ACDP survey underestimates average salary support of research faculty by including instructional positions, but other recent analyses suggest that total external salary support for research positions approaches 50 percent or more.[57]

See Recommendation 3.1

See Rec. 3.1.1

Dependence on external salary support results in greater career instability for researchers: The disappearance of salary guarantees and the proliferation of "soft money" positions (i.e., positions where researchers must bring in all or a large majority of their salary from external sources) have had a dramatic effect on the worklife of academic scientists and engineers. In times of increased competition or declining federal support for research, faculty members and their laboratory personnel are at a greater risk for job loss.

See Rec. 3.1.2

See Recommendation 1.14

Recent analyses have demonstrated that the level of career instability in the biomedical research population has increased. One study reported that the number of principal investigators exiting the NIH extramural research system has spiked in recent years. From 1985 through 2002, approximately 1,400 individuals exited the system each year, but this number tripled, reaching 4,200 in both 2010 and 2012.[58] Another study found that the number of investigators with NIH funding for six consecutive years declined from 10,030

See Recommendation 2.8

See Recommendation 2.9

54 **Decker.** *A Profile of Federal-Grant Administrative Burden*

55 **Schneider.** *Faculty Workload Survey Research Report*

56 **The Association of Chairs of Departments of Physiology (ACDP).** *ACDP Space and Budget Surveys. 1996-2013.*

Older editions can be found in *The Physiologist*, the newsletter of The American Physiological Society.

57 *The two following analyses are limited to specific segments of the research community and also, in the latter case, salary support derived from only specific types of research grants. However, both do report average salary support of approximately 50 percent among PhD faculty.*

Goodwin M, Bonham A, Mazzaschi A, Alexander H, Krakower J. Sponsored Program Salary Support to Medical School Faculty in 2009. *AAMC Analysis in Brief.* 2011; 11(1).

NIH Office of Extramural Research. *Ways of Managing NIH Resources*. PowerPoint. October 2011.

58 **Grantome**. Dynamic Instability: Analysis of PIs who lose their NIH grant. *Grantome Blog*. April 1, 2014. Accessed May 21,2014.

in the FY 2000-2005 period to 9,127 in FY 2008-2013, a reduction of 11 percent.[59]

See Recommendation 2.5

See Recommendation 2.6

See Recommendation 3.3

Facing diminishing career prospects, some faculty members and research staff may leave science entirely. This instability reduces the return on the U.S. investment in the training of these researchers and the establishment of their research programs. Loss of research talent is becoming especially pronounced after the award of the first grant, approximately the fifth or sixth year of an independent researcher's career. These investigators are no longer eligible for special "new" investigator status when competing for NIH research grants, the institutional resources provided to start their laboratories ("start-up funds") have been exhausted, and they are likely preparing for promotion and tenure review. At this point, their position is extremely precarious and dependent upon the availability of external research funding.

The loss of researchers at every stage of the pipeline and the termination of promising and productive lines of inquiry is wasteful. The technical skills and expertise they have acquired will need to be replaced, increasing the cost of research and delaying discovery.

The growing need for external support reduces productivity and raises the cost of research: More and more scholars are forced to expend greater levels of effort seeking money for their research. As they devote more time and effort to preparing grant applications, researchers have less time available for research projects and mentoring students. A growing amount of time spent writing proposals, coupled with declining success rates, produces frustration and reduces morale. Reliance on "soft money" salaries is also damaging to collegial relations.[60]

See Recommendation 2.4

See Recommendation 2.7

Fundraising pressures may encourage less creative and innovative work: There is growing concern that the greater reliance on external funding may negatively affect the types of research proposed and performed.[61] As researchers become increasingly dependent on securing external research funding, they eschew long-term, high-risk research programs in favor of shorter, safer projects that yield immediately publishable results. Potentially paradigm shifting research is more likely to create gaps in an investigator's publication record, jeopardizing their ability to secure future grants and continue their research.

See Recommendation 2.3

The growth in the number of applications is overwhelming the review systems: The large increase in the number of grant applications is straining many peer review systems. Funding agencies are struggling to keep pace with the rising number of funding requests. More applications raise the cost of merit review, reducing the amount of funding available for grants, and some

59 **Data Hound (Berg J).** Minding the Gap. *Data Hound Blog, Sciencetopia*. May 15, 2014. Accessed May 21, 2014.

60 **Bourne HR.** The writing on the wall. *eLIFE*. 2013 Mar;26(2):e00642.

61 **Alberts B, Kirschner MW, Tilghman S, Varmus H.** Rescuing US biomedical research from its systemic flaws. *Proc Natl Acad Sci*. 2014 Apr 22;111(16):5773-7.

agencies are also having difficulty finding enough qualified reviewers in the face of the increased volume of applications. There are also consequences for the quality and reliability of merit review when reviewers are forced to select a small number of applications from a large pool of highly meritorious proposals.

See Recommendation 2.5

2.3: The number of investigators seeking funding continues to grow

The extensive use of trainees (graduate students and postdocs) as the primary source of labor in the biological and medical sciences results in the creation of an increasing pool of bioscience researchers that is unconnected to any demonstrated demand for their services in an academic career. In recent years, the trainee population has increased at a faster rate than faculty positions or research grant budgets.

See Recommendation 3.2

The number of trainees has risen: The total number of biological and medical science graduate students in doctoral granting departments has steadily increased since 1990.[62] Doctorate degree awards in the biological and medical sciences (see Figure 11) doubled from 1990 to 2012.[63] The most dramatic changes occurred at the next stage of scientific training, the postdoctorate. Since 1979, the population of postdoctorates in the biological and medical sciences has nearly quadrupled, with the majority of the increase composed of temporary resident scholars (see Figure 12).[64] Only in the most recent survey cycles has growth in the pool of graduate students and postdocs abated.

See Recommendation 3.3

See Rec. 3.3.5

Stipend and tuition payments from research grants fuel the expansion of the trainee population: Bioscience trainees are supported through various federal funding sources using several different mechanisms, including training grants, fellowships, and research grants. Over the past few decades, an increasing proportion of graduate students (see Figure 13) and postdoctoral trainees in the biological and medical sciences are supported on research grants[65] (see box on use of trainee research labor).

62 **NSF National Center for Science and Engineering Statistics.** Survey of Graduate Students and Postdoctorates in Science and Engineering. Data from each annual report were compiled by FASEB.

63 **NSF National Center for Science and Engineering Statistics.** Survey of Earned Doctorates. Data from each annual report were compiled by FASEB.

64 **NSF National Center for Science and Engineering Statistics.** Survey of Graduate Students and Postdoctorates

65 Ibid.

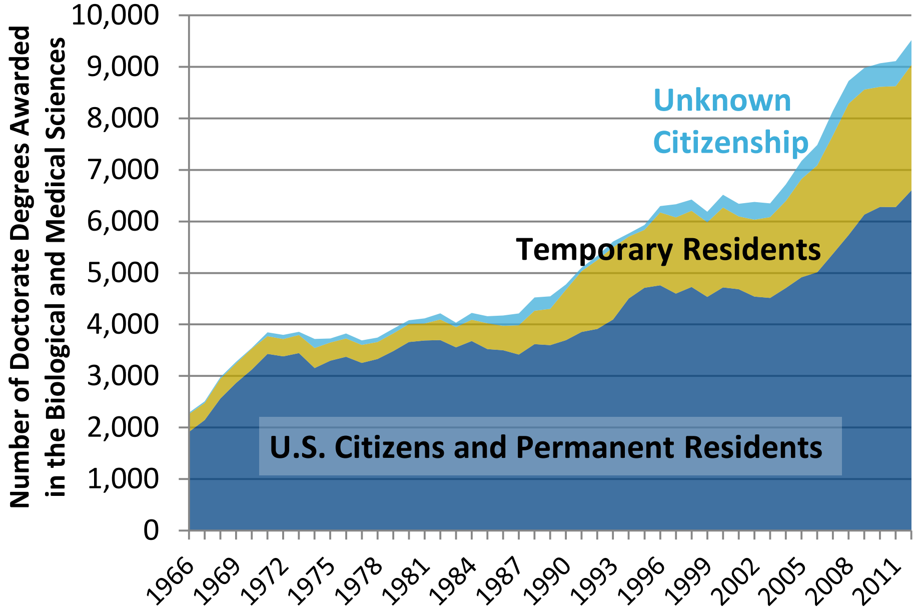


Figure 11: The number of doctorate degrees awarded in the biological and medical sciences doubled between 1990 and 2012. Citizenship/visa status is indicated.

Source: NSF National Center for Science and Engineering Statistics. Survey of Earned Doctorates. Data from each annual report were compiled by FASEB.

Technical notes: Data are collected directly from individual doctorate recipients as they submit their dissertations using a questionnaire distributed by the graduate deans. In the period from 1996-2005, survey response rates varied between 91 and 93 percent.

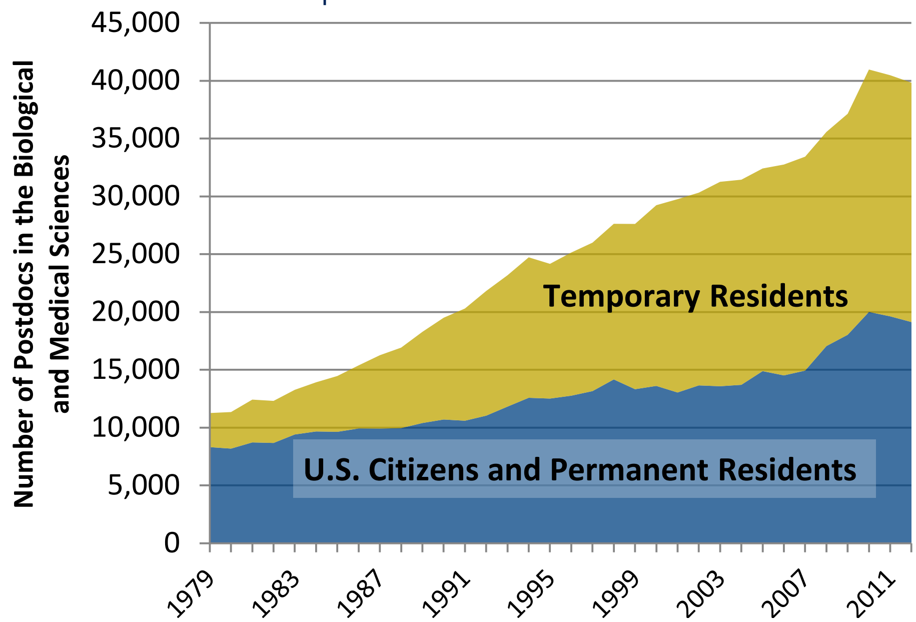


Figure 12: The number of biological and medical sciences postdocs has nearly quadrupled since 1979. Citizenship/visa status of postdocs is indicated.

Source: NSF National Center for Science and Engineering Statistics. Survey of Graduate Students and Postdoctorates in Science and Engineering. Data from each annual report were compiled by FASEB.

Technical notes: This biannual survey produces national estimates of graduate students, postdocs, and non-faculty researchers in all U.S. academic institutions that granted doctorates or master's degrees in any science, engineering, or selected health-related field. (Non-degree granting institutions like NIH are excluded. Thus, for postdoctoral scholars, the survey provides an incomplete count.) Information is provided by a school coordinator or departmental respondent. Response rates are greater than 95 percent.

See Recommendation 3.2

See Rec. 3.2.1

See Rec. 3.2.2

See Rec. 3.2.3

See Recommendation 3.7

The intimate connection between research and training encourages growth.[66, 67] When the number of research grants increase, the number of trainees rises as well; yet when research grant funding falls, the number of trainees may not substantially decline as their lower labor costs can help investigators stretch shrinking research budgets. One research group estimated that the average new tenure-track assistant professor in the biological and medical sciences will train 6.3 new PhDs over the course of his or her career.[68] Noting that the number of tenure-track positions in the biological and medical sciences has been relatively constant for the past three decades, they conclude that this academic "birth rate" for biomedical sciences is six times the replacement rate. Concerns about oversupply have led to calls to overhaul the current training paradigm in the life sciences and increase the proportion of non-trainee positions within the academic workforce.[69, 70]

See Recommendation 3.3

See Rec. 3.3.1

See Rec. 3.3.2

Is the reliance on trainee research labor harmful to the educational experience?

Support through research grants ensures that trainees have direct, hands on experience in their field and the opportunity to work directly with successful researchers. In the past, this apprenticeship model has often led to outstanding educational experiences and life-long collaborations. The dual nature of the employer-mentor relationship, however, may create a conflict of interest in some cases.

As the competition for external funding becomes increasingly important for professional survival, the relationship between students and mentors may change. When trainees are valued primarily for their ability to provide labor on research grants, there may less attention paid to their professional development or their potential to become independent investigators.

66 **Teitelbaum MS.** Structural Disequilibria in Biomedical Research. *Science*. 2008; 321(5889):644-5.

67 **Stephan P.** *How Economics Shapes Science*, (Harvard University Press, 2012).

68 **Ghaffarzadegan N, Hawley J, Larson R, Xue Y.** A Note on PhD Population Growth in Biomedical Sciences. *Systems Research and Behavioral Science.* 2014.

69 **Bourne HR.** A fair deal for PhD students and postdocs. *eLIFE*. 2013 Oct; 1(2):e01139.

70 **Teitelbaum MS.** Structural Disequilibria

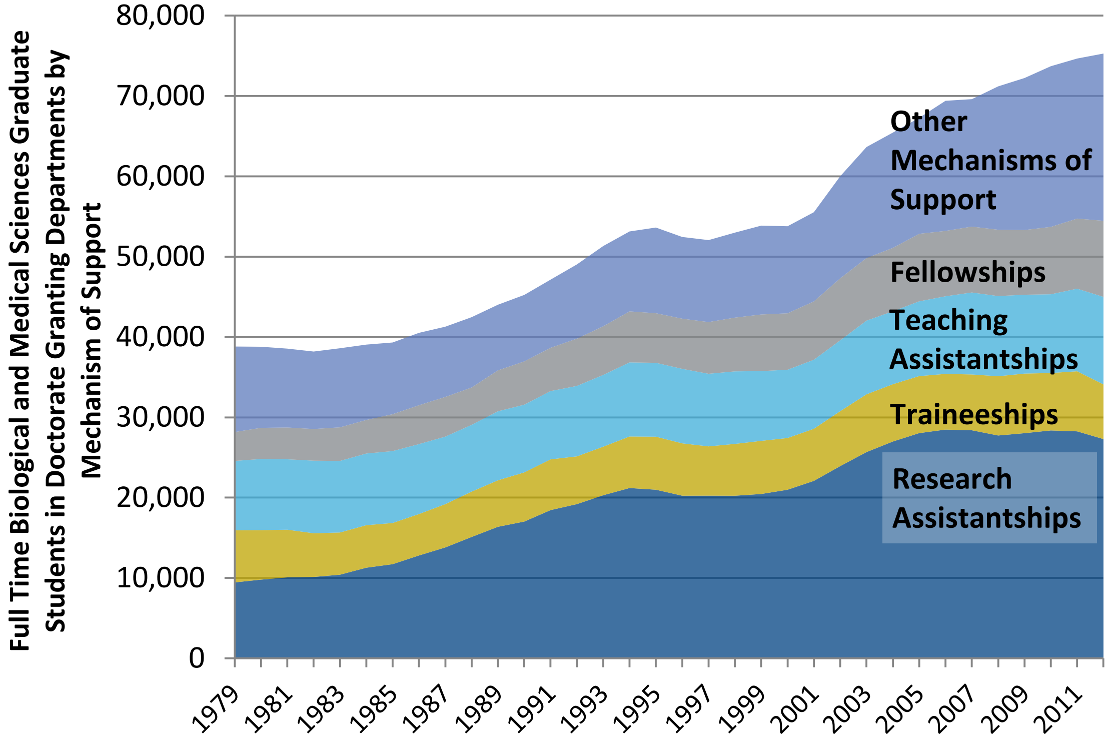


Figure 13: Full-time biological and medical sciences graduate students in doctorate granting departments increasingly are supported through research assistantships.

Source: NSF National Center for Science and Engineering Statistics. Survey of Graduate Students and Postdoctorates in Science and Engineering. Data from each annual report were compiled by FASEB.

Technical notes: This biannual survey produces national estimates of graduate students, postdocs, and non-faculty researchers in all U.S. academic institutions that granted doctorates or master's degrees in any science, engineering, or selected health-related field.

Information is provided by a school coordinator or departmental respondent. Response rates are greater than 95 percent. Respondent institutions assign of mechanisms of support, and the survey mechanism provides the following definitions:

Research Assistantships: *A financial award given to a graduate student where most of the student's responsibilities are devoted primarily to research assistant activities.*

Traineeships: *A financial award given to a graduate student or a postdoc selected by the institution.*

Teaching Assistantships: *A financial award given to a graduate student where most of the student's* responsibilities are devoted primarily to teaching assistant activities.

Fellowships: *A competitive award (often from a national competition) to a graduate student or a postdoc that requires no work of the recipient.*

Other support: *All other mechanisms of support for graduate students or postdocs.*

See Rec. 3.2.1

Faculty positions have grown modestly: The number of biomedical PhDs employed in tenured or tenure-track academic positions has not grown appreciably since the 1990s.[71] There were 19,400 tenured positions in 1993 and 24,300 in 2012, an increase of 25 percent or just over one percent annually. Tenure-track positions grew by 30 percent during that same period.[72] The number of biological and medical science PhDs granted by U.S. universities rose by 70 percent during this period,[73] and the number of biological and medical science postdocs at U.S. degree granting institutions rose by 72 percent.[74] A 1998 study by the National Research Council concluded that the number of new PhD degrees conferred exceeded the number of jobs for which doctoral training is required,[75] and a recently released study reported the increase in the number of postdocs far exceeds the increase in tenure-track jobs[76] (see box on the attractiveness of research careers).

See Recommendation 1.14

Some of the slow growth in traditional academic jobs may be explained by the rise in the number of non-tenure track faculty positions. As a result of this trend, the proportion of new faculty hires in U.S. medical school basic science departments with tenure or in tenure-track positions declined from 68 percent in 1985 to 51 percent in 2004.[77]

Will we be able to continue to attract and maintain the best and brightest talent?

To maintain the strength of the U.S. research enterprise, it is imperative that we continue to recruit high quality individuals. If research careers become less attractive, it will become harder to

71 Growth rates of tenured and tenure-track positions vary across biological and medical fields. A few fields, including biomedical engineering, have experienced a large increase in the number of new tenure-track positions over the past decade.

72 **NSF National Center for Science and Engineering Statistics.** Survey of Doctorate Recipients. Data from each annual report were compiled by FASEB.

73 **NSF National Center for Science and Engineering Statistics.** Survey of Earned Doctorates

74 **NSF National Center for Science and Engineering Statistics.** Survey of Graduate Students and Postdoctorates

75 **National Academies of Science.** *Trends in the Early Careers of Life Scientists*. Commission on Life Sciences, National Research Council, National Academies of Science. Washington, DC, National Academy Press. 1998.

76 **National Academies of Science.** *The Postdoctoral Experience Revisited*. Committee to Review the State of Postdoctoral Experience in Scientists and Engineers; Committee on Science, Engineering, and Public Policy; Policy and Global Affairs; National Academy of Sciences; National Academy of Engineering; Institute of Medicine. Washington, DC, National Academy Press. 2014.

77 **Bunton SA, Mallon WT.** The continued evolution of faculty appointment and tenure policies at U.S. medical schools. *Acad Med.* 2007; 82(3):281-289.

For all faculty (not just new hires), the proportion of tenure/tenure-track positions also declined, from 83 to 76 percent.

attract sufficiently talented and highly motivated individuals. Graduate students and postdocs are concerned about the stability of scientific employment following the training period, and there have been calls for the current training paradigm to be reassessed.[78]

See Recommendation 3.3

Employment prospects are declining. The most recent Survey of Doctorate Recipients documents a rise in the unemployment rate of recent biomedical PhD graduates (4.7 percent unemployment in 2012).[79] While this was below the national average in that year (8.1 percent), it was higher than the rate for all adults 25 years or older with at least a bachelor's degree (4.0 percent).[80]

See Recommendation 3.2

The lost income and benefits during the training period, even when offset by stipends and tuition waivers, may also become a disincentive for individuals with other career prospects. Research training takes significant time– a median of approximately seven years to complete a PhD in the life sciences[81] plus any postdoctoral positions. Ten years after earning a PhD, average earnings in the biomedical fields are substantially lower than those in the computer sciences and mathematics, the physical sciences, or engineering.[82] A recent study indicates that income lost during the training period is not regained in future employment.[83]

See Rec. 3.3.4

While we have no way to assess any change in the overall quality of the applicant pool, it is possible that deteriorating career prospects may be contributing to a decline in the number of prospective graduate students. In 2013, there were 5.6 percent fewer applications to doctoral programs in the biological and agricultural sciences than in 2012 and a corresponding drop in total doctoral graduate enrollment in these fields (-0.7 percent).[84]

See Rec. 3.3.3

See Recommendation 3.4

78 **McDowell GS, Gunsalus KTW, MacKellar DC et al.** Shaping the Future of Research: a perspective from junior scientists. *F1000Research* 2014 (3):291

79 **NSF National Center for Science and Engineering Statistics.** Survey of Doctorate Recipients

80 **Bureau of Census for the Bureau of Labor Statistics.** Current Population Survey, Labor Force Statistics, Annual average, Table 7. 2012. Accessed online on November 13, 2014.

81 **NSF National Center for Science and Engineering Statistics.** Survey of Earned Doctorates

82 **NIH Advisory Committee to the Director.** *Biomedical Research Workforce Working Group Draft Report*. June 14, 2012.

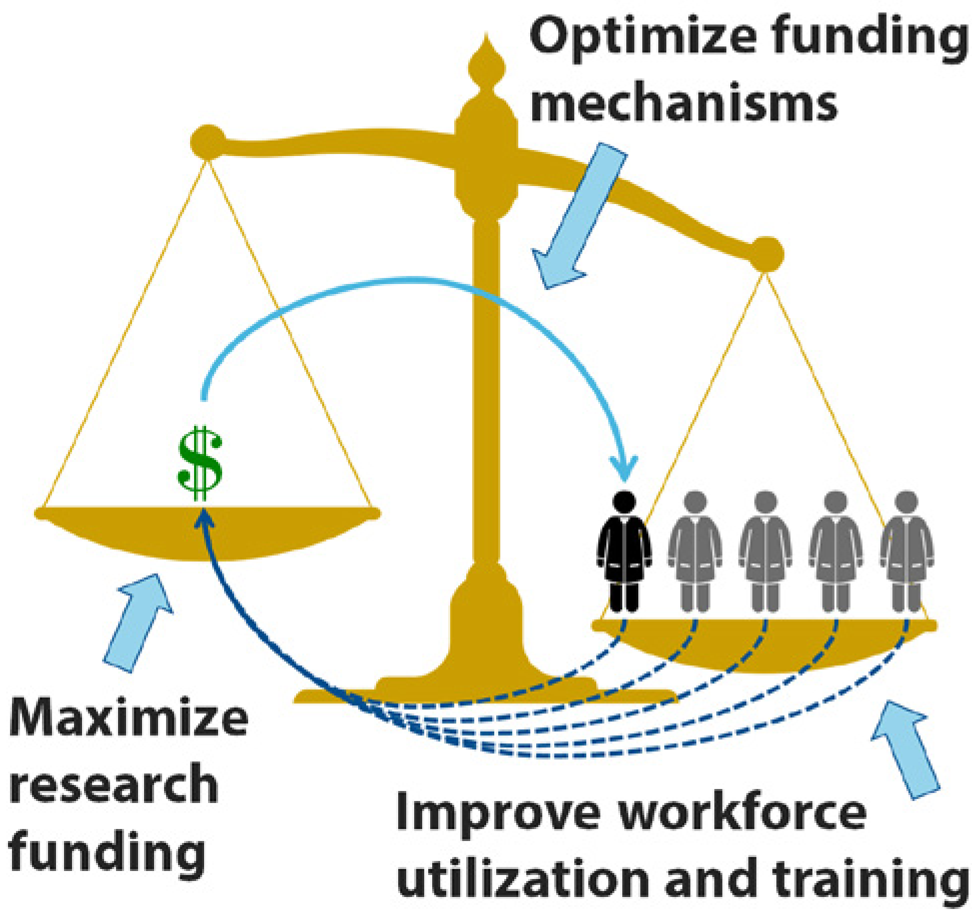
83 Donna Ginther, personal communication

84 **Council of Graduate Schools.** Graduate Enrollment and Degrees: 2003 to 2013. Tables 3.3, 3.22. September 2014.

Recommendations

Progress in biological and medical research is being delayed by insufficient funding and rising costs. At the same time, the research workforce has become increasingly reliant on external research grants, and funding rates are at an all-time low. The prospect of long-term shortfalls in funding for scientific research is driving skilled investigators out of the field and threatening permanent damage to the research capacity of the U.S.

Additional funding is needed to take full advantage of new scientific opportunities. We can also make better use of existing resources by reducing regulatory burden, making better arrangements for new facilities and sharing equipment, stabilizing the workforce, improving training, and developing better mechanisms for funding research. FASEB offers the following recommendations to maximize the amount and efficient use of funding, optimize the use of the research workforce, and improve the funding mechanisms used to support research.


Optimize funding mechanisms
$
Maximize research funding
Improve workforce utilization and training

1. Maximize research funding

Federal investment in biological and medical research has been unable to keep pace with the rapidly expanding opportunities and rising costs. Other sources of research funding are not able to replace the declining public support. The U.S. must raise federal funding levels, ensure sustainable growth, and optimize the allocation of resources.

See Section 1.1

See Section 1.2

Sustain funding

1.1 Congress and the Administration should restore the lost purchasing power of agency research budgets

Since 2003, the NIH has lost more than 20 percent of its capacity to fund research due to a combination of budget cuts and inflationary losses. Other funding agencies have faced similar declines in the past decade. To revitalize the research enterprise, Congress should restore the budgets of these agencies.

1.2 Congress and the Administration should provide sustainable and predictable funding for biological and medical research

The persistence of budgetary gridlock, with delayed appropriations and uncertain funding levels, is disruptive to progress. To maximize long-term planning and scientific progress, funding agencies need stable, predictable research budgets.

1.3 Funding agencies should expand mechanisms to facilitate financial support from stakeholders, such as industry, patient groups, and foundations

Federally funded research directly benefits many stakeholders, and some of these groups are in the position to individually or collectively supplement the federal investment. For some precompetitive work (typically basic research), there may be collective interest in extending the boundaries of scientific knowledge, but no convenient means for stakeholders to jointly support the research or seek researchers with the necessary expertise. The federal government can act as a convener to help identify interested stakeholders and connect them with talented investigators. In some circumstances, agencies may only need to act in a coordinating role and, in other situations, joint-funding opportunities may be most appropriate. Creative partnerships with industry, such as those promoted by the Foundation for NIH, should be encouraged.

1.4 The research community should expand its efforts to communicate more broadly the value of biological research and the importance of federal funding

The research community needs to continue to engage in a broad program of public education, from presenting research at science cafes to publishing editorials in their local newspaper. In addition to describing the results and value of biological and medical research, the research community – investigators, research institutions, scientific societies, and industry – must clearly communicate how bioscience research is done. This includes how it is funded, how it integrates discoveries from other fields, and how its outcomes and applications cannot always be accurately predicted.

1.4.1 Scientists need to increase their efforts to reach out to their elected representatives

The hundreds of thousands of biological investigators in the U.S., located in every state of the nation, need to cultivate broader enthusiasm and support for science by engaging in more frequent dialogs with local civic groups and elected representatives. FASEB and constituent societies also offer many resources to help, including Capitol Hill Days and e-Action alerts. Researchers must become more engaged, and efforts to assist and encourage them must be expanded.

1.4.2 FASEB should continue to provide analyses, federal funding recommendations, and advocacy materials for researchers and the public

For many years, FASEB has published recommendations for federal science funding, analyses of the research workforce and NIH funding, state and district factsheets, as well as topical factsheets on issues such as sequestration. FASEB's "Become an Advocate" webpage includes step-by-step instructions on how to advocate for sustained research funding, and FASEB webinars aid individuals interested in using these resources. FASEB must remain committed to supporting advocacy through provision of these resources.

1.4.3 Institutions need to support scientists seeking opportunities to engage the public

Institutions should encourage investigators to communicate with the public. Such communication activities are one of the many ways institutions serve their local communities. Principal investigators, in turn, need to be supportive of members of the laboratory.

1.4.4 Researchers should maintain a dialog with patient and other advocacy groups

Patient and disease-based groups are important advocates for federal research funding. The scientific community needs to continue to work closely with these groups and other organizations seeking ways to improve the nation's health and well-being. These interactions can also strengthen research efforts, informing investigators of the needs of and challenges faced by patients.

1.4.5 The research community should also encourage industry to advocate for federally funded research

Basic research is a critical foundation for future innovation, and the private sector greatly benefits from the public investment in research. Federal research funding also supports the training of the vast majority of the research workforce, which is also of great value to companies. FASEB and other science advocacy groups should encourage industry representatives to speak out in support of the federal research portfolio and include them in its advocacy efforts.

See Section 1.3

See Section 1.3.1

Optimize the use of resources

Reduce regulatory burden

1.5 The research community should vigorously and collectively oppose the addition of unnecessary or duplicative regulations

For decades, institutions, investigators, and the organizations that represent them have provided comments on federal rules and policies. These efforts must be expanded and intensified to match the growing number and complexity of regulatory proposals. We should insist that new regulations be based on a clearly demonstrated need and demand rigorous evaluation of their impact. New regulations should demonstrate benefits that exceed their costs.

1.5.1 Federal agencies should provide reasonable deadlines for public comment on new or proposed regulations

Official deadlines for providing comments are often far too short for the development of thoughtful, detailed statements. The research community must insist that agencies provide sufficient time for reactions to new or proposed regulatory decisions. When this is not the case, the research community must not restrict itself to the deadlines provided in the official announcements. The community must keep the discussion going until there is an adequate resolution of the issues.

1.5.2 Whenever possible FASEB and others in the research community need to coordinate comments for proposed regulations to maximize the effectiveness of our responses

Coalition statements, incorporating the perspectives of a wide segment of the research enterprise, should be developed whenever possible, and FASEB should take the lead in organizing these efforts.

1.5.3 Federal agencies should conduct cost-benefit analyses of new regulations or changes to regulatory policy

It is important that regulatory requirements be aligned with the risk that the new regulation aims to mitigate. Cost-benefit analyses can help clarify this relationship, and the societal cost of delayed research progress should be included in the calculation. When costs and benefits cannot be fully calculated, the research community should insist that new rules have sunset or mandatory review provisions. Agencies are required to conduct cost-benefit analyses in certain circumstances.[85] These analyses should be made publicly available during the comment period for the proposed regulation.

1.6 The federal government should eliminate unnecessary regulations, and it should streamline or harmonize those that serve important functions

The 2014 National Science Board (NSB) report on administrative workload for federally-funded research found that a "substantial lack of consistency and standardization remains with and among agencies in all aspects of grant management."[86] Ineffective, unnecessarily complex, and redundant regulations waste scarce resources; opportunities for cost savings are abundant. There are multiple efforts underway to reduce regulatory burden and bipartisan support in Congress for reform. FASEB must actively support these initiatives.

1.6.1 FASEB should identify specific regulations and policies that need to be eliminated, modified, or harmonized

The entire research community needs to employ a more active approach to regulatory reform, and FASEB should take a lead role in this endeavor. To this end, the community should provide concrete proposals with supporting data on ways to reduce the time and resources spent on unnecessary research regulation. These proposals should be shared with the NSB, the Research Business Models Subcommittee of the National Science and Technology Council, the FDP, relevant federal agencies, and research institutions. We must ensure, however, that efforts to harmonize regulations do not result in an increased burden when more restrictive policies are applied to new situations.

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85 Established under: Executive Order 12866 of September 30, 1993. Regulatory Planning and Review, Code of Federal Regulations, title 3.

Reaffirmed by: Executive Order 13563 of January 18, 2011. Improving Regulation and Regulatory Review, Code of Federal Regulations, title 3.

86 **National Science Board.** NSB-14-18.

1.6.2 FASEB needs to enthusiastically support and extend the work of the FDP and NSB initiatives on regulatory burden

FDP surveys and initiatives (like "just-in-time" submission of animal research protocols) have made important contributions to the effort to control regulatory expansion. Through the Task Force on Administrative Burden, the NSB has also taken steps to mitigate regulatory costs. FASEB should continue to work with these organizations on regulatory excess.

1.6.3 FASEB and the research community should advocate for the creation of an interagency federal working group to harmonize, streamline, and eliminate duplicative and unnecessary regulations

NSB urged the creation of a federal effort to harmonize research regulations, and this idea was embraced in legislation passed by the House of Representatives, the Research and Development Efficiency Act (H.R. 5056). It calls for the establishment of an interagency federal working group to harmonize, streamline, and eliminate duplicative federal regulations. The proposed legislation also addresses reporting requirements and minimization of regulatory burden for institutions conducting federally funded research. The Senate should pass this bill, and the President should sign it.

1.7 The federal government and research institutions should eliminate duplicative or unnecessary training and certification requirements

The federal government and research institutions should work together to minimize time spent on redundant re-certification and re-training activities. Training and certification are important tools to ensure that research is conducted safely and ethically. Excessive retraining, however, provides little value and wastes time and resources. Some of this duplication could be mitigated through greater coordination and standardization of federal agency and institutional requirements. Short refresher courses emphasizing general principles, new information (such as regulatory changes), and problems identified in post-approval monitoring by the institutions would provide greater value than repetition of the original training course. Standardization of training may also allow certification to be easily transferred between research sites, further reducing duplicative retraining and facilitating research collaborations.

1.8 Investigators and administrators must take steps to promote efficient regulatory compliance practices at their institution

Much of the increased cost of regulation is due to "over-compliance," a widespread problem caused by risk-averse institutional administrators. Curbing this costly and counterproductive behavior will require vigilance and a willingness to speak out in response to overzealous administration.

Individuals and institutions have begun to examine ways to reduce administrative costs,[87] including the development of comparative metrics and decision frameworks. When they prove successful, they should be shared with other institutions, as was done with a decision tree for assessing animal care and use programs.[88]

Institutions and their staff could make better use of data on regulatory activities. For example, member institutions collect and report information on the average time needed for approval of human research protocols to the Association for Accreditation of Human Research Protection Programs. If institutions publicly posted these average approval times, institutional staff and faculty could compare themselves to the national average and initiate improvement in cases of underperformance.

Individual institutions can foster these efforts through faculty task forces on administrative burden. These initiatives should be established and supported. Institutions and research organizations should also consider offering prizes and other incentives to promote efficient regulatory compliance.

1.9 The research community should encourage regulatory changes that permit efficient practices, such as multi-site Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs), whenever possible

Large-scale, multi-institutional studies are often subject to multiple levels of review. Currently, institutions provide complete oversight of any portion of a study conducted at the institution, even if the work was completed in full compliance with the protocols and processes approved by another IRB or IACUC. Redundant reviews for important large-scale, multi-site studies are wasteful and unnecessary.[89] They also delay research and lead to variation in procedures across sites. Several NIH Institutes support the use of a single IRB in their large clinical trials networks, and NIH is working to make this approach the default for all supported research.[90] If institutional liability were limited to ensuring that investigators maintain compliance with an external regulatory body, institutions would be more willing to utilize national or regional regulatory bodies for multi-site research projects. This would save time and money while still ensuring appropriate oversight.

There are other regulatory changes that reduce administrative costs while maintaining oversight. An FDP pilot project to replace effort reporting with

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87 **Kiley K.** Where Research Universities Can Be Cut. *INSIDE Higher Ed.* September 16, 2011.

88 **Haywood JR, Greene M.** Avoiding an overzealous approach: a perspective on regulatory burden. *ILAR J*. 2008;49(4):426-34.

89 **Wagner TH, Murray C, Goldberg J, Adler JM, Abrams J.** Costs and Benefits of the National Cancer Institute Central Institutional Review Board. J. *Clinical Oncology*. 2009; 28(4):662-666.

90 **Rockey S.** Streamlining IRB reviews of multi-site clinical research studies. *Rock Talk blog*. February 1, 2013.

a payroll certification system has generated payroll processing savings of approximately 90 percent at participating institutions. Support from federal agencies and auditors will be needed to move this pilot system into general practice. Similarly, NIH permits the use of "just-in-time" review for several portions of grant applications – such as project budgets and animal and human subjects institutional review – to save time, expedite grant review, and reduce burden on institutional oversight bodies. However, utilization of this approach has been limited among other research sponsors. These efforts to develop more efficient practices should be encouraged and supported.

See Section 1.3.2

Reduce the damage caused by budgetary uncertainty

1.10 Because of the breakdown in the appropriations process, federal research agencies should be allowed to carry funding over into the following fiscal year

The uncertainties associated with delayed appropriations and short-term continuing resolutions make it difficult for agencies to carry out their responsibilities in a timely fashion. When agency budgets are not finalized until well into the fiscal year, agencies that operate under an annual budget cycle must make spending decisions in a compressed timeframe or forfeit any funds unexpended in the fiscal year. A more predictable budget process, multi-year appropriations, or more flexible carry-over authority would allow other research agencies to optimize expenditures, use funds more efficiently, and fund more research.

See Section 1.3.3

Enhance deployment and use of resources

1.11 Research sponsors should provide greater flexibility in shared instrumentation and core facility programs to ensure that equipment is available to the widest possible range of users

Shared instrumentation programs give groups of scientists access to advanced equipment needed for their research in a cost efficient manner. Research sponsors need to expand the types of equipment purchases eligible for procurement through shared instrumentation programs by either modifying thresholds or developing new mechanisms.

Similarly, regional core facilities could broaden access to new technologies. To ensure efficient use, guidelines should be in place – mirroring those for institutional cores – to address the development, operation, and sunsetting of regional facilities.

1.12 Research sponsors should encourage greater resource sharing when funding infrastructure

Sponsors awarding infrastructure grants should consider plans for resource sharing when making the award. These plans should be a "scored" component of the funding decision.

1.13 The research community should examine the effect of reducing incentives for debt-financing of new facility construction

The ability to include interest expenses as part of an institution's F&A rate may be an incentive to expand facilities. It is possible that even a marginal change in interest rate policy could influence the behavior of decision makers and lead to more efficient use of current infrastructure.

More information is needed on reimbursement of interest expenses through F&A. We do not know what would happen if the debt servicing portion of F&A reimbursement were eliminated or capped for new facilities. The research community needs to determine if a change in policy would increase the amount of money available for other research costs (e.g., administrative expenses or direct funding for salaries and equipment), help counterbalance other expansionary pressures (including third-party salary payment), or substantially reduce infrastructure quality in the long-term.

1.14 Stakeholders should create a broader range of institutional ranking metrics (including indicators of a stable and sustainable research system) to reduce the likelihood of wasteful overcapacity

By focusing on the growth rate and amount of funded research, current institutional ranking metrics encourage expansion without regard for the sustainability of the larger research enterprise. Indicators that draw attention to destabilizing actions would promote healthier behaviors. These new measurements might include research faculty turn-over rates, number and percentage of endowed faculty positions, and the percentage of research faculty salary funded by the institution. Since the early 1980s, the National Research Council has produced an assessment of U.S. research doctorate programs, and over time it has refined the measures and indices to provide greater insight and value to users. The most recent study, published in 2010, included faculty publication and funding metrics.[91] Indicators of faculty salary support and stability should be added as measures of the institutional research environment.

Federal surveys should also be enhanced to monitor the health of the research enterprise. Future cycles of the NSF Survey of Science and Engineering (S&E) Research Facilities should include measurements to document space utilization trends, such as the number FTE research personnel by field and the net amount of research space reassigned to other uses.

91 **National Academies of Science.** *A Data-Based Assessment of Research-Doctorate Programs*. Committee to Assess Research-Doctorate Programs, National Research Council, National Academies of Science.

2. Optimize funding mechanisms

While it is essential to increase funding for biological and medical research, research sponsors and the bioscience research community may also be able to expedite progress by improving the mechanisms by which research is funded. Grant mechanisms that worked well in the past may no longer be the most effective way to fund biological and medical science in the 21st century.

See box on faculty administrative workload

See Section 2.2

Reduce the time spent preparing and reviewing applications

2.1 Research sponsors should make greater use of just-in-time components in grant applications

Due to historically low success rates, the vast majority of grant applications – including many highly meritorious proposals – will not be awarded funding. Given the low probability of success, agencies should allow investigators to submit short technical proposals and then submit detailed descriptions and regulatory approvals only if the proposal is likely to be funded. NIH currently permits just-in-time submission of select application elements, including IRB and IACUC approval, human subjects education certification, and small business research grant funding agreement; NIH could expand this to other elements, such as data sharing plans and select portions of regular (non-modular) budgets. Other agencies should follow NIH's lead and adopt just-in-time submission for information not absolutely essential for merit review.

2.2 Research sponsors should standardize grant application forms and materials to the greatest extent possible

Greater standardization of grant application forms will make it easier for scientists and engineers to submit and review research proposals. At present, individuals seeking funds must reformat their proposals for each source of funding. Reducing the unnecessary variation would expedite the application processes and enable reviewers to more efficiently assess the proposals that they are asked to review.

2.3 Research sponsors should explore the use of merit reviewed pre-proposals

At the present time, a substantial amount of time and energy are dedicated to the preparation and review of research proposals, and the tremendous volume of proposals has strained review systems. Several research funders, including some divisions of the NSF Directorate for Biological Sciences, require investigators to submit short pre-proposals before they are invited to submit full proposals to be considered for funding. Merit reviewed pre-proposals will reduce the amount of time investigators spend preparing applications and will alleviate some of the burden on the scientific community to serve as reviewers of applications.

2.4 Research sponsors should consider extending the duration of some investigator-initiated grant awards to decrease the amount of effort spent competing for funding

The amount of time that researchers spend writing and reviewing proposals has risen dramatically, while the chances of success have plummeted. Providing longer awards would shift the allocation of effort expended by researchers, reviewers, and agency staff, enabling them to spend more time on research and less time competing for funding. This would expedite the research process and provide a substantial benefit to the public. Benchmarks of accomplishment over the course of the award would permit sponsors to have an ongoing dialog with investigators and review of these longer grants.

The National Cancer Institute (NCI) recently announced a program-based R35 grant, the Outstanding Investigator Award, which provides support for seven years. The National Institute of General Medical Sciences (NIGMS) announced plans for its R35 grant, the Maximizing Investigators' Research Award (MIRA), which provides five years of support. Other NIH institutes, including the National Institute of Neurological Disorders and Stroke (NINDS), are also planning extended-time awards.

Longer grants could increase the demand for funding, and therefore it is important that research funders consider ways to offset this cost. The NCI award, for example, requires a specified level of institutional salary support for the principal investigators. NIGMS's MIRA award to established investigators contains provisions for limiting total amount of institute funding. To be most effective, the longer awards should consolidate the number of awards per person, but they should not reduce the number of individuals receiving support. FASEB supports the development of creative, new approaches to research funding, but urges that these initiatives be rigorously evaluated and the outcomes shared with the entire community.

See Section 1.1

See Section 2.1

See Section 2.2

Increase portfolio evaluation

2.5 Research sponsors should undertake regular evaluations of funding mechanisms and share findings with the broader community

Portfolio evaluation allows research sponsors to detect shifts in funding trends and to adjust their funding strategies to address changing scientific needs and opportunities. In 2008, for example, the NIGMS initiated major, external analyses of two of its larger programs: Large Scale Collaborative Project Awards or "Glue Grants," and the Protein Structure Initiative. After reviewing the evaluations, both programs were restructured and scaled back.[92] As part of its 2010 strategic planning process, NINDS undertook an analysis of its portfolio and found that its support for R01 grants decreased by ten percent between FY 2003 and FY 2008. Expanding the evaluation, NINDS staff found a surprising and substantial decline in basic research proposals[93] and is now conducting additional analyses to gain a better understanding of the reasons behind the dramatic change. These NIH Institutes should be commended for undertaking such analyses, and we urge other funding agencies and organizations to pursue similar reviews.

2.6 Advisory councils and boards of research sponsors should review portfolio allocations and prioritize investigator-initiated research

The path-breaking ideas that have advanced biological and medical science have been made, for the most part, by individuals and teams of scientists working on hypothesis-driven research. While large-scale projects and initiatives have aided science in many ways, they should be carefully scrutinized before funding and rigorously evaluated throughout their lifespan. Several groups have called for funding to be redistributed from large-scale

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92 For addition details, refer to the following:

Berg J. More on Assessing the Glue Grant Program. *NIGMS Feedback Loop Blog.* June 10, 2011.

Lorsch J. Examining Our Large-Scale Research Initiatives and Centers, Including the PSI. *NIGMS Feedback Loop Blog.* September 24, 2013.

93 **Landis S.** Back to Basics: A call for fundamental neuroscience research. *NINDS Blogs.* March 27, 2014.

The analysis found an increase in applied research as a percentage of total competing research budgets (from 13 to 29 percent from FY 1997 to 2012). Within the basic research category, funding was divided between the subcategories "basic/basic" and "basic/disease-focused." The "basic/basic" subcategory declined even more dramatically (from 52 to 27 percent of the competing budget). As success rates remained fairly steady within the subcategories, it suggests a shift in the types of applications submitted, which may, in part, be due to investigator perceptions of what is "fundable."

projects and centers to investigator-initiated research projects.[94] NIGMS determined that the targeted awards made under the Funding Opportunity Announcements component of its portfolio increased[95] and initiated steps to reverse the trend. Other federal agencies and NIH Institutes should review their portfolios and maximize funding for investigator-initiated research.

Continue to explore new mechanisms for research funding

See Section 2.1

See Section 2.2

See Section 2.3

2.7 Research sponsors should explore the impact of funding scientists or research programs instead of proposals for specific projects

Most federal funding agencies award research grants to individuals according to the scientific merit of the project proposed. Another approach, used by the Howard Hughes Medical Institute (HHMI), evaluates the potential success of individuals rather than their proposed projects. Both the NIH and the HHMI model have been successful, and in practice the two systems often operate in tandem. However, in the present funding environment with extremely low success rates, it is generally acknowledged that applicants, reviewers, and research sponsors have become more conservative in the science proposed and funded. Low success rates also increase the burden on scientists who must submit multiple proposals to obtain funding and keep their laboratories functioning.

Providing support for an investigator or an investigator's research program, potentially for longer time periods than currently allowed, could have several positive outcomes. First, it could provide financial stability that will encourage scientists to pursue riskier projects as a part of their laboratory's research and give them the flexibility to explore new lines of inquiry as they arise. Second, investigator-centered funding programs can be designed to minimize subsequent grant submissions during the funding period, reducing the burden on both investigators and research sponsors. Mechanisms should be implemented to ensure rigorous intermediate review of investigators funded through these programs to ensure that junior investigators are not disadvantaged and that there are no deleterious effects on the diversity of funded scientists.

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94 For examples, refer to the following:

American Society for Biochemistry and Molecular Biology. *ASBMB Is Concerned about the Decline in Support for Investigator-Initiated Research*. ASBMB whitepaper. March 11, 2011.

Genetics Society of America. *White Paper on the NIGMS Strategic Plan*. GSA. March 31, 2014.

95 **Lorsch J.** Bolstering Our Commitment to Investigator-Initiated Research. *NIGMS Feedback Loop Blog*. January 13, 2014.

Several pilot projects are presently underway in different NIH institutes, for example NIGMS and NCI. It is crucial that these institutes develop and release for public comment a robust evaluation plan for assessing the outcomes of their pilot programs. The program evaluation should include analysis of applicant and awardee demographics, including career stage, institution location and type, and amount of prior support from NIH and other federal agencies. To ensure trust and transparency, evaluation reports should be quickly disseminated to the scientific community.

2.8 Research sponsors should monitor the amount of funding going to a single individual or research group to ensure a broader distribution of research funding

Limiting the amount of funding awarded to any individual scientist or laboratory would enable more people to be actively engaged in research. With more "hands at the bench," the number of ideas would increase, and this could expedite progress in many areas of science. Analyses produced by NIH as part of the call for suggestions on "Ways of Managing NIH Resources"[96] show that limiting a principal investigator's total RPG support to $1 million would enable the funding of 2,000 additional RPG awards at an average cost of $400,000.

Evidence suggests that limiting the amount of funding to investigators might enhance the productivity of the portfolio overall. An analysis of NIGMS grants found that the correlation between funding and the number of research publications became attenuated at the highest funding levels.[97]

NIGMS requires special Advisory Council review before making an award to an investigator with grants totaling more than $750,000 in annual direct costs. In 2014, NIH adopted a policy requiring special Advisory Council review of any grant requesting more than $1 million per year in direct costs,[98] and some Institutes have established additional policies to constrain awarded funding. Further experimentation and analysis should be undertaken to assess the impact of efforts to broaden the distribution of research funding.[99]

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96 **NIH Office of Extramural Research.** *Ways of Managing*

97 **Berg J.** Measuring the Scientific Output and Impact of NIGMS Grants. *NIGMS Feedback Loop Blog.* September 27, 2010.

98 **NIH Office of Extramural Research.** Notice of NIH Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support. NOT-OD-12-140. *NIH website*. August 20, 2012.

99 For examples, refer to the following:

National Institute of Child Health and Human Development. NICHD Policy Guidelines: Large Grants. *NICHD website.* Last updated April 17, 2013. Accessed May 19, 2014.

National Cancer Institute. Requirement for Prior Approval to Submit Applications Over $500,000 Direct Costs. *NCI website.* Accessed May 19, 2014.

National Institute of Allergy and Infectious Diseases. Big Grant Applications: Questions and Answers. *NIAID website*. June 13, 2013. Accessed July, 1, 2014.

2.9 Research sponsors should examine the feasibility of awarding partial funding to grants based on their priority score

With an abundance of excellent research proposals and merit review scores tightly clustered, "all or nothing" funding decisions may not be the best approach.[100] A sliding scale for funding grants, with the highest scoring proposals getting full funding and other meritorious proposals getting various levels of partial funding based on their ranking[101] would enable more ideas to be tested.

Prioritizing grants for partial funding that just miss full funding during a competitive renewal has the added benefit of minimizing inefficiencies due to funding disruptions by keeping projects alive and maintaining a vital research infrastructure. NSF already "negotiates" with applicants to determine if a reduced budget would be feasible for their project. The pilot NIGMS research program award would taper off funding for proposals that are not renewed on the first round of review to mitigate the costs associated with halting and restarting research. These approaches may be more reasonable than setting budgets by formula. The amount of partial funding awarded should be consistent with project aims in the revised application.

2.10 Research sponsors should consider creating a transition award for senior investigators

One way to reduce competition and free up more grant funding for early and mid-career scientists is to provide an incentive for senior scientists to downsize their laboratories. Experienced, senior investigators might appreciate the opportunity to contribute their expertise and insights to research projects without the burden of full-time laboratory management. Research sponsors should consider establishing "transition awards" that would provide support for senior investigators who chose to become collaborators on the projects run by younger scientists. To ensure utilization of this type of award, sponsors will need to investigate ways to enhance mechanism efficacy for both junior and senior investigators.

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100 **Grinnell F.** It is time to update US biomedical funding. *Nature*. 2013 Sep 12;501(7466):137.

101 **American Society for Biochemistry and Molecular Biology.** *ASBMB Is Concerned*

3. Improve workforce utilization and training

Progress in biological and medical research is dependent on the availability of bright, well-educated, and highly motivated researchers. In the U.S., much of the laboratory work in the biosciences is performed by graduate students and postdoctoral scholars being trained for research careers. This system has produced outstanding scientists and engineers and has accelerated discovery. It has also led to a rate of increase in the population of researchers that far exceeds availability of new faculty positions and research funds to support them. Alternative ways to structure and train the workforce should be considered.

See Section 2.2

Maximize the creative potential of investigators

3.1 Research sponsors should take steps to reduce principal investigator dependence on external salary support

As the research enterprise has expanded over recent decades, investigators have been encouraged and even required to charge an increasing percentage of their salary to research grants. This practice has enabled a major expansion of the biomedical workforce while shifting salaries from employing institutions to research funding organizations. The ability to charge 100 percent of an individual's salary to extramural grants has also led to a proliferation of soft-money faculty positions. Over-reliance on sponsored funding for salary support has (1) interrupted and prematurely terminated many promising careers; (2) encouraged grantees to emphasize short-term success; (3) created a stressful work environment that is not conducive to creativity, risk-taking, or long-term planning; and (4) discouraged students and early career scientists from the pursuit of research careers. Highly leveraged investigator salaries also become particularly problematic during times of interrupted funding, further elevating workforce instability.

3.1.1 NIH should gradually reduce the percentage of principal investigators' salary that can be charged to research grants

Principal investigators with institutional responsibilities for teaching and service cannot be expected to devote 100 percent of their time to funded research. They also cannot be expected to compete for new awards if all of their time is charged to sponsored research. Agencies should set reasonable limits on salary support that recognize differences in institutional missions. A gradual approach would minimize shock to the system, allowing investigators and institutions time to adapt. The time frame recommended in the NIH Biomedical Workforce Working Group Report is 20 years.[102] This would slowly reduce the cost of NIH grants, enable it to support more research projects, and ultimately align NIH's grant practices more closely with NSF and other agencies that limit principal investigators' salary support. Any policy change should take in to account the different structures of academic institutions versus independent research institutes.

3.1.2 To reduce instability associated with the funding and renewal of individual grants, federal research funding agencies should create short-term, "bridge-funding" programs with mandatory institutional matching components that include partial salary support

Abrupt terminations of funding can halt valuable lines of research and end productive research careers. With grant proposal success rates at or near all-time lows, bridge funding mechanisms are needed to support promising projects and labs for short periods between grants. Institutions could receive block grants for bridge-funding based on their total agency funding, and an institutional salary matching requirement would minimize the cost to agency competitive grant portfolios.

Enhance the training experience

See Section 2.3

See box on attracting students to bioscience research careers

3.2 Institutions should communicate information about career prospects to incoming graduate students and provide information about career paths to current trainees

Academic employment is no longer the likely destination of new PhDs in the biomedical sciences, and the majority of recent graduates are now following other career paths. A recently released National Academies report, however, claims that "there is little evidence that universities and mentors are providing adequate information about preparation for other types of careers."[103] Students need access to better information about career options and the employment outcomes of earlier cohorts of trainees so that they can make more informed decisions about their education. Graduate students and postdocs recognize

102 **NIH Advisory Committee to the Director.** *Biomedical Research Workforce*

103 **National Academies of Science.** *The Postdoctoral Experience Revisited*

the great value of this information and also have called for greater access.[104]

3.2.1 Institutions should publish data on career outcomes of each department's graduate students and postdocs

This information should be readily available to prospective graduate students and applicants. The NIH Biomedical Workforce Working Group recommended that the "rates, time to degree, career outcomes for PhD trainees, as well as time in training and career outcomes from postdoctoral researchers over a 15-year period" be collected and "displayed prominently on the institution's web site."[105] This information can be collected efficiently using methods employed by the institution's fundraising office coupled with social media resources.[106]

3.2.2 Graduate programs should offer students a variety of scientific degrees that better align with career options

A research doctorate may not be the best option for everyone interested in pursuing advanced education or careers in science. Graduate programs should provide a range of degree options, such as master's degrees, professional science master's degrees, genetic counseling degrees, and other applied science degrees. These alternatives will enable research doctorate programs to focus on traditional scholarly goals while universities also provide market-oriented education and degrees that have proven to be very popular with both students and employers. Prospective students often do not fully appreciate the range of degrees and career paths available, and graduate programs need to enhance communications about the variety of educational options in the biological and medical sciences.

3.2.3 Trainees should be supported in their exploration of non-academic career paths

Career advice is an important component of good mentorship, but many faculty members lack the experience needed to provide it, especially for non-academic careers. Institutions should provide a career development office for graduate and postdoctoral trainees. Faculty need to urge their students to start taking advantage of this service early in their training. FASEB also recommends the use of myIDP, an individual development plan (IDP) developed in part by FASEB, to facilitate the dialog between faculty and trainees about career opportunities and training needs.

3.3 The research community should take additional actions to ensure quality training of graduate students and postdocs

We need outstanding scientists and engineers to conduct research and

104 **McDowell.** Shaping the Future

105 **NIH Advisory Committee to the Director.** *Biomedical Research Workforce*

106 **National Academies of Science.** *The Postdoctoral Experience Revisited*

perform a variety of essential jobs in a world increasingly dependent on technology.

3.3.1 PhD programs should help students acquire skills for professional success

Scientists and engineers need a broad range of skills (including leadership, project management, and communications) to succeed, no matter which career path they pursue. PhD programs should not sacrifice their primary purpose—research training—for job training, but they must help their students acquire the wide range of skills and experiences that are crucial for any professional career.

3.3.2 Institutions need to provide "protected time" for graduate students and postdocs to pursue skills and experiences beyond those directly related to their research projects

Many training grants explicitly include skill development experiences as a formal element of the program. But not all students and postdocs have access to these resources and must obtain them on their own. The majority of students and postdocs are funded as research assistants, and they must be given time outside the lab or research project to pursue these essential skills.

3.3.3 Institutions and graduate programs should re-evaluate admissions policies for PhD programs

In response to changes in the labor market and the reductions in research grant funding, some graduate programs have announced that they will reduce the number of new students that they will admit.[107] Reducing the size of incoming classes would help improve the employment prospects of future graduates.

3.3.4 Research sponsors and institutions should increase stipends for graduate and postdoctoral trainees

An overwhelming majority of graduate students and nearly all postdocs are supported on research grants. They provide an essential supply of labor for research in return for research training and a modest stipend. A recent study indicates that income lost during this training period is not regained in future employment.[108] Graduate students and postdocs are highly skilled workers and should be fully compensated for their contributions to research projects. The National Research Council has recommended increasing trainee stipends.[109] Higher stipends would also ensure that the U.S. will be able to continue to attract and retain the most talented people in science careers.

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107 **Balser J.** Rounds: A Message from the Vice Chancellor for Health Affairs. *Vanderbilt University School of Medicine Reporter*. November 5, 2013.

108 Donna Ginther, personal communication

109 **National Academies of Science.** Research Training in the Biomedical, Behavioral, and Clinical Research Sciences. Committee to Study the National Needs for Biomedical, Behavioral, and Clinical Research Personnel, National Research Council, National Academies of Science. National Academies Press, Washington, DC, 2011.

3.3.5 Federal agencies should reduce the amount of tuition support provided on research grants

Federal support of graduate education in the sciences was based on the premise that academic research careers were a public good, but faculty salaries were thought to be too low to attract sufficient numbers of tuition paying graduate students. Today, the number of new PhDs in the biomedical sciences far exceeds the demand for new faculty members. With funding for tuition and stipends coming from federal agencies, neither the students nor the universities are paying the full cost of graduate education. Thus, the market factors that regulate the size of entering classes in other fields cannot operate efficiently. A reduction of the federal tuition subsidy for graduate students working as research assistants would remove an incentive that has outlived its original purpose.[110]

3.4 The research community as a whole should continue to monitor graduate and postdoctoral education to ensure that changes do not undermine efforts to diversify the workforce

Changes in the number of trainees, as well as where and how they are trained, could affect the composition and diversity of the trainee population. Care should be taken to ensure that changes (both deliberate and unplanned) are consistent with efforts to increase participation of underrepresented groups.

See box on physician scientists

Ensure an adequate supply of physician scientists

Physician scientists and researchers holding other clinical degrees make critical and unique contributions to biomedical research, especially in human subjects research. However, the fraction of the research workforce with medical training is decreasing. Steps must be taken to ensure that there are adequate numbers for future needs.

3.5 NIH should create new funding mechanisms and modify current vehicles to increase the number of physicians and other clinicians entering research careers

Drawing upon recent studies, NIH should develop new programs and modify existing efforts to support their training and early research careers of physician scientists. Examples include a new transition to independence award for physicians, as recommended by the recent report on physician scientists, or modification of the terms of the current K99/R00 mechanism so that it does

110 **Penning T.** Can we do more research with less? *Chair's Corner, American Chemical Society Division of Chemical Toxicology Newsletter.* June, 2014.

not conflict with the requirements of residency and specialty training.[111] NIH and other research sponsors should also seek ways to increase and expand the Loan Repayment Program, which provides debt relief for physicians who pursue research careers in certain specified fields. The loan repayment levels need to be increased and the areas eligible for participation need to be broadened.

3.6 Congress should increase the NIH salary cap contingent upon a reduced F&A cost recovery at higher salary levels

Under the current salary caps, physician scientists – who also may have high student debt – frequently receive higher remuneration from clinical services than research. Raising the salary cap on extramural awards would remove a barrier to participation of physician scientists on grant-funded research projects. Since many administrative costs associated with employees are fixed rather than proportional to salary, the portion of the salary eligible for F&A recovery could be capped instead. A system that balanced higher salaries with reductions to F&A reimbursement at the upper-income levels would increase participation of physician scientists on research grants while offsetting some of the expense.

Make more extensive use of non-trainee research positions

See Section 2.3

3.7 The research community should employ more staff scientists and consider more extensive use of career technicians

Students and postdocs are temporary laboratory workers, moving to another laboratory or job after completing the current stage in their education. When they leave, the laboratory loses their project-specific knowledge, and new replacements must be trained to fill their place. An alternative structure is one in which the research is conducted by staff scientists, technicians, and a smaller proportion of graduate students or postdocs.[112, 113] While the salaries of staff scientists are higher, experienced staff scientists may raise productivity while providing the principal investigator with more time to oversee the research program and mentor a smaller group of graduate and postdoctoral trainees. Their laboratory experience might also make staff scientists excellent candidates for institutional positions in research administration. To the extent that technical and laboratory maintenance functions are currently performed by graduate students and postdocs, these functions may be more appropriately transitioned to technicians.

111 **NIH Advisory Committee to the Director.** *Physician-Scientist Workforce*

112 **Gerbi S, Garrison H, Perkins J.** Education. Workforce Alternatives to Graduate Students? *Science*. 2001; 292(5521):1489-90.

113 **Bourne.** A fair deal

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Appendix A: Common Acronyms

ACDP	Association of Chairs of Departments of Physiology
ARRA	The American Recovery and Reinvestment Act of 2009
BCA	Budget Control Act of 2011
BRDPI	Biomedical Research and Development Price Index
F&A	Facilities and Administrative costs
FASEB	Federation of American Societies for Experimental Biology
FDP	Federal Demonstration Partnership
FY	Fiscal Year
HHMI	Howard Hughes Medical Institute
IACUC	Institutional Animal Care and Use Committees
IRB	Institutional Review Board
MIRA	Maximizing Investigators' Research Award
NCI	National Cancer Institute
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NSB	National Science Board
NSF	National Science Foundation
R&D	Research and Development
RPG	Research Project Grants
SIG	Shared Instrumentation Grant

Appendix B: List of Key Contributors to the FASEB Draft Discussion Framework

A FASEB Science Policy Subcommittee conducted analyses, developed recommendations, and prepared draft version of the discussion framework. Following feedback from the FASEB community and the roundtable series, it was developed into this present document. This group's extensive work and insight was essential to this effort. The following individuals contributed to the Subcommittee's effort (positions are indicated at the time the framework was first drafted, June 3, 2014):

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Eduardo Rosa-Molinar, PhD (FASEB Board)
Lynn Wecker, PhD (FASEB Treasurer)

Appendix C: List of Roundtable Participants

To further review and extend the analyses and proposals, a series of three roundtable meetings were convened. In addition to representatives of FASEB and its constituent societies, participants included officials from funding agencies, subject matter experts from other fields, representatives from organizations of research institutions, and other stakeholder groups. The roundtables were organized into three separate themes, "Research Infrastructure," "Research Workforce," and "Funding Mechanisms." The individuals listed below generously participated in FASEB's roundtables. FASEB expresses its appreciation to those who joined us for the roundtable series and shared their expertise and perspective. **Please note that participation in the roundtables is not an endorsement of this document or the recommendations contained within it.**

Research Infrastructure Roundtable

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Drexel University College of Medicine
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President
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