

Recent NIH Initiatives to Sustain a Successful Biomedical Research Enterprise

Over the past three years, the NIH has taken steps to identify the nature and causes of the problems facing the biomedical research enterprise and to experiment with strategies to address them.

Three Major Studies of the Biomedical Workforce

NIH Director Francis Collins has commissioned three major studies to better understand the composition of the current biomedical research workforce and what needs to be done to sustain its vitality:

- The Biomedical Research Workforce Working Group Report (June 2012; http://acd.od.nih.gov/Biomedical_research_wgreport.pdf) described the demographic changes that have occurred in the workforce over the past 30 years and made recommendations that have led to new programs described below.

- The Physician-Scientist Workforce Working Group Report (June 2014; http://acd.od.nih.gov/reports/PSW_Report_ACD_06042014.pdf) focused on the dramatic decline in physician-scientists and proposed steps that the NIH should take.

- Working Group on Diversity and the Biomedical Research Workforce (June 2012; <http://acd.od.nih.gov/Diversity%20in%20the%20Biomedical%20Research%20Workforce%20Report.pdf>) documented the lack of diversity in the biomedical workforce and the disparities in success rates for grant applications among ethnic groups and proposed several remedies, some of which are mentioned below.

Responses to Recommendations in the Reports

1. Reform the training of biomedical scientists to reflect changes in the workforce

A. The BEST Program. NIH has launched the "Broadening Experiences in Scientific Training" (BEST) program (<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-12-022.html>) to fund graduate programs that broaden the training of students and fellows without increasing the duration of their education. In addition, BEST program recipients are exploring ways to identify those students, early in their training, who may not succeed in obtaining the Ph.D., with a plan to guide them to a successful career path other than the Ph.D.--- for example, through a Professional Master's Degree program.

The program currently is supporting graduate programs at 17 institutions for five years. Lessons learned through this program are being shared and evaluated with the goal of implementing the most

successful program concepts broadly to all training programs. The awards are \$250K in direct costs plus indirect costs. Eight to ten thousand pre-doctoral graduate students and 4-6000 post-doctoral fellows have the potential to receive augmented training from the 17 awards. A formal evaluation of the entire program will begin in the fall of 2015, but each site is also conducting its own site-specific evaluation, with an agreement share the data with the community. Awardees meet annually, and NIH is gathering information via surveys and interviews with principal investigators.

To complement the BEST program, NIH has also implemented a new policy directing all NIH-supported graduate students and postdoctoral fellows to have an Individual Development Plan (IDP); the IDP requires consultations with mentors early in the training process to provide guidance about choosing among a variety of career paths(<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-12-022.html>). This is an expectation of the NIH as currently we do not have a way to require it on research grants. A formal evaluation of this policy will commence in the fall of 2016.

B. The NRMN. NIH has just launched the National Research Mentoring Network (NRMN) to help a diverse group of students, postdocs and new faculty find excellent mentors (<http://commonfund.nih.gov/diversity/initiatives#NRMN>). The NRMN is a nationwide consortium to enhance the training and career development of individuals from diverse backgrounds who are pursuing biomedical, behavioral, clinical, and social science research careers through enhanced networking and mentorship experiences. The NRMN is developing a nationwide network of mentors and mentees spanning all disciplines relevant to the NIH mission. NRMN is also developing best practices for mentoring, providing training opportunities for mentors, and providing networking and professional opportunities for mentees. The NRMN is comprised of five regional hubs that provide research support for mentors/mentees in both urban and rural settings and establish a nationwide resource. These five regions include: (1) Northeast/Atlantic/Islands, (2) Southeast/ Deep South, (3) Midwest, (4) South, (5) West/ Northern Plains. The NRMN consists of more than 100 actively engaged partner institutions and organizations, including: Boston College, Morehouse School of Medicine, Northwestern University, Society for Advancement of Chicanos and Native Americans in Science, University of Colorado, University of Maryland College Park, University of Minnesota, University of North Texas Health Science Center, and University of Wisconsin. A full list is provided in Appendix A.

C. Transparency in Graduate Program Outcomes. NIGMS Director Jon Lorsch has recently advised all recipients of NIGMS training grants that they are “strongly encouraged” to make their alumni career outcomes publicly available to prospective and current students, preferably by posting the outcomes on their institutions’ websites and consolidating them by department or broad program, rather than just listing individual examples. He also strongly encourages new and renewal T32 program applicants to include information on how their institutions inform students about career outcomes.

2. Earlier Independence for Young Investigators

The Early Independence Award (<http://commonfund.nih.gov/earlyindependence/index>) allows individuals to be appointed to junior faculty positions directly after completing Ph.D. training but without a postdoctoral training experience. To make the expedited transition to faculty status as productive as possible, investigators are required to concentrate on research, with little if any other institutional responsibilities. The number of awards given annually continues to increase based on the recommendation of the report from the Biomedical Workforce Working Group--- from ten in 2011, 14 in 2012, 15 in 2013 and 17 in 2014. An evaluation process is currently underway, to be completed in a few years, when some of the initial grantees would be expected to have secured tenured appointments.

A program of longer standing, the K99/R00 or Pathway to Independence Award (<http://grants.nih.gov/grants/guide/pa-files/PA-14-042.html>), funds the final two years of postdoctoral training and provides a research grant to the individual when appointed to a faculty position. Between 189 and 216 awards have been given each year since 2007. The award was recently modified to reduce the time allocated to postdoctoral studies by one year--- part of an effort to move people to independence at an earlier age (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-013.html>). Based on a recommendation of the Biomedical Workforce Working Group, the number of awards was increased by almost 20 percent to 255 per year. Currently NIH tracks certain demographic information about K99/R00 award recipients, and monitors success in transitioning from the K to the R award phases and in obtaining other grants, such as R01s. A major evaluation will be undertaken next year at the ten year anniversary of the award. In the interim, outcomes so far demonstrate:

Characteristics of Awardees:

- At the time of application for the K, median age was 34
- For most of the program's history (FYs 2007-09 and 2011-12), the number of years from graduate degree to the time of the K99 application has been 4 years and grew slightly in 2013 and 2014.
- Since the program started, the vast majority of awardees have been PhDs
 - The percentage of PhDs seems to have been slowly increasing since 2011, and in 2014 was 95%
 - Among the other awardees, the majority are MD/PhDs
- Since the program started, approximately 60% of K99 awards have gone to men and roughly 40% to women
- Since the program started, just over 66% of K99 awards have gone to U.S. citizens and permanent residents and just under 33% to non-U.S. citizens.

Outcomes:

- The vast majority of K99 awardees (more than 85%) transition to the R00
 - In the first six years of the program, the transition rate ranged from 95% for the 2007 cohort; to 83% for the 2012 cohort
 - Non-citizens appear to transition to the R00 at slightly lower rates than citizens and permanent residents
- K99 awardees subsequently apply for – and receive – R01s at high rates
Of the 2007 cohort of K99 awardees, 87% have applied for and 58% have received an R01
- For those from the first six cohorts of K99 awardees (FYs 2007-11) who went on to receive an R01, the median age at the receipt of the R01 was 38, suggesting that that the K99 program is helping obtain an earlier independence.

Several NIH Institutes have specialized early stage investigator awards, including NIMH with the BRAIN awards (<http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-15-600.html>) and the NIEHS with the ONES program (<http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-13-014.html>).

NIGMS recently announced that its Maximizing Investigators' Research Awards or MIRA (<http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-002.html>; see below for a fuller description) will also be targeted towards early stage investigators (<http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-003.html>). No awards to early investigators have been issued yet, but NIGMS anticipates that the MIRA will eventually become the Institute's major type of funding mechanism.

The New Innovator Awards Program (<http://commonfund.nih.gov/newinnovator/index>) is a trans-NIH program to fund exceptional newly independent scientists. The program is different from traditional NIH grants in several ways. It is designed specifically to support unusually creative new investigators with highly innovative research ideas at an early stage of their careers, when they may lack the preliminary data required for a successful R01 application. No detailed budget is requested in the application. The procedure for evaluating qualifications is distinct from the traditional NIH peer review process and will emphasize the individual's creativity, the novelty of the approach, and the potential of the project, if successful, to have a significant impact on an important biomedical or behavioral research problem. This award has been offered for the past nine years, with the number of awards fluctuating between 40-55 per year.

3. Changing the Size and Structure of the Laboratory

NIGMS has studied the relationship between lab size and productivity (<https://loop.nigms.nih.gov/2015/01/a-shared-responsibility/>). The study reported that, on average, large budgets do not give the most efficient returns on investment in the basic sciences; this has been interpreted to mean that large laboratory budgets can reduce productivity per NIH dollar. In response

the NIGMS Council now prohibits any of its investigators to receive more than \$750,000 per year from any source. The NIH also now has a general policy that requires review by the IC advisory councils of any potential award to an investigator who would then receive over \$1 million of NIH funds per year

The Maximizing Investigators' Research Award (MIRA; <http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-002.html#sthash.FOvbvM2T.dpuf>) is a grant to provide support for all of the research in an investigator's laboratory that falls within the mission of NIGMS. The goal of MIRA is to increase the efficiency and efficacy of NIGMS funding. It is anticipated that the new program will increase the stability of funding for NIGMS-supported investigators, which could enhance their ability to take on ambitious scientific projects and approach problems more creatively. It will increase flexibility for investigators to follow important new research directions as opportunities arise, rather than being bound to specific aims proposed in advance of the studies. By combining all NIGMS funding into one grant it will also reduce the time spent by researchers writing and reviewing grant applications, allowing them to spend more time conducting research. The plan is to grow these over time. Although no MIRA's have yet been issued, NIGMS hopes that as many as 300 of these awards will be given in the first round, with a substantial proportion, perhaps one-third, awarded to early stage investigators.

In the interests of extending NIH support to more investigators, NIH has solicited ideas to help fund research in a more efficient way. A recent Request for Information (<http://nexus.od.nih.gov/all/2015/04/02/give-input-on-strategies-for-optimizing/>) was recently issued, and ideas from the community are being evaluated.

NIH is also examining the roles of existing core facilities, and requesting ideas for making them as efficient as possible. A recent paper published in the *Journal of Biomolecular Techniques* describes the outcome of an NIH -funded Core Consolidation activity (http://jbt.abrf.org/index.cfm/page/jbt_toc.htm). NIH co-hosted a recent session at the Association of Biomolecular Research Facilities meeting to discuss core efficiency. The report led to two sets of recommendations, directed to external institutions and to NIH. NIH has since formed a new trans-NIH working group to continue the search for efficiencies for these critical resources.

NCI has announced an extramural grant program to support staff scientists. Such individuals do not aspire to be principal investigators with independent laboratories, but instead perform bench work and train students and fellows in a single laboratory; direct the activities of a core facility; or provide bioinformatics and computational support to an institution. The award will be held by individual staff scientists to support their career paths (<http://news.sciencemag.org/biology/2015/03/cancer-institute-plans-new-award-staff-scientists>). An alternative model, which would award funds for science infrastructure, including positions for staff scientists, is currently under discussion with universities.

Other initiatives: Supporting people vs. projects and evaluating productivity

A central theme in the discussion of NIH funding has been the balance between support of talented investigators based on their past productivity (“career awards”) and support of proposed individual projects, exemplified by the traditional RO1 awards. The NCI has recently established an Outstanding Investigator Award (OIA: <http://grants.nih.gov/grants/guide/pa-files/PAR-14-267.html>) that provides up to \$600 thousand per year in direct costs for seven years to about 50 investigators per year. Review of the applications is based largely on past performance rather than on an abbreviated proposal of future projects, and the awards are intended principally for mid-career investigators who have been funded previously by the NCI for at least five years. The NCI recently completed its first review of applications and award notices are expected to be issued soon. The NIGMS MIRA program (mentioned earlier) is similar in design, and other institutes are considering related programs.

Many have argued that efforts to evaluate past performance in making peer-based decisions about faculty positions and awards of grants have come to depend too heavily upon the journals in which a scientist’s work has been published, rather than on a direct assessment of its quality. In an effort to reverse this practice, the NIH has changed the Bio sketch that accompanies grant applications (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html>), based on a proposal and pilot projects from the NCI. In the new format, applicants are asked to describe up to five of their most significant contributions to science, rather than simply list bibliographic citations.

APPENDIX A

NRMN Partner Institutions and Organizations

NIH Funded Centers (P20, P60, U54, CTSA)

California State University, Fullerton; Weaving an Islander Network for Cancer Awareness, Research and Training
Charles R. Drew University of Medicine & Science; EXPORT Center for Minority and Health Disparities
Clark Atlanta University, Center for Cancer Research and Therapeutic Development
George Washington University, Avance Center
Georgia State University, Center of Excellence for Health Disparities Research
Florida International University, Center for Research on U.S. Latino HIV/AIDS and Drug Abuse
Fred Hutchinson Cancer Research Center, Center for Hispanic Health Promotion: Reducing Cancer Disparities
Jackson State University, Center of Excellence in Minority Health and Health Disparities
Johns Hopkins University, Community Networks Program: The Johns Hopkins Center to Reduce Cancer Disparities
Loma Linda University, Center for Health Disparities & Molecular Medicine
Mayo Clinic, Spirit of Eagles Communities Network Program
Meharry Medical College, Community Health Centers – Community Networks Program Center
Moffitt Cancer Center, Tampa Bay Community Cancer Network
New York University School of Medicine, Center for the Study of Asian American Health
Northern Arizona University, Center for American Indian Resiliency
Penn State Hershey, Appalachia Community Cancer Network
Rush University Medical Center, Rush Center of Excellence on Disparities in HIV and Aging
SUNY Downstate Medical Center, Brooklyn Health Disparities Center
Temple University, Asian Community Cancer Health Disparities Center
The University of Texas at El Paso, Hispanic Health Disparities Research Center
University at Buffalo, Western New York Cancer Coalition to Reduce Health Disparities
University of Alabama Birmingham, Center for Clinical and Translational Science
University of California, Berkeley, Alameda County Network Program for Reducing Cancer Disparities
University of California, Los Angeles; Bridging Research, Innovation, Training & Education on Minority Health Disparities Solutions
University of California, San Francisco; Comprehensive Center of Excellence for Health and Risk in Minority Youth and Young Adults
University of
Hawaii, Center for Native and Pacific Health Disparities Research
University of Illinois at Chicago, Center of Excellence in Eliminating Disparities
University of Kansas Medical Center, Central Plains Center for American Indian Health Disparities
University of Maryland, Center for Health Equity
University of Massachusetts, Center for Clinical and Translational Science
University of Massachusetts, Center for Health Equity Intervention Research
University of Miami, South Florida Center for the Elimination of Cancer Health Disparities
University of Minnesota, Program in Health Disparities Research &, Minnesota Center for Cancer Collaborations
University of North Carolina at Chapel Hill, Carolina Community Network Center to Reduce Cancer Health Disparities
University of North Texas Health Science Center, Texas Center for Health Disparities
University of Puerto Rico, UPR-CHA Research Center of Excellence: Making a Difference for Latino Health
University of South Carolina, South Carolina Cancer Disparities Community Network
University of Texas Health Science Center San Antonio, Redes En Acción: The National Latino Cancer Research Network
University of Texas MD Anderson Cancer Center, Latinos Contra El Cancer

University of the Virgin Islands, Caribbean Exploratory NIMHD Research Center
 University of Washington, Regional Native American Community Networks Program Center, Partnerships for Native Health
 University of Wisconsin-Madison, Institute for Clinical and Translational Research
 University of Wisconsin-Madison, Collaborative Center for Health Equity
 Washington State University, Behavioral Health Collaborative in Rural American Indian Communities
 Washington University in St. Louis, Program for the Elimination of Cancer Disparities
 Wayne State University, Southeast Michigan Partners Against Cancer
 Weill Cornell Medical College, Comprehensive Center for Excellence in Disparities Research & Community Engagement

Academic Sites (Historically Black Colleges & Universities, Hispanic Serving Institutions, Research Universities)

Historically Black Colleges and Universities

Alabama A&M University
 Alabama State University
 Albany State University
 Benedict College
 Charles R Drew University of Medicine and Science
 Clark Atlanta University
 Fisk University
 Georgia State University
 Jackson State University
 Langston University
 Meharry Medical College
 Miles College
 Morehouse School of Medicine
 Oakwood College
 Rush University Medical School
 Rust College
 Savannah State University
 Southern University and A&M College
 Tougaloo College
 Trenholm State University
 University of Arkansas Pine Bluff
 University of Virgin Islands
 Xavier University of Louisiana

Hispanic Serving Institutions

California State University, Fullerton
 The University of Texas at El Paso
 Universidad del Este, Puerto Rico
 University of Puerto Rico at Cayey
 Texas A&M University Corpus Christi
 Texas A&M University-Kingsville

American Indian Serving University

Fort Lewis College

Research Universities and Centers

Cold Spring Harbor Laboratory
 Harvard Medical School
 Marine Biological Lab

Michigan State University
 Northwestern University
 San Francisco State University
 St. John Fisher College
 Texas Women’s University
 University of Alabama at Birmingham
 University of California, Davis
 University of Colorado
 University of Nevada-Las Vegas
 University of Pennsylvania
 University of Wisconsin Madison
 Washington University in St. Louis

Professional Societies, Organizations and Conferences

American Association for Cancer Research
 American Chemical Society
 American Educational Research Association
 American Indian Science and Engineering Society
 American Medical Women’s Association
 American Psychological Association
 American Society for Cell Biology
 American Society for Microbiology
 American Society of Plant Biologists
 American Sociological Association
 Annual Biomedical Research Conference for Minority Students
 Asian American Psychological Association
 Association for Psychological Science
 Association for Women in Science
 Association of American Indian Physicians
 Campbell-Kibler Associates, Inc
 Committee on Institutional Cooperation
 Compact for Faculty Diversity
 Consortium of Social Science Association
 Federation of American Societies for Experimental Biology
 Genetics Society of America
 Hispanic-Serving Health Professions Schools
 iBiology

Keystone Symposia on Molecular and Cellular
Biology

MentorNet

National Council for Diversity in Health Professions

Society for Advancement of Chicanos and Native Americans in Science

Society for Developmental Biology

Society for Neuroscience

National Hispanic Medical Association

National Organization of Gay and Lesbian Scientists
and Technical Professionals

National Postdoctoral Association