

# Research News Quarterly

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## Letter from the Editor

Our feature article this month is an interview with the NIH's National Institute of General Medical Sciences (NIGMS) Director Jon Lorsch, PhD. Dr. Lorsch discusses his vision for the NIGMS over the next five years, the institute's portfolio in sepsis and critical illnesses and other areas. Dr. Lorsch highlights the institute's Maximizing Investigators' Research Award (MIRA) program, including a companion program for early-stage investigators, as key to stemming workforce attrition.

Our next article is an important update from NIH on the delay of enforcement of clinical trials policy changes, followed by a *Quarterly* special feature on advances and research questions in lung cancer screening by Research Advocacy Committee Vice-Chair James Brown, MD. Moving to global health, we report on the Fogarty International Center's 50th anniversary, including a May symposium highlighting the institute's accomplishments and our continuing global health challenges.

The launch in May of the NIH's *All of US* program is next, followed by a funding opportunity announcement from the Patient-Centered Outcomes Research Institute (PCORI) and news of the retirement of the National Institute of Nursing Research (NINR) director. This edition of the *Quarterly* concludes with updates on the release of the NIH's new Data Science Plan and the report from the ATS Washington Office on 2019 health research and services funding.

## Veena Antony, MD

Editor



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## INTERVIEW WITH Jon Lorsch, PhD, Director, NIGMS

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### **Q: What is your vision for the Institute over the next five years?**

A: Over the past decades, basic biomedical research has flourished, leading to a deeper, more sophisticated understanding of living systems. As we build on these advances, we aim to deploy our resources in the most efficient ways possible. We also need to include a wide variety of scientists so we can benefit from the full spectrum of perspectives on biomedical questions. To accomplish these goals, we need to re-optimize the scientific enterprise. Specifically, I'd like to see NIGMS:

- Create more efficient and sustainable funding mechanisms for investigators at different stages of their careers
- Modernize graduate school education to take advantage of the latest educational methods and equip our future scientists with 21st-century skills
- Ensure rigor and reproducibility in research
- Increase diversity in the workforce and in the institutions, geographic regions, scientific topics, and approaches we support

*Funding mechanisms:* Historically, most NIGMS research grants funded individual projects that had specific goals defined at the beginning of a four- to five-year project period. Sometimes, during a project, observations and insights reveal exciting new research questions or unexplored areas. Under the current system, it can be difficult for investigators to pursue new directions with a grant tied to a set of specific aims proposed several years before the work starts. In addition, scientists who want to launch new projects must apply for additional grants. Any time spent writing and reviewing grant applications means less time for conducting research.

To address these issues, NIGMS initiated a new, five-year funding mechanism called the [Maximizing Investigators' Research Award \(MIRA\)](#). Rather than requiring scientists to focus on specific projects, this award provides support for any research in their laboratories that falls within the NIGMS mission. MIRA is designed to produce a more stable, flexible, and efficient research environment. We hope it will allow scientists to be more productive and more innovative—to take scientific risks and to pursue important, new scientific questions that arise during the course of their research. We have a companion MIRA program for early-stage investigators that aims to help young scientists overcome hurdles in becoming independent.

*Modernizing graduate school education:* Training the next generation of biomedical researchers is fundamental to the NIGMS mission. Toward that

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## John Lorsch Interview *(Continued from page 2)*

goal, NIGMS actively supports efforts to catalyze the modernization of biomedical graduate education. We have undertaken several initiatives to stimulate this process, such as hosting a symposium to [showcase innovations in biomedical graduate education career development, and skills development and developing a new training grant \(T32\) funding opportunity announcement](#) that addresses issues including:

- Enabling institutional innovations for finding optimal models for training scientists in the 21st century
- Identifying best practices for educators and mentors as they design and implement new education and training models
- Tracking student outcomes and evaluating program results

*Rigor and reproducibility:* To accurately reveal the complexities of living systems, biomedical research must be rigorous. Experiments should be robust and unbiased, and they should produce results that are high quality, reliable, and reproducible. In recent years, a number of publications have suggested that the rigor and reproducibility of biomedical experiments are eroding. The National Institutes of Health (NIH) is leading the effort to address this concern and is joined by the research community, scientific publishers, universities, and industry and professional organizations.

NIGMS is addressing these issues through several initiatives, including cohosting a trans-NIH [workshop on reproducibility in cell culture studies](#); providing extra funds to nearly two dozen (22) programs to [teach graduate students how to design high-quality experiments](#); and supporting, along with nine other NIH components, grants for [training modules to enhance data reproducibility](#), then publishing the products of these grants in an online [clearinghouse](#).

*Diversity and inclusion:* Achieving diversity in the workforce is also a key priority for the Institute. The biomedical workforce hasn't kept pace with changes in the nation's demographics. As a result, the field isn't benefiting from the creativity, energy, skill sets, and viewpoints of many within the U.S. populace. To better leverage the rich

diversity of thinking and experiences within our country, NIGMS offers several programs designed to enhance the diversity of the biomedical research [workforce](#).

In addition, NIGMS aims to broaden the geographic distribution of NIH funding. Through the [Institutional Development Award \(IDeA\)](#) program, NIGMS is boosting research capacity through faculty and student development and building research infrastructure in states that historically haven't received high levels of NIH funding.

The overarching goal for all of NIH is to advance medical science and improve human health. My hope is that through our support of investigator-initiated research, effective training programs, and new technologies, NIGMS will play an important role in reaching that goal.

**Q: NIH received a substantial funding increase of \$3 billion for fiscal year 2018. How does NIGMS plan to distribute their portion of this additional funding?**

A. Of the roughly \$3 billion increase to NIH's FY 2018 Enacted level, NIGMS will receive approximately \$139 million of additional funding over FY 2017's level. The appropriation language also specifies a \$350.575 million total program level for the IDeA program, a \$17.2 million increase over IDeA's FY 2017 level. Additionally, the appropriation language specifies that the [Science Education Partnership Award \(SEPA\)](#) receives a total program level of \$19.498 million, or roughly a \$1 million increase.

While most mechanisms of funding will receive increases, most of the remaining funds will support investigator-initiated research in Research Projects Grants (RPGs). This includes activities like R01, R35, R15, and DP2s. By putting the majority of the increase into RPGs, this will assure healthy success rates for early-stage investigators and new investigators. Consistent with NIH training policy for National Research Service Awards, NIGMS will increase stipends by 2 percent and increase Training-Related Expenses and Institutional Allowance benefits for postdoctorate trainees. The Institute will also be making investments in supplements to allow innovation

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## John Lorsch Interview *(Continued from page 3)*

in training grants and the purchase of needed equipment by researchers.

**Q: Trauma-related and nontrauma-related sepsis is a significant cause of death in the U.S. How are NIGMS's programs addressing sepsis and critical illness across the critical care disciplines?**

A: NIGMS is one of several institutes within the NIH that supports sepsis research. Some of the supported studies evaluate the effectiveness of potential treatments. Others seek molecular clues in patients' blood that could diagnose sepsis early, allowing doctors to treat the condition before it's too late. Still others examine sepsis in specific populations, such as premature babies, people with traumatic injuries, or long-term survivors. The Institute is beginning a review of its sepsis portfolio with an eye to accelerating progress in the field. Some of the questions we will ask—and seek community input on—include:

- The optimal balance between animal model and human studies.
- The utility of current animal models for advancing an understanding of the mechanisms underlying human sepsis and its resolution.
- Whether the current state of our understanding of the mechanism of sepsis and its resolution is sufficient to support high-impact clinical trials for new treatments.
- The roles that data science and systems biology approaches might play in deepening our understanding of sepsis.

**Q: The pulmonary, critical care, and sleep medicine research community has seen an attrition of young investigators due to reduced NIH funding. How can the NIGMS help stem the loss and at the same time increase the representation of women and minorities in research training?**

Since the launch of the Early Stage Investigator (ESI) MIRA program, NIGMS has seen a 60 percent increase in the number of applications it receives per year from ESIs and [has nearly doubled the number of ESIs we fund per year](#). In the end, the key to stemming attrition will be to fund more ESIs, fund them earlier in their careers, and

provide more stable support for them once they attain their initial independent funding. These are all goals of the MIRA program. As I discussed in my recent presentation to our [Advisory Council](#), we are carefully monitoring the review and funding outcomes for MIRA grants to ensure that biases are not preventing us from supporting a broad and diverse portfolio of meritorious scientists.

Fostering a diverse and inclusive future workforce has long been a key priority for NIGMS. The Institute strongly believes that incorporating a full range of perspectives, skills, and experiences will benefit the biomedical research enterprise—and our [society as a whole](#). This standpoint is one of the factors that attracted me to the NIGMS Director's position. Two of the Institute's five divisions are dedicated to developing a robust, highly skilled, geographically widespread, and inclusive biomedical research workforce. The [Division of Training, Workforce Development, and Diversity](#) offers a suite of programs to science students and scientists already in the workforce. The [Division for Research Capacity Building](#) focuses on states that historically haven't received significant levels of NIH research funding. NIGMS also participates in NIH-wide programs to [enhance the diversity of the NIH-Funded Workforce](#) and to provide [research supplements to promote diversity in health-related research](#).

**Q: What are the key differences between NIGMS' Maximizing Investigators' Research Award (MIRA) and NHLBI's R35 awards?**

A: The differences between the two programs include the following:

1) The applicant pools are different. NIGMS allows ESIs the opportunity to apply for an R35 grant while National Heart, Lung, and Blood Institute's program is restricted to later career stages; NHLBI limits eligibility to emerging investigators (EIs) who already hold two NHLBI R01 awards, one of which must have been made when the EI was an ESI.

For established investigators, NIGMS now allows PIs who hold a single NIGMS R01-equivalent grant to apply. NHLBI limits eligibility to PIs who hold at least two R01-equivalent awards and have received continuous R01-

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## Richard Hodes Interview *(Continued from page 4)*

equivalent support from NHLBI for at least the past four years.

2) NHLBI directs reviewers to emphasize PIs—specifically, the importance of their past contributions, their productivity in the past five years, and their potential for future impact/influence, whereas NIGMS asks reviewers to balance the strengths of the applicant and the quality of the proposed research program.

3) Both programs are intended to be revenue neutral, but the NIGMS Funding Opportunity Announcement specifically asks reviewers to consider the cost-effectiveness of the proposed research. In addition, an explicit goal of the MIRA program is to improve the distribution of funding so that the institute can support more meritorious researchers and increase the median funding level. To do this, budgets for well-funded (>\$400,00 direct costs from NIGMS), established investigators receiving a MIRA grant are reduced relative to the principal investigator's recent NIGMS funding level in order to free some funds to support additional researchers' work. ■

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## NIH

### NIH Delays Enforcement of Some Clinical Trials Policies

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In response to a directive from Congress directing NIH to delay enforcement of new clinical trials policies which the agency began implementing in January 2018, the NIH recently released new guidance concerning a changing of the definition of clinical trials to encompass more basic science studies and notably, require registration and reporting of basic science studies.

The congressional directive outlined in the fiscal year 2018 spending omnibus, states that Congress “appreciates efforts NIH has taken to increase transparency and improve oversight of its clinical trials and recognizes that the results of NIH-funded clinical trials have not always been reported in a timely manner, reducing the potential benefit from the findings.” Congress continued “We urge NIH to continue

to address this problem through enhanced registration and reporting through ClinicalTrials.gov. There is concern, however, that in addressing this issue, many fundamental research studies involving human participants are being redefined as clinical trials without sufficient notification and consultation with this segment of the research community.”

The Congress also noted a concern from the scientific community that policy changes could have long-term, unintended consequences for this research, add unnecessary regulatory burdens, and significantly increase the number of studies in the clinicaltrials.gov database that are not clinical trials.

The instructive then directs NIH as follows, “*For fiscal year 2018, the agreement directs NIH to delay enforcement of the new policy published in the Federal Register on September 21, 2017 including NIH’s more expansive interpretation of “interventions”-in relation to fundamental research projects involving humans.*

In response to this congressional directive, the new NIH guidance, released on June 19, 2018 and to be distributed more broadly within days, states that NIH will delay enforcement of the clinical trials policy mandating registration and reporting of more basic science studies as clinical trials, until July 1, 2019. The new guidance states that “NIH recognizes that not all trials occur within a clinical sphere (e.g. basic science trials, public health trials).” The NIH update continued, “The agency will be announcing the opening of an implementation phase in which the agency will monitor, refine, but not penalize through July 1, 2019. Reporting of basic science studies on existing basic science portals will continue, with the expectation that data will eventually be transported to clinicaltrials.gov, even if it is coming via another portal or reporting system.”

The June 19 NIH update indicates that while NIH is announcing a delay of enforcement of the new clinical trials policy, the expectation for investigators to begin migrating to registering and reporting basic science trials on clinicaltrials.gov remains.

NIH said it plans to issue a public request for information by October 30, 2018, which will be open for comment

## NIH Delays Enforcement of Some Clinical Trials Policies *(Continued from page 5)*

for 90 days. The agency will also issue a basic science parent FOA for fundamental human studies that meet the new NIH definition of clinical trial. For all trials that do not meet the definition of basic science, NIH will proceed with enforcement of the clinical trial policies as outlined in the September 2016 policy.

In response to the NIH announcement, Veena Antony, M.D., Chair of the ATS Research Advocacy Committee, said, “This directive gives some much needed time for researchers and scientists working on basic science trials to compile and analyze complex data before being required to report it.” She continued, “All scientists and the public at large will be allowed to give their input via the public request for information to the NIH. At the end of this period, I am confident that the NIH will evaluate and implement the best methods for transparency and disclosure of basic science or public health trials.” ■

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## VETERANS HEALTH

### Opportunities for Research: Lung Cancer Screening in the Veterans Health Administration

*James K. Brown, MD, Vice Chair,  
ATS Research Advocacy Committee*

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#### **Why is it so important to study lung cancer screening in the VA?**

Many Veterans started smoking while serving in the military. Between 1942 and 1975, a small pack of cigarettes was placed in the K-rations of every soldier, and tobacco companies promoted cigarette smoking as a means for reducing stress during active military duty. Rates of active cigarette smoking among young male Veterans are much higher than among non-Veteran males of the same age. Historically, 80 percent of all lung cancer cases have been detected at an advanced stage with five-year survival rates of 16 percent. In recognition of these facts, ATS led advocacy efforts urging the Veteran’s Administration to initiate lung cancer screening for veterans.

In 2011, the National Lung Screening Trial (NLST), a large randomized trial comparing lung cancer screening using annual low-dose helical computed (LDCT) scans to chest radiography, demonstrated a shift to early-stage detection of cancers and a 20 percent reduction in lung-cancer specific mortality in the group screened with LDCT. The findings led to a 2013 US Preventive Services Task Force (USPSTF) B-level recommendation in favor of lung cancer screening using LDCT scans and guidelines for patient selection based on age, cigarette smoking status, and longevity. NLST did not include VA’s among its sites for patient recruitment. Therefore, there are many questions about how best to implement lung cancer screening in the VA and about what the beneficial effects may be.

#### **What is the status of establishing lung cancer screening programs nationally in the VA?**

Shortly after the publication of NLST, VHA initiated its own eight-site Lung Cancer Screening Demonstration Project. This program had several key features: (i) Veterans’ eligibility for screening, using USPSTF selection criteria, was determined using clinical reminders in the electronic medical record; (ii) each site had its own full-time coordinator, as well as embedded smoking cessation programs for active cigarette smokers; (iii) a centralized tracking tool, developed at the Minneapolis VA, was used to monitor results; (iv) multidisciplinary review was carried out for high-risk findings; and (v) radiation dose and radiographic reporting were standardized.

Rates of lung cancer detection in the Demonstration Project, which ended on Sept. 30, 2015, were only 1.5 percent compared to 3.9 percent in NLST, perhaps because the duration of screening and follow up was only slightly more than one year in the Demonstration Project compared to 6.5 years in NLST. On the other hand, invasive procedures were used in only about 3.5 percent of patients in the Demonstration Project, compared to in about 10 percent of patients in the LDCT arm of NLST. This difference may have related to the use of mandatory multidisciplinary review of high-risk findings in the Demonstration Project but not in NLST. In any case, the VA’s pilot project demonstrated the feasibility of implementing lung cancer screening across

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## NIEHS Releases Draft Strategic Plan *(Continued from page 6)*

multiple sites in the VHA using a reasonably consistent approach for patient selection and a common database.

After the Demonstration Project ended, most of the eight sites obtained local support for their coordinators and could continue screening. At that point, it was not clear if VHA would adopt a national policy in support of program-based lung cancer screening. Rather, it appeared that an approach would be taken in which screening would be offered on-demand to appropriate veterans, and their primary care providers then would be asked to undertake the request for screening with neither programmatic support nor a registry for long-term tracking. In October 2016, the ATS, working through its Washington DC Office of Advocacy and Government Relations, arranged for a small delegation to visit the office of David Shulkin, MD, then the VHA's undersecretary for health. In a meeting with Dr. Shulkin and his staff, the delegation advocated for a robust lung cancer screening program in VHA starting with creation of centers of excellence, each of which had fully developed programs as described in [ATS/American College of Chest Physicians Guidelines](#).

Subsequently, VHA convened a Lung Cancer Screening Interdisciplinary Project Team under its National Center for Health Promotion and Disease Prevention (NCP). Recommendations, released in November 2017, included that screening be made available to appropriate veterans on request but only in VA facilities with well-developed programs. Furthermore, a small team from the Minneapolis VA was designated to assist in implementing screening in sites without well-developed programs, including via installation of the database and tracking tool that had been further developed by the Minneapolis VA in partnership with NCP. To date, four sites have completed this training and are up and running and approximately 15 others are in the implementation process.

Also, in September 2017, VA-PALS (VA Partnership to Increase Access to Lung Screening) was formed. With support from VHA's Office of Rural Health and the Bristol Myers Squibb Foundation, VA-PALS will be providing coordinators to each of 10 sites in the VA. The program plans to employ a database that it is in the process of developing as well as the International Early Lung

Cancer Action Program for patient selection and nodule management. It should be noted that the roll-out in the VHA nationally has not been without its problems. Perhaps the most important is that currently there is no centralized mechanism for obtaining VA support for coordinators. Thus, many VA's have had to initiate lung cancer screening without the benefit of this key component of any screening program.

### **What are some of the key questions for research?**

Some of these questions need to be addressed in the VA to assess best practices for implementation, and the likely efficacy, of LCS in the VA. Two examples are:

- *How should LCS be provided to Veterans living in rural areas or near VA facilities not fully staffed to carry out LCS?* Options here may include use of mobile vans with CT scanners and/or teleconferencing for centralized review of high-risk findings. VHA's Quality Enhancement Research Initiative may afford metrics useful for comparing different implementation strategies addressing these needs.
- *How common is the problem of overdiagnosis among Veterans participating in LCS programs in the VA?* In the context of LCS, overdiagnosis may be defined as discovering a lung cancer in a patient with a co-morbid condition that leads to his or her death before the lung cancer affects well-being. Patients participating in VA-based LCS programs are older and have more co-morbid conditions than those screened outside of the VA. Therefore, overdiagnosis may be particularly important in the VA. Since overdiagnosis may lead to unnecessary procedures or treatments, it will be important to know how common this problem is in the VA.

In addition, of course, there are many unanswered questions about implementing lung cancer screening that pertain both within and outside of the VA. Three issues related to patient selection were discussed during an enlightening pro/con debate at the recent ATS International Conference:

- *Should patient selection be based on USPSTF criteria versus on personalized lung cancer risk models?*

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## Lung Cancer Screening in the Veterans Health Administration *(Continued from page 7)*

USPSTF guidelines for selection, based on patient age, cigarette smoking status, and lack of health problems limiting life expectancy, have been widely adopted in the United States. Individualized risk calculators that account for certain demographic, clinical, and smoking characteristics may enhance the effectiveness and efficiency of lung cancer screening programs. Evidence favoring superiority of these model-based risk calculators is based largely on retrospective studies. Prospective studies are needed to address the question.

- *Should patients with moderate to severe COPD undergo lung cancer screening or not?* Increasing severity of COPD linearly increases the risk of lung cancer. On the one hand, this finding suggests that the more severe the COPD, the more likely the patient is to benefit from LCS. On the other, greater severity of COPD may increase risk of diagnostic procedures and surgery, as well as limit the benefits of life extension from treating the cancer. More information is needed about these issues.
- *Should biomarkers be utilized in determining patient selection for lung cancer screening or not?* Noninvasive lung cancer biomarkers have the capacity to detect lung cancer before a nodule is visible, distinguish aggressive from indolent tumors, and predict responsiveness to different forms of treatment. Many candidate biomarkers have been identified, but validating them has been slowed in part because of insufficient numbers of samples. A large centrally organized LCS program in the VA may help to accelerate this validation process.

In conclusion, it's worth noting that implementation of LCS outside of the VA is proceeding relatively slowly in the U.S. The hope is that development of LCS programs for veterans obtaining care in the VA will move more quickly. If that happens, there will be many opportunities for research in the VA to address key issues related to the implementation and potential benefits of LCS. More advocacy may be needed, particularly directed to convincing the VA to provide more LCS coordinators. ■

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## FOGARTY INTERNATIONAL CENTER

### Fogarty International Center Celebrates 50th Anniversary

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In 2018, the Fogarty International Center (FIC) is celebrating its 50th anniversary as an NIH institute. The FIC supports and promotes global health research, with a special focus on training both U.S. and foreign researchers working in the developing world.

In his [March/April Message](#), FIC Director Roger Glass, MD, PhD, reviewed the Center's accomplishments since its founding in 1968 in honor of Rep. John Edward Fogarty (D-RI). Pointing to advances against smallpox, polio, and HIV/AIDS, Dr. Glass concludes that we have come far in global health, but much remains to be done.

The institute held a 50th anniversary symposium on May 1, 2018, entitled, *What Are the New Frontiers in Global Health Research?* The event featured remarks from U.S. Senator Jack Reed (D-RI), NIH Director Francis Collins, MD, PhD, and a number of former FIC trainees who are now prominent biomedical researchers and leaders of global health organizations, such as Glenda Gray, MBBCH, chair of the Global Alliance for Chronic Diseases, president of the South African Medical Research Council, and former Fogarty trainee.

Dr. Collins praised the FIC's fellowship programs, which he said have reached the world in remarkable ways, providing low- and middle-income countries with critical public health and research capacity, pointing to the 2015 Ebola outbreak in East Africa, where many former FIC fellows battled to contain the outbreak.

The keynote address was delivered by Richard Horton, MD, editor of the *Lancet*. In his remarks, Dr. Horton pointed to the "unprecedented political threat" that the

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## Fogarty International Center *(Continued from page 8)*

FIC recently came under, a reference to President Trump's 2018 budget proposal to eliminate the FIC and merge its research programs with other NIH institutes. He noted that the NEJM, Lancet, and JAMA came together to support the FIC.

In addition to select remarks, the full-day symposium was composed of the following four panels:

- What has been accomplished and what is needed to advance infectious disease research and actually achieve the end of AIDS?" Panel speakers included National Institute of Allergy and Infectious Diseases Director Anthony Fauci, MD, and Linda Gail-Bekker, president of the International AIDS Society.
- "Noncommunicable diseases: How can we leverage existing research and training platforms to stem the tide of deaths and disability?" This multi-issue panel included breakout sessions on cancer, featuring remarks by the deputy director of the National Cancer Institute and on cardiology and sick cell disease, featuring remarks by National Heart, Lung, and Blood Institute Director Gary Gibbons, MD.
- "Global brain disorders: We're on the agenda, where do we go from here? What are the priorities for advancing the global mental health research agenda?" This panel, which also spanned several different health areas, included a breakout session on epilepsy featuring remarks by the director of the National Institute for Neurological Disorders and Stroke; on Alzheimer's disease, featuring remarks by National Institute on Aging director; and on schizophrenia in low-income countries, featuring remarks by the deputy director of the National Institute of Mental Health.
- "Multigenerational models of long-term capacity building: the trainees become the trainers". This panel was chaired by Dr. Glass and featured researchers and trainees from Peru, South Africa, and Uganda.

You can view a webcast of the entire FIC 50th Anniversary symposium [here](#). ■

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## PRECISION MEDICINE

### NIH All of US Program is Launched

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The [All of Us Research Program](#) began national enrollment on May 6, 2018, inviting people ages 18 and older, regardless of health status, to join this momentous effort to advance individualized prevention, treatment and care for people of all backgrounds. Part of the NIH, *All of Us* is expected to be the largest and most diverse longitudinal health research program ever developed.

#### How *All of Us* Benefits Pulmonary, Critical Care and Sleep Providers

Today there are too few conditions with evidence and options for individualized care. Too often, patients from underserved communities have not been included in clinical research, and our ability to care for diverse populations is diminished as a result. More data, discoveries, and tools can help providers give their patients customized care more easily, especially for those communities that are disproportionately impacted by health issues.

ATS Research Advocacy Committee Chair Veena Antony, M.D., says, "The *All of Us* Research Program will provide critically needed information for diseases in pulmonary, critical care and sleep medicine. For example, COPD is the third largest cause of mortality in US and there remain many lacunae in our understanding of the evolution of the disease." Dr. Antony continued, "Participating citizens in all their diversity will help us better understand the spectrum of disease and allow us to gain valuable insight into lung disease to fulfil the promise of predictive, personalized therapy."

*All of Us* participants are asked to share different types of health and lifestyle information, including through online surveys and electronic health records, which will continue to be collected over the course of the program. Those who join will have access to study information and data about themselves, with choices about how much or little they want to receive.

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## NIH All of Us Program is Launched *(Continued from page 9)*

Data collected will be broadly accessible to researchers of all kinds, including citizen scientists, to support thousands of studies across a wide range of different health topics. By doing so, they are hoping to discover how to more precisely prevent and treat other health conditions. Knowledge gained from this research could help researchers improve health for generations to come.

### **Why All of Us is Important for Patients**

Health care is often “one size fits all” and is not able to fully consider differences in individuals’ lifestyles, environments, or biological makeup. This is because we have limited data from past research studies about how those elements interact. The average patient is often prescribed drugs and treatments as if they are all the same. Learning more about the differences between individuals can help researchers develop tailored treatments and care for all people.

### **Why Diversity Matters**

Historically, many segments of the U.S. population have been left behind in medical research, including people of color, sexual/gender minorities, those with lower socioeconomic and educational status, rural communities, and other groups. The result is significant health disparities. The All of Us Research Program seeks to help fill in the gaps of information about those communities that previously have not been well represented.

### **How to Join the All of Us Research Program**

The program is seeking one million or more people from all walks of life to participate in this historic endeavor. Those interested in joining the program can do so by visiting, [www.JoinAllofUs.org](http://www.JoinAllofUs.org). Enrollment is open to all eligible adults who live in the U.S. ■

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## PCORI

### PCORI Broad Funding Announcement Open

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The Patient-Centered Outcomes Research Institute (PCORI) is seeking investigator-initiated applications for Cycle 2 patient-centered comparative clinical effectiveness research (CER) projects in the following areas:

- Addressing Disparities
- Assessment of Prevention, Diagnosis, and Treatment Options
- Communication and Dissemination Research
- Improving Health Systems

Applications should address needs of patients, caregivers, clinicians, and other healthcare stakeholders in making personalized clinical decisions across a wide range of conditions, populations, and treatments. Letters of intent are due June 28, 2018. Those selected to submit a full application will be notified by July 23, 2018 and full applications will be due September 25, 2018. Interested investigators should visit [PCORI's Broad Funding Announcement](#), which includes a variety of resources including the application guidelines and a sample letter of intent template. ■

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## NINR

### NINR Director Announces Retirement

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On May 31, Director of the National Institute on Nursing Research Patricia Grady, PhD, announced that she will retire from the institute at the end of summer 2018. Dr. Grady became the institute’s second permanent director in 1995, after the NINR, originally founded as the National Center for Nursing Research in 1985, was elevated to Institute status in 1993. A neuroscientist by training,

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## NINR Director Announces Retirement *(Continued from page 10)*

Dr. Grady served as deputy and acting director at the National Institute of Neurological Disorders and Stroke before serving as NINR director.

In her director's message in the NINR's newsletter, Dr. Grady looked back on some of the institute's achievements over her 23-year tenure. These include the creation of institute boot camps, a robust intramural research program, and a tripling of the NINR budget. Dr. Grady said, "After 30 years, the Institute is strong, but still rests on your shoulders." She continued, "I am confident that the Institute will be well served in the years to come by the collective wisdom of the established scientists, the emerging generation of new researchers, the policy gurus, and our outstanding educators and administrators." ■

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## DATA SCIENCE

### NIH Releases Data Science Strategic Plan

On June 4, NIH released its first [Strategic Plan for Data Science](#). The Plan, developed as part of NIH-Wide Strategic Plan, is a roadmap for modernizing the NIH's biomedical data science ecosystem, which is critical to accelerating cutting-edge science. The following are the plan's five overarching goals and strategic objectives:

- 1) Data Infrastructure
  - Optimize data storage and security
  - Connect NIH data systems
- 2) Build a Modernized Data Ecosystem
  - Modernize data repository ecosystem
  - Support storage and sharing of individual datasets
  - Better integrate clinical and observational into biomedical data science
- 3) Data Management, Analytics and Tools
  - Support useful, generalizable, and accessible tools and workflows
  - Broaden utility of and access to specialized tools
  - Improve discovery and cataloging resources

#### 4) Workforce Development

- Enhance the NIH data-science workforce
- Expand the national research workforce
- Engage a broader community

#### 5) Stewardship and Sustainability

- Develop policies for a FAIR data ecosystem
- Enhance stewardship

In order to enhance data science across the extramural and intramural research communities, NIH plans to recruit a chief data strategist. The chief strategist will supervise the development and implementation of NIH's data science efforts and ensure leadership across the broader biomedical research data system. NIH will continue to seek community input during the implementation phase. ■

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## HEALTH RESEARCH FUNDING

### House Panel Proposes \$1.25 Billion NIH Funding Increase

The fiscal year (FY) 2019 spending process is underway in Congress, where the House Labor-Health and Human Services (LHHS) Appropriations subcommittee, chaired by Rep. Cole (R-OK), met on June 15 and approved a \$1.250 billion funding increase above current funding of \$37.1 billion for the NIH as part of the FY2019 health research and services spending bill, for a total proposed FY2019 funding level of \$38.3 billion. The House bill also includes some good news for the Centers for Disease Control and Prevention (CDC) in the form of a \$427 million funding increase for the agency. Details on CDC programs that the ATS monitors, such as asthma and tuberculosis, have not yet been released.

The Senate LHHS subcommittee, chaired by Sen. Blunt (R-MO), is tentatively scheduled to meet the last week of June. The Senate panel is also expected to approve a funding increase for NIH, though the amount is not yet known.

*(Continued on page 12)*

## Health Research Funding *(Continued from page 11)*

The outcome of the individual House and Senate health spending bills is uncertain in this election year, but regardless, the funding levels for NIH included in the House and Senate Labor-HHS bills are expected to move forward. Congress will negotiate final NIH funding from the two differing bills, so the House subcommittee's action is a strong indicator that NIH will receive a funding increase in FY2019.

Regarding final FY2019 government spending, we expect that as we get closer to the election, the congressional appropriations process will halt and Congress will pass a series of omnibus spending bills for FY2019. With the impending election it is also very possible that the spending bills will be used as leverage, as the president has already mused about shutting the government down. Congress and the president will need to agree on FY2019 spending by September 30, 2018, when the current fiscal year ends. ■



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## INTERVIEW WITH Jon Lorsch, PhD, Director, NIGMS

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### **Q: What is your vision for the Institute over the next five years?**

A: Over the past decades, basic biomedical research has flourished, leading to a deeper, more sophisticated understanding of living systems. As we build on these advances, we aim to deploy our resources in the most efficient ways possible. We also need to include a wide variety of scientists so we can benefit from the full spectrum of perspectives on biomedical questions. To accomplish these goals, we need to re-optimize the scientific enterprise. Specifically, I'd like to see NIGMS:

- Create more efficient and sustainable funding mechanisms for investigators at different stages of their careers
- Modernize graduate school education to take advantage of the latest educational methods and equip our future scientists with 21st-century skills
- Ensure rigor and reproducibility in research
- Increase diversity in the workforce and in the institutions, geographic regions, scientific topics, and approaches we support

*Funding mechanisms:* Historically, most NIGMS research grants funded individual projects that had specific goals defined at the beginning of a four- to five-year project period. Sometimes, during a project, observations and insights reveal exciting new research questions or unexplored areas. Under the current system, it can be difficult for investigators to pursue new directions with a grant tied to a set of specific aims proposed several years before the work starts. In addition, scientists who want to launch new projects must apply for additional grants. Any time spent writing and reviewing grant applications means less time for conducting research.

To address these issues, NIGMS initiated a new, five-year funding mechanism called the [Maximizing Investigators' Research Award \(MIRA\)](#). Rather than requiring scientists to focus on specific projects, this award provides support for any research in their laboratories that falls within the NIGMS mission. MIRA is designed to produce a more stable, flexible, and efficient research environment. We hope it will allow scientists to be more productive and more innovative—to take scientific risks and to pursue important, new scientific questions that arise during the course of their research. We have a companion MIRA program for early-stage investigators that aims to help young scientists overcome hurdles in becoming independent.

*Modernizing graduate school education:* Training the next generation of biomedical researchers is fundamental to the NIGMS mission. Toward that

*(Continued on page 3)*

## John Lorsch Interview *(Continued from page 2)*

goal, NIGMS actively supports efforts to catalyze the modernization of biomedical graduate education. We have undertaken several initiatives to stimulate this process, such as hosting a symposium to [showcase innovations in biomedical graduate education career development, and skills development and developing a new training grant \(T32\) funding opportunity announcement](#) that addresses issues including:

- Enabling institutional innovations for finding optimal models for training scientists in the 21st century
- Identifying best practices for educators and mentors as they design and implement new education and training models
- Tracking student outcomes and evaluating program results

*Rigor and reproducibility:* To accurately reveal the complexities of living systems, biomedical research must be rigorous. Experiments should be robust and unbiased, and they should produce results that are high quality, reliable, and reproducible. In recent years, a number of publications have suggested that the rigor and reproducibility of biomedical experiments are eroding. The National Institutes of Health (NIH) is leading the effort to address this concern and is joined by the research community, scientific publishers, universities, and industry and professional organizations.

NIGMS is addressing these issues through several initiatives, including cohosting a trans-NIH [workshop on reproducibility in cell culture studies](#); providing extra funds to nearly two dozen (22) programs to [teach graduate students how to design high-quality experiments](#); and supporting, along with nine other NIH components, grants for [training modules to enhance data reproducibility](#), then publishing the products of these grants in an online [clearinghouse](#).

*Diversity and inclusion:* Achieving diversity in the workforce is also a key priority for the Institute. The biomedical workforce hasn't kept pace with changes in the nation's demographics. As a result, the field isn't benefiting from the creativity, energy, skill sets, and viewpoints of many within the U.S. populace. To better leverage the rich

diversity of thinking and experiences within our country, NIGMS offers several programs designed to enhance the diversity of the biomedical research [workforce](#).

In addition, NIGMS aims to broaden the geographic distribution of NIH funding. Through the [Institutional Development Award \(IDeA\)](#) program, NIGMS is boosting research capacity through faculty and student development and building research infrastructure in states that historically haven't received high levels of NIH funding.

The overarching goal for all of NIH is to advance medical science and improve human health. My hope is that through our support of investigator-initiated research, effective training programs, and new technologies, NIGMS will play an important role in reaching that goal.

**Q: NIH received a substantial funding increase of \$3 billion for fiscal year 2018. How does NIGMS plan to distribute their portion of this additional funding?**

A. Of the roughly \$3 billion increase to NIH's FY 2018 Enacted level, NIGMS will receive approximately \$139 million of additional funding over FY 2017's level. The appropriation language also specifies a \$350.575 million total program level for the IDeA program, a \$17.2 million increase over IDeA's FY 2017 level. Additionally, the appropriation language specifies that the [Science Education Partnership Award \(SEPA\)](#) receives a total program level of \$19.498 million, or roughly a \$1 million increase.

While most mechanisms of funding will receive increases, most of the remaining funds will support investigator-initiated research in Research Projects Grants (RPGs). This includes activities like R01, R35, R15, and DP2s. By putting the majority of the increase into RPGs, this will assure healthy success rates for early-stage investigators and new investigators. Consistent with NIH training policy for National Research Service Awards, NIGMS will increase stipends by 2 percent and increase Training-Related Expenses and Institutional Allowance benefits for postdoctorate trainees. The Institute will also be making investments in supplements to allow innovation

*(Continued on page 4)*

## John Lorsch Interview *(Continued from page 3)*

in training grants and the purchase of needed equipment by researchers.

**Q: Trauma-related and nontrauma-related sepsis is a significant cause of death in the U.S. How are NIGMS's programs addressing sepsis and critical illness across the critical care disciplines?**

A: NIGMS is one of several institutes within the NIH that supports sepsis research. Some of the supported studies evaluate the effectiveness of potential treatments. Others seek molecular clues in patients' blood that could diagnose sepsis early, allowing doctors to treat the condition before it's too late. Still others examine sepsis in specific populations, such as premature babies, people with traumatic injuries, or long-term survivors. The Institute is beginning a review of its sepsis portfolio with an eye to accelerating progress in the field. Some of the questions we will ask—and seek community input on—include:

- The optimal balance between animal model and human studies.
- The utility of current animal models for advancing an understanding of the mechanisms underlying human sepsis and its resolution.
- Whether the current state of our understanding of the mechanism of sepsis and its resolution is sufficient to support high-impact clinical trials for new treatments.
- The roles that data science and systems biology approaches might play in deepening our understanding of sepsis.

**Q: The pulmonary, critical care, and sleep medicine research community has seen an attrition of young investigators due to reduced NIH funding. How can the NIGMS help stem the loss and at the same time increase the representation of women and minorities in research training?**

Since the launch of the Early Stage Investigator (ESI) MIRA program, NIGMS has seen a 60 percent increase in the number of applications it receives per year from ESIs and [has nearly doubled the number of ESIs we fund per year](#). In the end, the key to stemming attrition will be to fund more ESIs, fund them earlier in their careers, and

provide more stable support for them once they attain their initial independent funding. These are all goals of the MIRA program. As I discussed in my recent presentation to our [Advisory Council](#), we are carefully monitoring the review and funding outcomes for MIRA grants to ensure that biases are not preventing us from supporting a broad and diverse portfolio of meritorious scientists.

Fostering a diverse and inclusive future workforce has long been a key priority for NIGMS. The Institute strongly believes that incorporating a full range of perspectives, skills, and experiences will benefit the biomedical research enterprise—and our [society as a whole](#). This standpoint is one of the factors that attracted me to the NIGMS Director's position. Two of the Institute's five divisions are dedicated to developing a robust, highly skilled, geographically widespread, and inclusive biomedical research workforce. The [Division of Training, Workforce Development, and Diversity](#) offers a suite of programs to science students and scientists already in the workforce. The [Division for Research Capacity Building](#) focuses on states that historically haven't received significant levels of NIH research funding. NIGMS also participates in NIH-wide programs to [enhance the diversity of the NIH-Funded Workforce](#) and to provide [research supplements to promote diversity in health-related research](#).

**Q: What are the key differences between NIGMS' Maximizing Investigators' Research Award (MIRA) and NHLBI's R35 awards?**

A: The differences between the two programs include the following:

1) The applicant pools are different. NIGMS allows ESIs the opportunity to apply for an R35 grant while National Heart, Lung, and Blood Institute's program is restricted to later career stages; NHLBI limits eligibility to emerging investigators (EIs) who already hold two NHLBI R01 awards, one of which must have been made when the EI was an ESI.

For established investigators, NIGMS now allows PIs who hold a single NIGMS R01-equivalent grant to apply. NHLBI limits eligibility to PIs who hold at least two R01-equivalent awards and have received continuous R01-

*(Continued on page 5)*

## Richard Hodes Interview *(Continued from page 4)*

equivalent support from NHLBI for at least the past four years.

2) NHLBI directs reviewers to emphasize PIs—specifically, the importance of their past contributions, their productivity in the past five years, and their potential for future impact/influence, whereas NIGMS asks reviewers to balance the strengths of the applicant and the quality of the proposed research program.

3) Both programs are intended to be revenue neutral, but the NIGMS Funding Opportunity Announcement specifically asks reviewers to consider the cost-effectiveness of the proposed research. In addition, an explicit goal of the MIRA program is to improve the distribution of funding so that the institute can support more meritorious researchers and increase the median funding level. To do this, budgets for well-funded (>\$400,00 direct costs from NIGMS), established investigators receiving a MIRA grant are reduced relative to the principal investigator's recent NIGMS funding level in order to free some funds to support additional researchers' work. ■

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## NIH

### NIH Delays Enforcement of Some Clinical Trials Policies

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In response to a directive from Congress directing NIH to delay enforcement of new clinical trials policies which the agency began implementing in January 2018, the NIH recently released new guidance concerning a changing of the definition of clinical trials to encompass more basic science studies and notably, require registration and reporting of basic science studies.

The congressional directive outlined in the fiscal year 2018 spending omnibus, states that Congress “appreciates efforts NIH has taken to increase transparency and improve oversight of its clinical trials and recognizes that the results of NIH-funded clinical trials have not always been reported in a timely manner, reducing the potential benefit from the findings.” Congress continued “We urge NIH to continue

to address this problem through enhanced registration and reporting through ClinicalTrials.gov. There is concern, however, that in addressing this issue, many fundamental research studies involving human participants are being redefined as clinical trials without sufficient notification and consultation with this segment of the research community.”

The Congress also noted a concern from the scientific community that policy changes could have long-term, unintended consequences for this research, add unnecessary regulatory burdens, and significantly increase the number of studies in the clinicaltrials.gov database that are not clinical trials.

The instructive then directs NIH as follows, “*For fiscal year 2018, the agreement directs NIH to delay enforcement of the new policy published in the Federal Register on September 21, 2017 including NIH’s more expansive interpretation of “interventions”-in relation to fundamental research projects involving humans.*

In response to this congressional directive, the new NIH guidance, released on June 19, 2018 and to be distributed more broadly within days, states that NIH will delay enforcement of the clinical trials policy mandating registration and reporting of more basic science studies as clinical trials, until July 1, 2019. The new guidance states that “NIH recognizes that not all trials occur within a clinical sphere (e.g. basic science trials, public health trials).” The NIH update continued, “The agency will be announcing the opening of an implementation phase in which the agency will monitor, refine, but not penalize through July 1, 2019. Reporting of basic science studies on existing basic science portals will continue, with the expectation that data will eventually be transported to clinicaltrials.gov, even if it is coming via another portal or reporting system.”

The June 19 NIH update indicates that while NIH is announcing a delay of enforcement of the new clinical trials policy, the expectation for investigators to begin migrating to registering and reporting basic science trials on clinicaltrials.gov remains.

NIH said it plans to issue a public request for information by October 30, 2018, which will be open for comment

## NIH Delays Enforcement of Some Clinical Trials Policies *(Continued from page 5)*

for 90 days. The agency will also issue a basic science parent FOA for fundamental human studies that meet the new NIH definition of clinical trial. For all trials that do not meet the definition of basic science, NIH will proceed with enforcement of the clinical trial policies as outlined in the September 2016 policy.

In response to the NIH announcement, Veena Antony, M.D., Chair of the ATS Research Advocacy Committee, said, “This directive gives some much needed time for researchers and scientists working on basic science trials to compile and analyze complex data before being required to report it.” She continued, “All scientists and the public at large will be allowed to give their input via the public request for information to the NIH. At the end of this period, I am confident that the NIH will evaluate and implement the best methods for transparency and disclosure of basic science or public health trials.” ■

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## VETERANS HEALTH

### Opportunities for Research: Lung Cancer Screening in the Veterans Health Administration

*James K. Brown, MD, Vice Chair,  
ATS Research Advocacy Committee*

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#### Why is it so important to study lung cancer screening in the VA?

Many Veterans started smoking while serving in the military. Between 1942 and 1975, a small pack of cigarettes was placed in the K-rations of every soldier, and tobacco companies promoted cigarette smoking as a means for reducing stress during active military duty. Rates of active cigarette smoking among young male Veterans are much higher than among non-Veteran males of the same age. Historically, 80 percent of all lung cancer cases have been detected at an advanced stage with five -year survival rates of 16 percent. In recognition of these facts, ATS led advocacy efforts urging the Veteran’s Administration to initiate lung cancer screening for veterans.

In 2011, the National Lung Screening Trial (NLST), a large randomized trial comparing lung cancer screening using annual low-dose helical computed (LDCT) scans to chest radiography, demonstrated a shift to early-stage detection of cancers and a 20 percent reduction in lung-cancer specific mortality in the group screened with LDCT. The findings led to a 2013 US Preventive Services Task Force (USPSTF) B-level recommendation in favor of lung cancer screening using LDCT scans and guidelines for patient selection based on age, cigarette smoking status, and longevity. NLST did not include VA’s among its sites for patient recruitment. Therefore, there are many questions about how best to implement lung cancer screening in the VA and about what the beneficial effects may be.

#### What is the status of establishing lung cancer screening programs nationally in the VA?

Shortly after the publication of NLST, VHA initiated its own eight-site Lung Cancer Screening Demonstration Project. This program had several key features: (i) Veterans’ eligibility for screening, using USPSTF selection criteria, was determined using clinical reminders in the electronic medical record; (ii) each site had its own full-time coordinator, as well as embedded smoking cessation programs for active cigarette smokers; (iii) a centralized tracking tool, developed at the Minneapolis VA, was used to monitor results; (iv) multidisciplinary review was carried out for high-risk findings; and (v) radiation dose and radiographic reporting were standardized.

Rates of lung cancer detection in the Demonstration Project, which ended on Sept. 30, 2015, were only 1.5 percent compared to 3.9 percent in NLST, perhaps because the duration of screening and follow up was only slightly more than one year in the Demonstration Project compared to 6.5 years in NLST. On the other hand, invasive procedures were used in only about 3.5 percent of patients in the Demonstration Project, compared to in about 10 percent of patients in the LDCT arm of NLST. This difference may have related to the use of mandatory multidisciplinary review of high-risk findings in the Demonstration Project but not in NLST. In any case, the VA’s pilot project demonstrated the feasibility of implementing lung cancer screening across

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## NIEHS Releases Draft Strategic Plan *(Continued from page 6)*

multiple sites in the VHA using a reasonably consistent approach for patient selection and a common database.

After the Demonstration Project ended, most of the eight sites obtained local support for their coordinators and could continue screening. At that point, it was not clear if VHA would adopt a national policy in support of program-based lung cancer screening. Rather, it appeared that an approach would be taken in which screening would be offered on-demand to appropriate veterans, and their primary care providers then would be asked to undertake the request for screening with neither programmatic support nor a registry for long-term tracking. In October 2016, the ATS, working through its Washington DC Office of Advocacy and Government Relations, arranged for a small delegation to visit the office of David Shulkin, MD, then the VHA's undersecretary for health. In a meeting with Dr. Shulkin and his staff, the delegation advocated for a robust lung cancer screening program in VHA starting with creation of centers of excellence, each of which had fully developed programs as described in [ATS/American College of Chest Physicians Guidelines](#).

Subsequently, VHA convened a Lung Cancer Screening Interdisciplinary Project Team under its National Center for Health Promotion and Disease Prevention (NCP). Recommendations, released in November 2017, included that screening be made available to appropriate veterans on request but only in VA facilities with well-developed programs. Furthermore, a small team from the Minneapolis VA was designated to assist in implementing screening in sites without well-developed programs, including via installation of the database and tracking tool that had been further developed by the Minneapolis VA in partnership with NCP. To date, four sites have completed this training and are up and running and approximately 15 others are in the implementation process.

Also, in September 2017, VA-PALS (VA Partnership to Increase Access to Lung Screening) was formed. With support from VHA's Office of Rural Health and the Bristol Myers Squibb Foundation, VA-PALS will be providing coordinators to each of 10 sites in the VA. The program plans to employ a database that it is in the process of developing as well as the International Early Lung

Cancer Action Program for patient selection and nodule management. It should be noted that the roll-out in the VHA nationally has not been without its problems. Perhaps the most important is that currently there is no centralized mechanism for obtaining VA support for coordinators. Thus, many VA's have had to initiate lung cancer screening without the benefit of this key component of any screening program.

### **What are some of the key questions for research?**

Some of these questions need to be addressed in the VA to assess best practices for implementation, and the likely efficacy, of LCS in the VA. Two examples are:

- *How should LCS be provided to Veterans living in rural areas or near VA facilities not fully staffed to carry out LCS?* Options here may include use of mobile vans with CT scanners and/or teleconferencing for centralized review of high-risk findings. VHA's Quality Enhancement Research Initiative may afford metrics useful for comparing different implementation strategies addressing these needs.
- *How common is the problem of overdiagnosis among Veterans participating in LCS programs in the VA?* In the context of LCS, overdiagnosis may be defined as discovering a lung cancer in a patient with a co-morbid condition that leads to his or her death before the lung cancer affects well-being. Patients participating in VA-based LCS programs are older and have more co-morbid conditions than those screened outside of the VA. Therefore, overdiagnosis may be particularly important in the VA. Since overdiagnosis may lead to unnecessary procedures or treatments, it will be important to know how common this problem is in the VA.

In addition, of course, there are many unanswered questions about implementing lung cancer screening that pertain both within and outside of the VA. Three issues related to patient selection were discussed during an enlightening pro/con debate at the recent ATS International Conference:

- *Should patient selection be based on USPSTF criteria versus on personalized lung cancer risk models?*

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## Lung Cancer Screening in the Veterans Health Administration *(Continued from page 7)*

USPSTF guidelines for selection, based on patient age, cigarette smoking status, and lack of health problems limiting life expectancy, have been widely adopted in the United States. Individualized risk calculators that account for certain demographic, clinical, and smoking characteristics may enhance the effectiveness and efficiency of lung cancer screening programs. Evidence favoring superiority of these model-based risk calculators is based largely on retrospective studies. Prospective studies are needed to address the question.

- *Should patients with moderate to severe COPD undergo lung cancer screening or not?* Increasing severity of COPD linearly increases the risk of lung cancer. On the one hand, this finding suggests that the more severe the COPD, the more likely the patient is to benefit from LCS. On the other, greater severity of COPD may increase risk of diagnostic procedures and surgery, as well as limit the benefits of life extension from treating the cancer. More information is needed about these issues.
- *Should biomarkers be utilized in determining patient selection for lung cancer screening or not?* Noninvasive lung cancer biomarkers have the capacity to detect lung cancer before a nodule is visible, distinguish aggressive from indolent tumors, and predict responsiveness to different forms of treatment. Many candidate biomarkers have been identified, but validating them has been slowed in part because of insufficient numbers of samples. A large centrally organized LCS program in the VA may help to accelerate this validation process.

In conclusion, it's worth noting that implementation of LCS outside of the VA is proceeding relatively slowly in the U.S. The hope is that development of LCS programs for veterans obtaining care in the VA will move more quickly. If that happens, there will be many opportunities for research in the VA to address key issues related to the implementation and potential benefits of LCS. More advocacy may be needed, particularly directed to convincing the VA to provide more LCS coordinators. ■

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## FOGARTY INTERNATIONAL CENTER

### Fogarty International Center Celebrates 50th Anniversary

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In 2018, the Fogarty International Center (FIC) is celebrating its 50th anniversary as an NIH institute. The FIC supports and promotes global health research, with a special focus on training both U.S. and foreign researchers working in the developing world.

In his [March/April Message](#), FIC Director Roger Glass, MD, PhD, reviewed the Center's accomplishments since its founding in 1968 in honor of Rep. John Edward Fogarty (D-RI). Pointing to advances against smallpox, polio, and HIV/AIDS, Dr. Glass concludes that we have come far in global health, but much remains to be done.

The institute held a 50th anniversary symposium on May 1, 2018, entitled, *What Are the New Frontiers in Global Health Research?* The event featured remarks from U.S. Senator Jack Reed (D-RI), NIH Director Francis Collins, MD, PhD, and a number of former FIC trainees who are now prominent biomedical researchers and leaders of global health organizations, such as Glenda Gray, MBBCH, chair of the Global Alliance for Chronic Diseases, president of the South African Medical Research Council, and former Fogarty trainee.

Dr. Collins praised the FIC's fellowship programs, which he said have reached the world in remarkable ways, providing low- and middle-income countries with critical public health and research capacity, pointing to the 2015 Ebola outbreak in East Africa, where many former FIC fellows battled to contain the outbreak.

The keynote address was delivered by Richard Horton, MD, editor of the *Lancet*. In his remarks, Dr. Horton pointed to the "unprecedented political threat" that the

*(Continued on page 9)*

## Fogarty International Center *(Continued from page 8)*

FIC recently came under, a reference to President Trump's 2018 budget proposal to eliminate the FIC and merge its research programs with other NIH institutes. He noted that the NEJM, Lancet, and JAMA came together to support the FIC.

In addition to select remarks, the full-day symposium was composed of the following four panels:

- What has been accomplished and what is needed to advance infectious disease research and actually achieve the end of AIDS?" Panel speakers included National Institute of Allergy and Infectious Diseases Director Anthony Fauci, MD, and Linda Gail-Bekker, president of the International AIDS Society.
- "Noncommunicable diseases: How can we leverage existing research and training platforms to stem the tide of deaths and disability?" This multi-issue panel included breakout sessions on cancer, featuring remarks by the deputy director of the National Cancer Institute and on cardiology and sick cell disease, featuring remarks by National Heart, Lung, and Blood Institute Director Gary Gibbons, MD.
- "Global brain disorders: We're on the agenda, where do we go from here? What are the priorities for advancing the global mental health research agenda?" This panel, which also spanned several different health areas, included a breakout session on epilepsy featuring remarks by the director of the National Institute for Neurological Disorders and Stroke; on Alzheimer's disease, featuring remarks by National Institute on Aging director; and on schizophrenia in low-income countries, featuring remarks by the deputy director of the National Institute of Mental Health.
- "Multigenerational models of long-term capacity building: the trainees become the trainers". This panel was chaired by Dr. Glass and featured researchers and trainees from Peru, South Africa, and Uganda.

You can view a webcast of the entire FIC 50th Anniversary symposium [here](#). ■

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## PRECISION MEDICINE

### NIH All of US Program is Launched

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The [All of Us Research Program](#) began national enrollment on May 6, 2018, inviting people ages 18 and older, regardless of health status, to join this momentous effort to advance individualized prevention, treatment and care for people of all backgrounds. Part of the NIH, *All of Us* is expected to be the largest and most diverse longitudinal health research program ever developed.

#### How *All of Us* Benefits Pulmonary, Critical Care and Sleep Providers

Today there are too few conditions with evidence and options for individualized care. Too often, patients from underserved communities have not been included in clinical research, and our ability to care for diverse populations is diminished as a result. More data, discoveries, and tools can help providers give their patients customized care more easily, especially for those communities that are disproportionately impacted by health issues.

ATS Research Advocacy Committee Chair Veena Antony, M.D., says, "The *All of Us* Research Program will provide critically needed information for diseases in pulmonary, critical care and sleep medicine. For example, COPD is the third largest cause of mortality in US and there remain many lacunae in our understanding of the evolution of the disease." Dr. Antony continued, "Participating citizens in all their diversity will help us better understand the spectrum of disease and allow us to gain valuable insight into lung disease to fulfil the promise of predictive, personalized therapy."

*All of Us* participants are asked to share different types of health and lifestyle information, including through online surveys and electronic health records, which will continue to be collected over the course of the program. Those who join will have access to study information and data about themselves, with choices about how much or little they want to receive.

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## NIH All of Us Program is Launched *(Continued from page 9)*

Data collected will be broadly accessible to researchers of all kinds, including citizen scientists, to support thousands of studies across a wide range of different health topics. By doing so, they are hoping to discover how to more precisely prevent and treat other health conditions. Knowledge gained from this research could help researchers improve health for generations to come.

### **Why All of Us is Important for Patients**

Health care is often “one size fits all” and is not able to fully consider differences in individuals’ lifestyles, environments, or biological makeup. This is because we have limited data from past research studies about how those elements interact. The average patient is often prescribed drugs and treatments as if they are all the same. Learning more about the differences between individuals can help researchers develop tailored treatments and care for all people.

### **Why Diversity Matters**

Historically, many segments of the U.S. population have been left behind in medical research, including people of color, sexual/gender minorities, those with lower socioeconomic and educational status, rural communities, and other groups. The result is significant health disparities. The All of Us Research Program seeks to help fill in the gaps of information about those communities that previously have not been well represented.

### **How to Join the All of Us Research Program**

The program is seeking one million or more people from all walks of life to participate in this historic endeavor. Those interested in joining the program can do so by visiting, [www.JoinAllofUs.org](http://www.JoinAllofUs.org). Enrollment is open to all eligible adults who live in the U.S. ■

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## PCORI

### PCORI Broad Funding Announcement Open

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The Patient-Centered Outcomes Research Institute (PCORI) is seeking investigator-initiated applications for Cycle 2 patient-centered comparative clinical effectiveness research (CER) projects in the following areas:

- Addressing Disparities
- Assessment of Prevention, Diagnosis, and Treatment Options
- Communication and Dissemination Research
- Improving Health Systems

Applications should address needs of patients, caregivers, clinicians, and other healthcare stakeholders in making personalized clinical decisions across a wide range of conditions, populations, and treatments. Letters of intent are due June 28, 2018. Those selected to submit a full application will be notified by July 23, 2018 and full applications will be due September 25, 2018. Interested investigators should visit [PCORI's Broad Funding Announcement](#), which includes a variety of resources including the application guidelines and a sample letter of intent template. ■

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## NINR

### NINR Director Announces Retirement

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On May 31, Director of the National Institute on Nursing Research Patricia Grady, PhD, announced that she will retire from the institute at the end of summer 2018. Dr. Grady became the institute’s second permanent director in 1995, after the NINR, originally founded as the National Center for Nursing Research in 1985, was elevated to Institute status in 1993. A neuroscientist by training,

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## NINR Director Announces Retirement *(Continued from page 10)*

Dr. Grady served as deputy and acting director at the National Institute of Neurological Disorders and Stroke before serving as NINR director.

In her director's message in the NINR's newsletter, Dr. Grady looked back on some of the institute's achievements over her 23-year tenure. These include the creation of institute boot camps, a robust intramural research program, and a tripling of the NINR budget. Dr. Grady said, "After 30 years, the Institute is strong, but still rests on your shoulders." She continued, "I am confident that the Institute will be well served in the years to come by the collective wisdom of the established scientists, the emerging generation of new researchers, the policy gurus, and our outstanding educators and administrators." ■

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## DATA SCIENCE

### NIH Releases Data Science Strategic Plan

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On June 4, NIH released its first [Strategic Plan for Data Science](#). The Plan, developed as part of NIH-Wide Strategic Plan, is a roadmap for modernizing the NIH's biomedical data science ecosystem, which is critical to accelerating cutting-edge science. The following are the plan's five overarching goals and strategic objectives:

- 1) Data Infrastructure
  - Optimize data storage and security
  - Connect NIH data systems
- 2) Build a Modernized Data Ecosystem
  - Modernize data repository ecosystem
  - Support storage and sharing of individual datasets
  - Better integrate clinical and observational into biomedical data science
- 3) Data Management, Analytics and Tools
  - Support useful, generalizable, and accessible tools and workflows
  - Broaden utility of and access to specialized tools
  - Improve discovery and cataloging resources

- 4) Workforce Development

- Enhance the NIH data-science workforce
- Expand the national research workforce
- Engage a broader community

- 5) Stewardship and Sustainability

- Develop policies for a FAIR data ecosystem
- Enhance stewardship

In order to enhance data science across the extramural and intramural research communities, NIH plans to recruit a chief data strategist. The chief strategist will supervise the development and implementation of NIH's data science efforts and ensure leadership across the broader biomedical research data system. NIH will continue to seek community input during the implementation phase. ■

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## HEALTH RESEARCH FUNDING

### House Panel Proposes \$1.25 Billion NIH Funding Increase

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The fiscal year (FY) 2019 spending process is underway in Congress, where the House Labor-Health and Human Services (LHHS) Appropriations subcommittee, chaired by Rep. Cole (R-OK), met on June 15 and approved a \$1.250 billion funding increase above current funding of \$37.1 billion for the NIH as part of the FY2019 health research and services spending bill, for a total proposed FY2019 funding level of \$38.3 billion. The House bill also includes some good news for the Centers for Disease Control and Prevention (CDC) in the form of a \$427 million funding increase for the agency. Details on CDC programs that the ATS monitors, such as asthma and tuberculosis, have not yet been released.

The Senate LHHS subcommittee, chaired by Sen. Blunt (R-MO), is tentatively scheduled to meet the last week of June. The Senate panel is also expected to approve a funding increase for NIH, though the amount is not yet known.

*(Continued on page 12)*

## Health Research Funding *(Continued from page 11)*

The outcome of the individual House and Senate health spending bills is uncertain in this election year, but regardless, the funding levels for NIH included in the House and Senate Labor-HHS bills are expected to move forward. Congress will negotiate final NIH funding from the two differing bills, so the House subcommittee's action is a strong indicator that NIH will receive a funding increase in FY2019.

Regarding final FY2019 government spending, we expect that as we get closer to the election, the congressional appropriations process will halt and Congress will pass a series of omnibus spending bills for FY2019. With the impending election it is also very possible that the spending bills will be used as leverage, as the president has already mused about shutting the government down. Congress and the president will need to agree on FY2019 spending by September 30, 2018, when the current fiscal year ends. ■