Keynote Dialogue with NIH Extramural Research Leadership

Session Transcript: 2022-2023 NIH Grants Conference

Megan Columbus: Welcome. My name is Megan Columbus. I'm the Communications Director for NIH's Office of Extramural Research, and I'm your moderator for this session. The Office of Extramural Research holds a special place in NIH. It's housed in the NIH Office of Director, and it supports the entire extramural research community by providing policy and guidance and systems and other types of support. It's really that corporate framework for NIH research administration, supporting scientific integrity, public accountability and more. It provides other things like valuable resources for the community like the NIH Grants and Funding website or, more importantly maybe, this conference. So I am so pleased today to introduce you to the Office of Extramural Research leadership, Drs. Mike Lauer, our Director, and Liza Bundesen, Deputy Director. They're here today to share their perspectives on NIH priorities with us. Mike also serves the important role of NIH's Deputy Director for Extramural Research where he serves as a principal scientific leader and advisor to the NIH Director on the Extramural Research program. In fact, you might be familiar with Mike's blog, "Open Mike." Thank you both for joining us today. With that, Mike, I'd like to turn it over to you.

Michael S. Lauer, M.D.: Great. Megan, thank you very much, and, boy, I'm looking at the chat here, and I see that people are from all over the country, all over the world. This is just amazing. And so I also want to on behalf of my colleagues at NIH take this opportunity to welcome you to our conference and thank you so much for coming. It also gives me great pleasure that I'm going to be joined today by Dr. Liza Bundesen. We had .. . Our last conference was in November of 2021, and shortly after that, Dr. Bundesen was appointed as the Deputy Director of our Office of Extramural Research. She's been at NIH for a long time, but she took over this new role more recently. So we're doing a little bit of an experiment today. Instead of my giving a longer talk as those of you who have been to this conference before might recall, the two of us are going to split a brief presentation, and then we're going to engage in a conversation that will follow, and you'll hear more about that as we go forward.

All right. So NIH consists of communities, and, boy, this, again, this chat says it. It says it all. So one way we can think about it is, is that we've got two sets of communities. One is here in Bethesda or primarily here in Bethesda. That is our Intramural program. That is a large program, but it only accounts for about 11 percent of our budget, and of course you, nearly all of you, come from our various extramural communities all over the United States and really all over the world, and that's more than 80 percent of our budget. So let me talk a little bit about our budget at a high level. This is the budget from FY22. It's over $40 billion, and this gives you a sense of how we spend our money. Now the largest component of the budget are Research Project Grants, and I'm guessing that this is probably what most of you are most interested in. So this includes everything from R01, the standard R01 grant, to large cooperative agreements and program progress grants. That's about 54 percent of our budget. We spend about 2.7 percent of our money on SBIR and STTR grants. The 6 percent on research centers, research centers would be like CTSAs or cancer centers. Nearly $1 billion we spend on training, this is the so-called NRSA program, which includes both predoctoral and postdoctoral training, 8 percent on contracts, 11 percent on intramural research, and then 5 percent is our own overhead. So as I said, we spend about 54 percent of our money on Research Project Grants, so what I'm going to show you now is a series of graphs that describe trends that we've seen over time. On the x-axis is time from fiscal year 1998 through our most recent data of fiscal year 2022. The red line with the circles, that shows the total amount of money that NIH is getting in billions of dollars, and that has increased over time. Back in 1998, it was about $15 billion, and now it is in the $40 billion range. You'll see also there was a period of time from 2003 to about 2015 when the NIH budget was relatively flat. When you take into account inflation, that means that our buying power was going down. But over the last 7 years or so, we have seen substantial increases in our budget. This is due to strong bipartisan support for the work of our agency and really the work that you all do. This is something, of course, we're all pleased to see. The blue line on the bottom with the red squares represents the total amount of money that we're giving to Research Project Grants, and then the green line on the top with the triangles shows then the percentage that we're giving to Research Project Grants, and that's remained remarkably constant over the years between 50 to 55 percent. Now another way of looking at trends over time is, how many Research Project Grants are we actually giving, and how many principal investigators are supported on Research Project Grants? So again, we're going from 1998 to two thousand and .. . to 2022. The green on the top with the triangles represents the number of unique awards, each individual project, and you'll see that increase dramatically during the time of the NIH doubling between 1998 and 2003. That's when our budget increased nearly twofold. During the time when the budgets were relatively stagnant from 2003 to 2015, we actually had a decrease in the number of awards that we were giving out, and then, since 2015, there has been a substantial increase, so we are now giving out more Research Project Grants than we have ever given in our history. The red line with the circles indicates the number of unique people who can say that they are principal investigator on at least one NIH Research Project Grant. You'll see a similar trend, and that number has also increased substantially over the last 6 years. This shows the career stages, and for convenience sake, we say that someone is in their early career if they're in their .. . if they're age 45 or less. They're mid-career between ages 45 and 60, and they're late career if they're over the age of 60. So the red line with the circles shows the proportion of our Research Project Grant investigators who are early career. That number had been going down, but since over the last 12 years or so, that has remained actually quite stable. You'll see that the blue with the squares are mid-career, and that number had been going down and had been a source of a great deal of concern but has stabilized over the last 6 to 7 years. And then the green line are the .. . are late-career investigators. The green line with the triangles are the late-career investigators, and that number had been going up. That proportion been going up quite substantially but has stabilized. So what we're seeing here is that, for any of a variety of reasons, over the last 6 to 7 years, this has followed a stable pattern. Now we're going to take a look at what proportion of our Research Project Grant investigators are men or women, so the green line on the top with the triangle shows the proportion or the percentage who are men. That number has been steadily going down, but it is still well over 50 percent, and then the red line with the circle shows the proportion who are women. That number has been steadily going up. It's starting to approach 40 percent, but it's still quite far from parity. One major focus that we've had for .. . particularly for the last 6 to 7 years, has been funding early-stage investigators. This is part of our Next Generation Researchers Initiative. So what I'm showing you here are the number of early-stage investigators. We define an early-stage investigator somebody who is within 10 years of their terminal research degree or finishing their clinical training. And so we show here the number of early-stage investigators that are being funded for their first major R01-equivalent award. Pleased to say that this number has increased also substantially over the last 7 years from less than 1,000 to over 1,600 in FY2022. Now, having presented these trends, which in many respects look quite good, it is important to keep in mind, and I don't think I need to tell this audience, that the NIH world is a very competitive one and, in fact, has been referred to by some authorities as being hypercompetitive, and there are concerns about that. So now what I'm showing you here, if you look at the red line, this is the .. . with the circles .. . this shows the number of Research Project Grant applications that we received in any given year, and that number has increased substantially over the last 25 years. Look what happened in 2021. In 2021, we had a jump from about 55,000 to 59,000 applications. In 2022, it came back down to where we were in 2021, and presumably this was a pandemic effect. That's what we're guessing this is. The green light at the bottom with the triangle shows the number of unique RPG competing awards that we gave in that year, and then the blue line with the square shows the success rate. So back in the late 1990s and early 2000s, the success rate was running around 30 to 35 percent. Now most recently it's running around 20 percent. So we're in a very competitive environment, and that continues to be the case. So let me summarize the trends that we have seen. We are a growing community. We are a community of researchers and people interested in research, people who support research, literally all over the world and all over the United States. Over time, we have seen an increased number of awards and principal investigators. We're very pleased that the number of early-stage investigators that we're supporting is going up. There's an increasing proportion of our Research Project Grant principal investigators are women, but this is still well below parity. Our success rates are better than they were 6 or 7 years ago despite the fact that we are receiving somewhat more applications, but this is still a very hypercompetitive environment. So I presented you with some high-level data to review some of the trends that we are seeing, and at this point, it is my pleasure to turn this over to Dr. Bundesen.

Liza Q. Bundesen, Ph.D.: Great. Thank you, Mike, and thank you, Megan. I'm so pleased to be with both of you today and everyone in the virtual audience. This is very exciting. So yes, Mike, the data shows some very encouraging trends, but as you said, the environment's still very competitive, and our landscape is always evolving, and so, because of this, we have to constantly evaluate the ways in which we fund research. And we do this through a number of approaches, and that includes ways to improve our grant application and review processes, developing and implementing new policies to ensure the transparency and integrity of the research we fund, and ways, of course, to continue to support the biomedical workforce. So the Advisory Committee to the NIH Director, or the ACD for short, serves a very critical role in advising us, NIH, on the pressing issues that face the research community, and they help us to develop recommendations to guide our path forward. And the ACD met about 2 months ago in December 2022 and discussed four priority areas shown here, so they are simplifying peer review criteria, novel alternative methods to advance biomedical research, a working group to re-envision postdoctoral research training and NIH efforts to support open data, including NIH's new Data Management and Sharing Policy.

So we'll .. . Whoops, apologies. Oh, goodness, the controls are going wild. All right. So we'll start with simplifying review criteria. The goal of this effort is to facilitate the mission of peer review, which is essentially to identify the strongest, highest impact research, and currently, as many of you know, applications for Research Project Grants are evaluated based on five scored criteria, which are specified in regulation. These include significance, investigators, innovation, approach, and environment and a number of additional review criteria, such as human subjects' protections. Now NIH has proposed to simplify this framework, which would allow peer reviewers to focus on the scientific merit of the applications by evaluating the importance of the research and the potential scientific impact, so in other words, should it be done? The feasibility and the proposed research and rigor, can it be done well? And whether or not the appropriate expertise and resources are available to conduct the research, or will it be done? So this last individual criterion would not be scored, though it would be considered as part of the overall score. The goal here is to reduce potential bias and mitigate any undue influence of the reputation of the institution or the investigators, again, to allow the reviewers to focus on the science, so we want to acknowledge the Center for Scientific Review and their advisory council for initiating this important work, and we've issued a Request for Information, or an RFI. The link is at the bottom of the slide, and we're seeking feedback on this framework, so please take a look. The comment period ends March 10th.

All right. So moving on to novel alternative methods, so we know that innovative technologies are creating some wonderful scientific opportunities and have the potential to serve as complimentary approaches to animal models. Examples include cell-free methods, in vitro microphysiological systems and in silico approaches like machine learning, AI and mathematical modeling. So we have formed a working group of the ACD, the Advisory Committee to the NIH Director, to explore these opportunities. And this is their charge, to identify the types of alternative methods along with the strengths and weaknesses, the types of research conditions or diseases for which these methods are most beneficial, and to articulate the high-priority areas for NIH. And we look forward to following this work group's activity over the coming months.

So many of you have seen likely recent pieces in journals like Nature and Science that describe struggles that scientists are having in recruiting postdoctoral fellows to their laboratories, and this is happening across the STEM fields. We've also seen discussions on social media where investigators are saying they're receiving far fewer applications to open positions than they've seen in past years, and then the slowdown in the hiring means that research projects may be delayed, and this has only been compounded by the pandemic. Many surmise that postdocs are pursuing higher-paying jobs in other sectors and are very happy to enter the professional workforce directly after years of graduate training. And while postdocs in academia offer a potential to learn additional specialized skills, it's not without risk because the reality is there's no guarantee of a 10-year track position on the other side. And as Mike said at the beginning of the session, this is a hypercompetitive environment, and this isn't just an issue in the United States. It's being observed in many other countries.

So once again, we have formed an Advisory Committee to the NIH Director working group, and they're going to further analyze this issue, and this is their charge: to evaluate the perceived shortages in PhDs seeking postdocs. What is the data telling us?; to assess and consider factors influencing the scope and persistence of this issue; to review and compare other approaches to postdoc training; consider ways to support postdocs' quality of life, which is so important, including work-life balance with a goal of increasing retention; and then, of course, engage in key internal and external stakeholders.

Okay, so just a few days ago on January 25th, we announced the implementation of the new NIH Data Management and Sharing Policy, and while it was officially rolled out last year, it's not exactly new. The policy was announced in 2020, and we've been working on it for many years before that. Essentially the policy requires researchers to submit a plan with their applications outlining how scientific data and accompanying metadata will be managed and shared. The policy expects that data sharing becomes a fundamental component of the research process, And we realize this is a culture shift for the community, but over time, it will become part and parcel to how research is conducted and has the potential to have far-reaching impact, such as accelerating scientific advances while also maximizing the public's access to results from that early-funded research. And as you can see articulated here by Dr. Larry Tabak, who's performing the duties of the NIH Director, the amazing speed at which COVID-19 vaccines and treatments were developed demonstrates the power of data sharing to catalyze this research.

And we've also developed a suite of resources to help you, the community, navigate this new requirement, so please check out our website. It contains information about how to write a plan; how to budget for data sharing; key principles for managing data like making it findable, accessible, interoperable and reasonable - the FAIR principles; the length of time to maintain data, data security and more. It also has guidance on selecting repositories and different data-sharing approaches. We actually have a separate session entirely on the Data Management and Sharing Policy at 4 p.m. today, so please check that out, and we'll continue to engage with the community and listen to your feedback as everyone adjusts to this new policy.

So just in closing, this has been a snapshot of only a few of the important issues for both NIH and you in the community, but we're working on much, much more. As Mike showed you, we've seen some very encouraging trends regarding the number and characteristics of the science and the people that we support, including early-career investigators. We've talked about efforts to enhance peer review not just to make the process easier on reviewers but to enhance the rigor of the review and to mitigate bias that might creep in during the review of an application. We've talked about exploring alternative methods to complement the use of animal models. We're re-examining the postdoctoral training experience and looking for ways in which we as a community, both NIH and research institutions, can support postdoctoral careers and also advance the research enterprise and, of course, implementing the Data Management and Sharing Policy. So that's all for our prepared slides. Back to you, Megan.

Megan Columbus: Hey. Thank you so much, Liza. So now we're going to do something a little bit different. I am going to ask for a choose-your-own adventure, so I'm going to ask our tech team behind us to put a poll up because we don't have the opportunity to answer very many questions in the session. There's something like almost 4,000 of you here right now, but we did want to see .. . hear what you wanted to talk about, and then we can have our leadership talk about those things. And so, DeRon, could you put a poll up for us? So kind of the topics that you can select from, select up to three of these topics, is the changing NIH leadership, what NIH is doing to build a stronger biomedical research workforce, how NIH is supporting a safe and healthy workplace for NIH-supported researchers, where rigor hits the road, what integrity really means that NIH is taking to strengthening recipient reporting and oversight, how NIH engages the community in program development and ways we can improve trust in science. So if you want to make some selections, go ahead and do that. I'll give you another moment to do that. And then go ahead. DeRon, could you show us the results of the poll so we can see what people are looking for? Okay. We have a lot of even splits here. Mike, given some of the .. . All right. So let me just make a note of .. . Actually, we can go ahead and leave these on the screen, can't we? Let's leave this on the screen, and, Mike, because of some of the conversations I saw in the chat, I thought maybe we could start with how NIH is .. . I'm sorry .. . what NIH is doing to build a strong biomedical research workforce.

Michael S. Lauer, M.D.: So thank you. I'll start with that. This is something that has been top priority for NIH leadership for quite a while. As a number of you may recall, in 2011, there was a landmark paper that was published by Donna Ginther in the journal Science that indicated that Black principal investigators were less likely to receive funding than white principal investigators even after accounting for a variety of potential confounding factors. Now, in the follow up to that, we set up .. . We, NIH leadership, set up an Office of Scientific Workforce Diversity that was initially headed by Dr. Hannah Valentine from Stanford University and now more recently is being headed by Dr. Marie Bernard. There are a variety of activities that this group is doing. I'll just give out as one example something called the FIRST initiative, F-I-R-S-T, and this is an initiative to fund cohorts of new investigators to work in the extramural environment. We have another program called UNITE, U-N-I-T-E, and this is focused on the damaging effects of structural racism on all aspects of the biomedical research enterprise, including the Extramural Research workforce. We have a Division of Biomedical Research workforce within our office, which is headed up by Dr. Ericka Boone. They are focused on lots of things and workforce diversity as well as enhancing training, and, of course, we're all going to be participating in the efforts that Liza mentioned on re-envisioning the postdoctoral experience.

Megan Columbus: Thank you so much, Mike. All right. Let's go to the highest-ranked one here. How about ways we can improve trust in science? What a great question.

Michael S. Lauer, M.D.: Okay.

Liza Q. Bundesen, Ph.D.: Sure. I .. .

Michael S. Lauer, M.D.: Liza, want to start with that one?

Liza Q. Bundesen, Ph.D.: Yeah, yeah, I can handle that one. So there are lots of different ways that we can improve trust in science, I think. So within the Office of Extramural Research, we have been ramping up our efforts to address research integrity, and so research integrity is an umbrella term that we use to describe the actions that scientists take to behave with integrity, and when they violate practices that promote integrity, it may be cases such as research misconduct. So that would be fabrication, falsification, plagiarism of research data, grant fraud. Also professional misconduct, whether that's harassment, discrimination, bullying in the laboratory or the work[place that's associated with NIH research. So we take these issues of integrity very seriously. We actually have a website on promoting a safe work environment in the labs that we .. . in the research areas that we support. If we learn of breaches of integrity in the context of NIH-funded research, we will work with the institutions to see what is going on, how that may be affecting the research that we support and the researchers that we support, and there are a number of actions that we might take that are outlined on our website. It could be changing, working with the institution to change a PI. It could be just other adjustments that we do to ensure the oversight and compliance with NIH Grants Policy. So knowing that we are taking actions when there are bad actors, we're hoping that that will improve the trust in science, and we actually post data. We've dealt with hundreds of different integrity cases, and we post that on our website. We have different portals where the community, anyone anonymously can notify us if they become aware of harassment or other actions that affect the safety of their work environment, and then they can describe the situation, and then we will work with the institution to address it, and we post this data of the cases on our website because we want to not only show people that we're taking action but possibly by seeing that we're doing this that it will encourage people to come forward and share their stories. So that's .. . Go ahead.

Megan Columbus: Yeah, no, thank you, Liza. I'm noting there was a comment that's pertinent here, which is, these are great actions that NIH is taking, but there's also this larger societal issue, right, which is a harder one to tackle.

Liza Q. Bundesen, Ph.D.: Yeah, absolutely. That's why we need to work in partnership with the research institutions, and it's about slowly changing the culture. We want it to change quickly, but we're moving the needle, I think, and that is a great comment. Another example or efforts to reduce bias, implicit or explicit, so we mentioned earlier about efforts to simplify peer review and to reduce bias by de-emphasizing the importance of an individual's pedigree, their institution, and to focus again on the proposed research. It's also important that we are transparent with NIH policies and our processes, that our policy expectations are applied uniformly, again, that we post evaluations, self-evaluations and analyses of our policies, and we also encourage and expect the community to be transparent as in the case with our new Data Management and Sharing Policy. And then there's always a need for scientists, communicators and storytellers who can translate complex topics. Some people may not trust science because it's just not been presented to them in a way in which they can understand it or see the value of it, so we need people who can bridge that gap. And honestly I think humility is a very important characteristic that we all must have. We have to have a willingness for scientists to hear the concerns of the members of the public may have and not just disregard them outright but to truly listen to their points of view and engage in a constructive dialogue.

Megan Columbus: Thank you. Let's pick another one of these topics. It looks like we have three that are pretty much the same. How about how NIH engages the community in program development?

Michael S. Lauer, M.D.: So I think there are a couple ways of thinking about this. One is at the level of our institute, so as you know, NIH is the National Institutes of Health. We are a federated structure. We're collection of institutes, and each institute has its own set of strategic priorities and strategic goals. They post their strategic plans on their websites, and actually we have a central website where we have them all available, and they engage with their communities in a variety of different ways. Of course, each institute has an advisory council, and that's another way in which they interact with the community. I think another way of thinking about this on a more general level, NIH writ large, are we have a variety of venues. Liza mentioned the Advisory Committee to the Director and the working groups of the Advisory Committee to the Director. These working groups are extraordinarily active. I've had the privilege of being part of a number of them over the years, and they involve people from the community, from different walks of life to help us figure out what's the right way of doing things, and not infrequently these .. . the work of these advisory committees leads to RFIs, Request for Input, from the community. I'll also finally mention that when we develop policies, very frequently as part of our policy-making process, we request comments. So for example, the Data Management and Sharing Policy, which we're now in the process of implementing. There were three separate instances going all the way back to 2016, I think 2016, 2018 and 2019, when we put out requests for input or request for comment. So there are many ways in which we interact with the community and engage in conversation to help us move forward in the right way. And then maybe I'll just say the last thing is what we're doing right now.

Megan Columbus: Very true. Well, and we do things like this. We're talking with the community all the time at all kinds of levels at all kinds of venues, right? How about steps NIH is taking to strengthen recipient reporting and oversight?

Liza Q. Bundesen, Ph.D.: I can start. So we work collaboratively with a lot of different stakeholders, so professional organizations, entities like the Federal Demonstration Project, our departmental colleagues in HHS, the White House Office of Science Technology Policy, or OSTP. There are a lot of activities going on because recipient reporting oversight is very critical to ensuring the integrity of our process, and of course we recognize that with every bit of reporting that that's administrative burden, and so we do the best that we can to balance the needs to be stewards of federal research dollars, taxpayer dollars. But then to do it in a way where we're very mindful to the administrative burden on the institutions, and it's a constant balancing act. But we work with these stakeholders on a variety of issues. We remind the community about the various compliance and oversight requirements. One example that we recently reminded the community of was the financial conflict of interest and other support requirements. We issued a notice in the NIH Guide for Grants and Contracts, and an example of this is that our recipients play a critical role in protecting the integrity and security of research, and we require that investigators have to disclose their significant financial interests and sources of other support. This has garnered a lot of attention with the HHS Office of Inspector General. In the media, they would be called a government watchdog. But they issued a report specifically about this topic, and so we request information on active and pending support as part of just-in-time procedures to ensure that there's no scientific, budgetary and commitment overlap. And this, again, is very important to protect the integrity of our research enterprise. So I'll stop with that example. But, Mike, do you have anything else that you wanted to add about strengthening?

Michael S. Lauer, M.D.: No, that's great. Thank you. Nothing to add to that.

Megan Columbus: No? Okay. So we have time for one more short answer before I have to do some closing reminders and comments. Representatives [Indistinct]. Okay. Can you talk a little bit about .. . We've talked about integrity. What about rigor?

Michael S. Lauer, M.D.: Liza, you can take that one.

Liza Q. Bundesen, Ph.D.: Okay. And I'll try to be fast. It's hard to be fast when talking about rigor, but when we talk about rigor, we mean designing and performing scientific research and strictly applying the scientific method and having well controlled experimental design methodology, et cetera. So we ask applicants to address all of these elements of rigor in their applications, and another government watchdog, the Government Accountability Office, has a great interest in this as well and has also issued a report and asked NIH to look into ways to evaluate the rigor of our application, such as using AI or machine learning. We have a web page with resources and tools on rigor, such as an experimental design assistant, case examples on rigor and reproducibility, sample authentication plans for cell lines, biological resources. The ACD issued a report last year and had several recommendations on how to better improve rigor in vertebrae and cephalopod research, and so we're working on implementing those recommendations. One idea was to encourage all of our grantees to use the ARRIVE Essential 10 in all of their publications. So those are essentially randomization, study design, blinding, things like that. Again, we mentioned our simplifying peer review criteria effort. Rigor will be a component in the review criteria. And again, the Data Management and Sharing Plan, we're hoping that by having transparent access to more data that folks can test against that and will be able to root out challenges and build upon existing data and extend to new hypotheses. So I will stop with 2 minutes to go.

Megan Columbus: Great. Hey, thank you so much to you both for joining us today.