“Open Mike” with Dr. Michael Lauer

Session Transcript: 2022-2023 NIH Grants Conference

Megan Columbus: Welcome to the 2023 Virtual Grants Conference. If you attended the keynote session, that's great, and you've heard some of this before, but what I love most about this conference is the ability to bring people together from across the enterprise, right? We have researchers and research administrators and students and all kinds of people, and we have them from all over the world. Feel free to use the chat to introduce yourselves or to interact with each other as I'm talking. One thing I want to point out is that if you need help or advice during the conference, please go to the Event Support tab in the Conference Center. It's right at the top there. And I just can't emphasize enough the value of making personal connections with NIH staff outside of these sessions, right? We literally have 200 staff here today at this moment, I believe, ready and willing to chat with you. And so don't leave them hanging there. And if you don't know who to talk to, or you don't know which institute to talk to, that's fine. Our Central Resource Room in the Exhibit Hall has booths that are staffed that are Policy and Compliance and Grants Management staff, Program staff for the science, Health Science Administrator types, who are running programs, Scientific Review Officers, people who deal with our eRA and other systems - all kinds of things for you to look for there. So don't be shy, all right? That's the best way to make the most of this conference. Before we begin, a few logistics specific to this session, okay? This is going to be a 45-minute session. This is going to be all kinds of questions. Whatever your questions are, we're looking to answer. This is a leadership perspective, and so that's what we're doing. Use the Q&A box for questions, and you can use the chat box to interact with each other. That way, I know that as I'm moderating, I can monitor the Q&A. Although, I'll be reading the chat too, at least it gives me a place to focus. If you're distracted by the chat and everybody introducing themselves, that's fine. Just click the arrow next to the chat icon and turn off those notifications, or you can just minimize the chat box, and it'll be out of your way. There's no slides for this session, so we won't have them posted, but the recording will be posted within 7 business days. All right? If you have any issues during the conference, feel free to e-mail our team at nihgrantsevents@nih.gov. All right? Now, let's go ahead and get started. Let's see. I realize that I probably had .. . Huh! I'm sorry. There we go. Let's go ahead and get started. So my name is Megan Columbus. I am the Communication Director for NIH's Office of Extramural Research, and I'm your moderator for this session. Why do you care about the NIH Office of Extramural Research? We don't award grants, but we do provide leadership, right? We're in the NIH Office of the Director. We support the entire NIH Extramural Research community internally and external to NIH by providing policy and guidance and systems and other support. You know, we provide that corporate framework for NIH's Research Administration, supporting scientific integrity and public accountability and those kinds of things as well. And I think most importantly, we provide valuable resources for the community, like the NIH Grants and Funding website or things like this conference. I'm so pleased to welcome my leadership from the NIH Office of Extramural Research: Dr. Mike Lauer, our Director; and Dr. Liza Bundesen, our Deputy Director today. They're here today for our version of what I like to call an "Ask Me Anything" session. Mike also serves as important role of NIH Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the Extramural Research program. The reason that we called this session "Open Mike," besides the obvious, is that you may be familiar with the "Open Mike" blog. The blog, you know .. .In that blog, we're striving to connect the NIH community with the NIH leadership perspective and connect us with yours. So thank you, both, for joining us today. And I'm going to go to the Q&A box, and people should feel free to just start putting in questions and answers. It's interesting, in the keynote session, we saw a lot about ChatGPT, right? And some people know, this is quite a sophisticated chatbot that's being tested out these days. I wondered if you all had some perspective on that and what it means for plagiarism or grant-writing.

Michael Lauer: So, boy, we live in a new world. So a few weeks ago, one of Megan's colleagues typed in something in the ChatGPT about NIH. You know, "write something about NIH," and I think it was write it in the form of a sonnet, and so what came back was amazing. It was actually .. . It was a sonnet. It was iambic pentameter, had the right number of lines, and the content was actually accurate and interesting. So for fun, I read this out loud to my wife. We were working together early that morning, and I just read this thing out loud. She thought it was very clever, and then she said, "Who wrote that?" And I said, "Well, that is exactly the right question to ask."

Megan Columbus: That's right.

Michael Lauer: Because actually, nobody wrote it. Or maybe a better way of saying it is, "Everybody wrote it," but I can't tell exactly who, and so I pointed out, this was ChatGPT. Now, at around the same time, I know that there have been some interesting articles that have come out. There was an article, I think on the front page of the New York Times, talking about a college professor who was seeing a term paper that seemed to be absolutely beautifully written, one of the best papers that they had ever seen. Turned out to be written by ChatGPT, and so now, in the academy, I understand various things are happening. Like people have to write their essays in a moderated space or in the blue notebooks that we used to .. . some of us, who are a bit older, used to use. And there are also .. . I saw there was an article in Nature about ChatGPT being a coauthor on papers. So this is a whole new world that we're in right now. I'm not exactly sure what it means and how it's going to affect our particular environment. On the one hand, I think we are our reviewers certainly appreciate well-written grants. That's for sure. But we also make an assumption that when an application comes in that it is a piece of original work and that the people who say that they wrote it are the people who actually wrote it. So we're going to have to figure this one out, and I'm not totally sure where this is going to go.

Megan Columbus: Yeah. It's an interesting question, isn't it?

Liza Bundesen: Yeah.

Megan Columbus: It looks like we have a number of people who are interested in the new peer review factors that Liza had talked about in the keynote. And they're asking when those would become effective.

Michael Lauer: So we're going through a process of vetting. And part of that vetting includes communication and engagement with the community. So as Liza mentioned, there is an RFI, request for input, that is currently out. The timing of this conference is perfect, because the deadline I think is March 9th or March 10th. So there is time, not much time, but there is time. And so this is a shameless plug: please go there and provide your comments, cause your comments are extraordinarily important to help us think about what is the best way to move forward with this? This is not going to happen in the next grant cycle. We're not talking about that kind of a time line. I think the time line is going to be a bit longer. Part of it will depend upon what kind of responses that we get. Liza, you have other thoughts about this, about the .. .

Liza Bundesen: Yeah. Yeah, thank you. We're obviously .. . At NIH, we're very excited about this new framework, and we've heard that folks outside of NIH are also intrigued and excited. But as Mike mentioned, this is not on a fast track. We are very mindful about rolling out new things, new policies, new procedures to the community. And we have this session on the New Data Management and Sharing Policy at 4 o'clock today. This is the big issues, big sea change for the community, so we don't want to roll out another big change. So we want to make sure that we stagger these new implementation priorities in a way that's thoughtful and considerate of burden on our institutions and our investigators.

Megan Columbus: Yeah. That's great. And, yes, I will .. . Oops. Someone already put the RFI in the chat. Thank you so much. What about what NIH will be doing in the future to increase compliance with the results reporting within clinicaltrials.gov?

Michael Lauer: Okay. This is something I'm spending a lot of time on. So thanks very much for asking about that. And actually, it's something that I personally had been interested in for a long time. I'll tell a very quick story to start. So back in, I think, 2012, there was a paper that was published in the British Medical Journal that suggested that half of all NIH-funded trials did not see their main results published either at all or within a reasonable period of time. That may have been 30 months. And my boss - I was working at the National Heart, Lung and Blood Institute - and my supervisor came to me, and she said, "I don't believe this. This is wrong. They totally misunderstand the data, and I want you to go ahead and refute this." I said, "Okay." I took this as an assignment from .. . That was the NHLBI Director at the time, and I had turned and walked down the hall, and I met one of my colleagues, David Gordon. And I said, "David, I have a little assignment for you. I think this will take you about 3 days. And what I need you to do is take a look at the trials that we're funding here at the Heart, Lung and Blood Institute, particularly the cardiovascular trials, and demonstrate that, in fact, all these trials are getting published, and they're getting published in a timely way." So David smiled, and he said, "Okay. I'll do that." Well, it took about a year and a half. So 3 days turned into a year and a half. It turned into a megaproject. We actually published the results of our work in the New England Journal of Medicine in late 2013, and what we found was really disturbing. What we found was that, in fact, what that paper had reported was correct, that a very large proportion of trials did not see their results published either at all or only after a substantial delay. All right. So now, as we all know, in 2016, NIH rolled out a whole new series of policies regarding clinical trials, and one of them involved mandatory registration and reporting. We required the trial results be reported in clinicaltrials.gov within 1 year of the primary completion date. The thing is, is that setting up something like this is much easier said than done. And we spent millions of dollars to set up a system, an IT system within the NIH Office of the Director. And it's linked with our colleagues over in the National Library of Medicine so that we can actually keep track of clinical trials, where reports are due, where results are due, where the results have not been reported in yet, and that are linked to grants that are subject to the policy. And we've now been rolling this out over the last few years. And I will say that while we are not there yet, we are not yet seeing the vast majority of our trials being reported in a timely way, we are much closer than where we were a number of years ago. And so for example, if we look at trials for which results were due in FY20, FY21 and FY22, well over 90 percent of those trials now have results that have been submitted to clinicaltrials.gov. We are .. . We've talked with leaders in the community about how important it is that these results do be submitted in a timely way. We are definitely seeing improvements. One thing that we are doing is that when we discover that a trial report has not been submitted, we contact the institution, and we let them know that we're seeing a delinquent report. The report is not in yet. And I'm happy to say that we're seeing about a 90 percent response rate, that approximately 90 percent of the institutions that we contact respond by either getting the results posted in clinicaltrials.gov or demonstrating to us that, in fact, the results are not due for any of a variety of reasons. So this is very much a work in progress. We're not where we want to be, but I think we're getting there.

Megan Columbus: All right. Thank you. From Catherine: "Kudos for the effort to address bias equity and inclusivity discussed a bit in the last session, but what about environmental sustainability and the need to address the climate impact caused by NIH-funded Extramural Research? NIH has a Green Labs Program for intramural NIH, but what about actions for extramural, which is a much larger portion of the NIH budget? Could a post-conference session focus on this or a session in next year's Grants Conference?"

Michael Lauer: That's a very interesting idea about having a session in next year's Grants Conference, although, Megan, I don't know whether .. . We'll have to think that one through. I will say, I'm aware of this, and a number of groups have met with us over the years to talk about their concerns. The impact of a variety things that we do on the climate is a high priority of the current administration. And so as you mentioned, it is certainly something that we are paying attention to on our own campus. Now, having said that, we operate under a legal authority. It's a legal authority that comes from the Public Health Service Act. And so there's certain things that we can do and certain rules, regulations and laws and so forth that we absolutely can and do enforce. And then there are other areas where we can certainly encourage, but we cannot necessarily take more concrete action than some people would like. So it is certainly something that we're aware of. We've had some interesting discussions about this, and the idea of maybe holding a webinar or something of that sort is an interesting one. We can certainly take that back.

Megan Columbus: Great.

Liza Bundesen: And just to chime in, this is tangentially related to the question, but as you know, with the pandemic, we switched to 100 percent virtual peer review for a while. Before the pandemic, when we would talk about peer review meetings, we thought, "Goodness. There's probably a significant environmental impact on flying reviewers back and forth to different locations." And I'm not entirely sure if CSR has done an environmental impact analysis, but we are presuming that just by going virtual that that has had an impact on pollution and other things.

Megan Columbus: Great. Thank you, Liza. Here's a question. "Thank you to the NIH for its tremendous efforts in providing resources to the community on data management and sharing. Researchers have expressed a concern with providing data at the end of the grant before publications, specifically concerned with their research being scooped. What's NIH's plan to address this concern or recommendations that you might have for researchers?"

Michael Lauer: So the policy says that data needs to be reported out at the time of publication. So in most cases, you know, hopefully, you'll be publishing your results. And at the time of publication, that's when the data would be made publicly available. I know that a number of journals have made that part of their standard operation procedure. I just had a paper that was accepted in eLife, and they made it very clear that with the acceptance came the sharing of data, and so we have done that. Now, the other part is, well, what happens if a project comes to an end? And in other words, the NIH project comes to an end, but the data haven't been published? And what the policies states is that if the project comes to an end, let's say the final competing segment comes to an end, and the project is not being renewed, then at that point, other data, which may be unpublished would need to be shared. Exactly how this is going to be operationalized, we don't completely know yet. Right now, we're just at the very beginning of implementing this. I do understand researchers' concerns about being scooped. And I think the most important thing is publish your work, and publish your work, do it well, and at the time that you publish your work, that's when the data will be released and not before.

Megan Columbus: Yeah. And I want to point people to the fact that we do have a session on Data Management and Sharing later today that I would encourage people to go to because that's where we have the people who .. . our boots on the ground working on the policy and working on the implementation of those policies. Followed by .. . I think tomorrow morning at 11, I believe, we have a session on Genomic Data Sharing and Other Sharing Policies, and so feel free to jump in to any of those. We have a number of people here who look like they're interested in the salary cap, and so, "With repeated increases in the NIH salary cap and increasing stipends for fellows, is there a plan to increase direct cost limits?"

Michael Lauer: Okay. So the salary cap is very interesting, and actually, I'll point out that I had the great privilege of working with some of our colleagues on what we call grant inflation. How much does a grant actually cost? And what's happened to the inflation-adjusted cost of grants over time? And what's interested is, is that those costs have not really changed by very much. The nominal costs have gone up with inflation, but the inflation-adjusted costs haven't gone up by much. Now, some critics point out, correctly, that part of the reason for that is the salary cap. Back in 2011, the salary cap .. . Or 2012, I think it was. The salary cap was reduced from exec level one to exec level two, which at that time meant going down from about $195,000 to about $175,000. And then since that time, the salary cap is increased, but it's increased at the rate at which federal salaries are increasing. And as a general rule, federal salaries increase at a slower rate than private-sector salaries. So as a result of this, over time, the highest-level salaries within institutions and our salary cap are getting further and further apart, and that is leading to a fair amount of tension and concern. I think the latest salary cap was just pointed in the NIH Guide, and I believe it was $212,000. Now, yes, there is a pressure to increase the amount of money that we're spending on each individual grant. Whether we're doing it through salary support or direct cost or stipends on other types of grants, and we certainly hear that, and here's the hard part. The hard part is, is that the money has to come from somewhere. There are opportunity costs. So if we increase the amount of money that we are spending on any individual grants, then that means that those particular .. . that that recipient will be getting more money, but it also means that there may be fewer recipients. We have a challenge already that we're in a hypercompetitive environment. Only about 21 to 22 percent of our grants are being funded. So if we were to make those kinds of of very substantial increases in cost per grant, that would drive our success rates down. So I don't have any magic answer to this. I think it's fair to say that we're very much aware of the concerns and tensions that are there. This will certainly come up in the ACD working group, Advisor Committee to the Director working group on postdoctoral researchers. Cause, certainly, one of the very biggest issues is that they're underpaid, and I don't think I'm going out on a limb to say that. Postdocs are underpaid. So if we're going to increase the amount of money that we, as an agency, are giving the postdocs, there's going to be opportunity costs. And we have to think through, what's the best way to do that?

Megan Columbus: Mike, I'm just wondering, I know people talk about these direct-cost limits fairly frequently, but if we're talking about the $500,000 threshold, that's not a threshold that you can't ask for more money. It's just a threshold where you let NIH know before you're going to. So that's not actually a cap, right?

Michael Lauer: Right. There's no cap on the total amount of money that can go to an individual grant, and we have some grants that are in the high hundreds of thousands. We have grants in the millions. We even have grants in the tens of millions. So that is certainly possible. Over $500,000 requires prior approval from the affected institute, and another cap .. . Well, it's not a cap. Another level that's often talked about is $250,000: $250,000 is the cap for our modular budget. That originally was set back in 1998 or 1999. We get reminded about this, oh, about every other day that we have not increased the modular caps since that time. That means that now .. . We just recently looked at our 2022 data. Less than 20 percent of the R01 applications that came in, in 2022, used the modular budget. Back in 2008, it was over 70 percent, and that number has been steadily going down. But that's not a cap. All what that means is, is that you have to provide a more detailed budget, but it doesn't .. . Maybe the best way of thinking about this: I saw this very nice blog that Ned Sharpless .. . Ned Sharpless was the former Director of the National Cancer Institute. He posted a blog about the modular budget, and he said, really, the best thing to do is to submit an honest budget. Whatever you think that the project is going to cost, that's what you submit, and then if the NIH institute is interest in funding your project, then there will likely be a conversation back and forth about the budget so that we can meet the goal in supporting high-quality work but, at the same time, funding as many projects as we possibly can.

Megan Columbus: Thank you. I have an interesting question about whether grant reviews .. . what you think about grant reviews being 100 percent blinded at the first level of review and then revealing the investigator and institution at the next tier.

Michael Lauer: So that's a really interesting question. And we have, we meaning NIH, have looked at this in a systematic way. So one is, we did a study called the Anonymization Study. I take absolutely no credit for this. I watched this with great interest. There's an Anonymization Study, which, what they did was, they took, I think, 1,600 applications.