Interview with Dr. Mike Lauer, Director, NIH Office of Extramural Research

So much is going on at NIH, we thought it was a good time to visit Dr. Mike Lauer, Director of the NIH Office of Extramural Research. We’re grateful that he took time out from overseeing the NIH grants program to answer our questions about the future of NIH grants and peer review systems.

We hear you have strong feelings about confidentiality and conflicts of interest. Can you discuss them?

Almost every round, there are breaches in confidentiality, and they put the whole process into question. We have enough problems as it is, trying to figure out how to optimally give out awards in this era of hypercompetition, but if the process is not fair, all else is moot.

So I want to remind reviewers that the information we show you is important and sensitive; you should keep it to yourself. You should destroy the files when you're done. You should develop a case of amnesia when you reengage with the community. And please speak up if an applicant contacts you attempting to get an unfair advantage. We have a deliberate process for sorting things out. But when we encounter a true breach, we're not afraid to pursue severe actions, like engaging the Office of Research Integrity and/or the Office of the Inspector General. We take this business seriously!
What would you like to say to reviewers this round?

Thank you! And thank you again! Your role in NIH’s success is front and center, so we are grateful. But, for all our successes, we face major problems, and we greatly appreciate your working with us to help address them.

Peer reviewers are in the vortex of a big problem – some say, the number one problem facing modern biomedical research: We have too many scientists vying for too few dollars. When we had fewer scientists, peer review was asked to differentiate between those projects that had merit and those that did not. Peer review does that well. But now, with an oversupply of scientists, peer review is asked to distinguish between outstanding projects and outstanding projects. Some would say that, with paylines so low, it’s an impossible task. This situation is made worse by the fact that many scientists are dependent upon soft money, so the loss of NIH funding is more devastating than it was 20 years ago. Meanwhile, our system is producing an oversupply of postdocs given the number of available faculty positions.

Reviewers play big roles in our efforts to address concerns about the rigor of NIH research. We have revised our guidance to applicants and reviewers, highlighting our concerns about premise, rigorous unbiased methods, inclusion of relevant biological variables (including sex), and authentication of biological and chemical resources. These issues are relevant across the spectrum of the work we fund, from pre-clinical basic science to clinical trials (which as you know is high-profile since trials entail doing experiments on people). So more than ever before, your role in NIH’s success is front and center and we are very grateful for all you do.

Can you talk about the big changes coming for those who propose or review human subject research?

Half of all NIH-supported clinical trials are done yet never reported out, or only after an unacceptably long delay. That’s a waste. It’s also an abuse of the participants who thought they were contributing to science. Prompted by an act of Congress, the Department of Health and Human Services proposed a policy in 2014 that would require that scientists given public money to do experiments on people, should report their results within one year of completion to ClinicalTrials.gov. After public comment, the policy was finalized in 2016.

We are now implementing this policy, and anyone proposing human subject research should take notice since three years ago the definition of what is considered to be a clinical trial was expanded, and PIs may have to deal with new application requirements beginning on January 25, 2018. Reviewers will be given guidance soon on their role in reviewing these applications in the spring of 2018.

We are getting push back. So I think it’s important for people to know why we were moved to take this action and also know what they can do to be prepared so the transition is as smooth as possible. These efforts are critically important, because
posting research results is critical to maintaining credibility with Congress and the public and to facilitating greater success for U.S. biomedical research.

**Why couldn’t we have required grantees to just publish their results instead?**

To publish, you have to get your work accepted by a medical journal. But this can be difficult because some journals aren't interested in certain types of studies or results. Sometimes journals will sit on a manuscript for many months before rejecting it.

Clinicaltrials.gov offered a mechanism by which people can post the results without being thwarted by these problems.

**Since this and other initiatives mean extra work for NIH applicants and reviewers, can you talk about overall ways to reduce their burdens?**

**Outstanding Investigator Awards (R35):** We are thinking about ways by which we can reduce the amount of time that scientists spend on grant related activities. One concrete example is the R35 mechanism. The way NIGMS has envisioned it, an investigator or a laboratory might have one grant that supports their needs for a sustained time. If they continue to do good work, the agency would continue to fund them.

**Initial Applications:** Since more than 80% of applications don’t get funded, one of the ideas we have been exploring would be to ask PIs to just supply a research plan, the PI’s biosketch, and a total budget number. If it has potential for funding, we can start to ask for more details in stages. We might save applicants and reviewers a lot of work.

**New Way to Produce Biosketches:** We’re working with ORCID, the organization that produces unique research identification numbers used by PIs and journals. Our goal is to use ORCID data to help generate biosketches.

**Certificates of Confidentiality:** Right now, PIs must apply for these certificates, which allow researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands. As of October 1, 2017, NIH will automatically issue certificates when an NIH grant or contract is awarded.

**Given the intense competition for NIH funds, what more can NIH do to help vulnerable early- and mid-career researchers?**

We just launched, as a partial implementation of the 21st Century Cures Act, the [Next Generation of Researchers initiative](https://www.nih.gov) to help address longstanding challenges faced by researchers trying to advance and sustain independent research careers. We are committed to funding 200 more early career researchers and 200 more early established researchers each year.
NIH has been exploring the use of bibliometrics to assess the impact of NIH grants. Do you see a role of bibliometrics in assessing grant applications?

Only to a limited degree. I know some people are worried we’ll run applications through a cookie cutter, generate an RCR or H-index, and use it to determine if it gets funded. That would be a bad idea. Of course, we should take notice if a PI with prior NIH support comes in with a history of zero productivity (yes, that happens) or with a series of highly influential publications.

Bibliometrics have become increasingly sophisticated, linked with other kinds of data like patent and licensing data and economic data. We believe they can, along with other measures and tools, play a role in helping us understand the NIH ecosystem and in helping us with overall policy and strategic development.

Can you talk about the role and future of peer review at NIH?

Peer review will continue to be front and center. It’s wonderful that CSR is nurturing a science of peer review, and I’m encouraged by similar efforts of others. I believe that peer review will evolve as it becomes more and more data-driven.

There are some interesting, even radical ideas, that some are considering for the future of peer review. These include limiting grant applications to anonymous 3-page white papers, asking applicants to review each other’s proposals, like the Patient-Centered Outcomes Research Institute (PCORI) is doing, asking non-scientists (including patients) to review proposals. There are some data to suggest that these approaches may add value.

I'm not saying we should do these things, but they are interesting ideas.

Can you tell us a little bit about the role of community input in helping NIH improve the NIH grants and review processes?

Its role is extraordinarily important. One big community collaboration we’re involved in is the Federal Demonstration Partnership (FDP), which is a cooperative initiative among 10 federal agencies and 155 institutional recipients of federal funds to reduce the administrative burdens associated with research grants and contracts. It was an FDP survey that showed us that over 40% of the scientists' time is spent on grant related activities. We worked with our FDP colleagues to reduce the burdens of IRB approvals, progress reports and other things. We also have good working relations with the Association of American Medical Colleges, the American Association of Universities, and others. They have been enormously helpful, as have the community leaders who serve on the many NIH advisory councils and working groups. And of course, we get valuable feedback from social media via the NIH Director’s blog and our Open Mike blog.
Don’t Think Your Human Subjects Research Is a Clinical Trial? READ THIS!

Many investigators will be surprised to know that the mechanistic human studies they have been doing for years may now fall under the NIH definition of clinical trials. The NIH clinical trial definition is very broad and it may not be the same definition used by other organizations, including your own institution.

Why is this so important now?

After January 25, 2018, applications containing an NIH-defined clinical trial of any size or complexity can only be submitted through one of the new NIH funding opportunity announcements that require or allow clinical trials. Additional human subjects information will be required, and that information may be different from what you have submitted with earlier applications.

Reviewers need to be prepared for change, too. The new PHS Human Subjects and Clinical Trials Information form consolidates and extends the types of human subjects information that was collected in previous applications, so reviewers will receive guidance on where in the application to look for important information that they need to review. Additional review questions will be used to evaluate clinical trial applications, and reviewers will be trained on that, too.

Information about this change, and useful tools to help you successfully submit your clinical trial application can be found at:

- Why Changes to Clinical Trial Policies
- Clinical Trial Requirements for Grants and Contracts
- New Human Subjects and Clinical Trial Information Form
Online Briefings for R15/AREA and Small Business Grant Applicants

CSR will host two online briefings in October 2017 for applicants Academic Research Enhancement Award (AREA/R15) grants or Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) grants.

**AREA/R15 grants** support meritorious research, expose undergraduate and graduate students to hands-on research, and strengthen the research environment of schools that have not been major recipients of NIH support.

**SBIR/STTR grants** support early-stage research technology commercialization in the United States.

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<td>8 Ways to Successfully Navigate NIH Peer Review and Get an AREA/R15 Grant</td>
<td>Monday October 16, 2017 2:00 – 3:00 p.m. EDT</td>
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<tr>
<td>8 Ways to Successfully Navigate NIH Peer Review and Get an SBIR/STTR Grant</td>
<td>Wednesday October 18, 2017 2:00-3:15 p.m. EDT</td>
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Each briefing will include presentations by a CSR official and the NIH official who oversees the respective program. A 30-minute Q&A session will follow.

**How to Participate in the Briefing**

- **Go to** [www.csr.nih.gov/webinar](http://www.csr.nih.gov/webinar) **to register for the briefing you wish to join.** You will not need to download special software. You will just need a reliable Internet connection and an *up-to-date* browser.
  - **Register by October 12, 2017**

- **Submit questions for the Q&A session before or during the briefing** by sending them to the moderator at AskExperts@csr.nih.gov.

- **Go to** [www.csr.nih.gov/webinar](http://www.csr.nih.gov/webinar) **on the day/time your briefing is scheduled.** Click on the link that will be provided there.
View Archived Briefings and Past Webinars

- View archived webinars and PowerPoint slides on our webinar web page: Meet the Experts in NIH Peer Review webinars for R01 and Fellowship grant applicants as well as a webinar for university research administrators.

- View the 2017 R15 and SBIR/STTR video briefings about two weeks after broadcast on our webinar web page.

New Tool to Help Applicants Find a CSR Study Section

Curious about where your application might be reviewed, and want to have a look at those study sections and their rosters to see if you have a preference for review in one group over another?

The new online Assisted Referral Tool (ART) will make a potential match between the science in your application and an appropriate CSR study section(s). After you enter your application summary or specific aims, ART will show you both strong and potential matches, and provide you with direct links to descriptions of those study sections and their rosters of reviewers.

Your query is confidential. No input text from your application or the fingerprint generated during the search will be retained after your query is completed.

The NIH Center for Scientific Review developed ART in partnership with the NIH Center for Information Technology.

User Feedback Has Been Very Positive

ART replaces the old “browse and wonder” method of finding a study section, where investigators have to manually look through study section descriptions and sometimes make a best guess as to where their application might fit. ART makes fact-based recommendations by matching a fingerprint of your application information with a database of applications actually reviewed in each study section. User feedback has been very positive, including comments such as “ART was easy to use, worked well, and returned results quickly” and “the tool appears to be accurate and robust.”
How to Suggest a Study Section

Requests for study section or Institute assignments should be submitted on the optional PHS Assignment Review Request form, which is found with the other optional forms in each application packet. CSR endeavors to honor requests whenever possible, dependent upon funding opportunity announcement participation and locus of review agreements within NIH and other PHS agencies.

What Applicants Should Know About Study Section Chairs

CSR welcomed 89 new study section chairs this round, and we thought it’s a good time to tell applicants how we pick and train the chairs who will help manage the review of their applications.

What Role Does a Chair Have?

Study section chairs:

- Partner with their Scientific Review Officer to conduct the meeting
- Manage scientific discussions at the meeting, e.g., balance thoroughness with timeliness
- Ensure all study section member opinions are given careful consideration
- Guide and summarize study section discussion

What Do We Look for When We Recruit a New Chair?

We would never call a new chair a novice. A chair needs to be a senior scientist with robust funding; have a strong publication history; and have high stature, respect and credibility in the community.

In addition, a chair should be a current member of their review group with about 2 years of service. During this time, they should have demonstrated a broad scientific perspective, sense of fairness, and respect for the peer review process. They also should have displayed good management and interpersonal skills while serving as an ad hoc chair.

What Does CSR Do to Ensure New Chairs Are Well Prepared?

“Applicants deserve a consistent and familiar experience when their applications are reviewed,” said CSR Director Dr. Richard Nakamura. “This is why we ask incoming chairs to attend an orientation session. We go over new and key review policies and discuss practical ways to be a successful chair.”
Key Points Emphasized in Chair Orientation

If you could witness a chair orientation session, you would see how incoming chairs take an active role -- raising challenges chairs face running meetings and joining with CSR staff in discussing ways to maximize fairness and thoroughness. Here are some of the best practices they frequently discuss to ensure they treat applicants as fairly as possible:

- **Be prepared:** Take a closer look at applications in areas that are farther afield from their own area of science: Chairs should also check scores prior to the review meeting and be prepared to facilitate discussions of applications that have divergent scores.

- **Keep in mind that what they say as chair can carry more weight than what other reviewers say:** Their opinions can sometimes be better expressed as a question, which stimulates discussion that may address their concern. They should avoid dominating review discussions.

- **Facilitate productive discussions by keeping reviewers focused on score driving points and key differences in their reviews.**

- **Welcome differing opinions and foster thoughtful and collegial discussions:** Consensus is not needed, but it is important to get the key issues on the table.

- **Encourage unassigned reviewers to speak up:** Chairs should invite them to ask questions and challenge scores given by assigned reviewers if the scores do not seem consistent with the discussion or the merit of the application.

- **Run a tight ship:** When time gets away from them, fairness suffers because eventually they run out of time, and later discussions become rushed. Chairs should cut off repetitive arguments, or discussions of methodological minutia. They should be polite but firm, and set the pattern early.

Scientific Review Officers also work closely with their new chairs to go over general goals, instructions, emerging issues and any meeting specific needs. Learn more about how we prepare chairs by visiting the NIH chair orientation Web page.
Images of NIH Peer Review 2017

A lot of care goes into the review of NIH grant applications. But how can we communicate this to applicants?

Knowing the power of pictures, we recently sent two photographers to a couple of our review meetings so you could get a close-up look at real reviewers at work.

We then put the most compelling photos into a YouTube video: Images of NIH Peer Review 2017. (We couldn’t record reviewers, so there is no sound!)

Subscribe to Peer Review Notes: www.csr.nih.gov/prnotes
Send comments or questions: PRN@csr.nih.gov

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