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How Well Is NIH Identifying and Advancing Innovative Research?



Dr. Sally Rockey, Director for the [NIH Office of Extramural Research](#), recently shared her insights on advancing innovative research in a lively interview for readers of CSR's Peer Review Notes. Her office oversees trans-NIH grant and review policies and practices.

How well does the NIH peer review system work in identifying innovative research?

Since we restructured our critiques and aligned them with our applications, both reviewers and applicants are now more focused on “innovation,” and I believe reviewers find it a critical aspect of the job NIH asks them to do.

Identifying innovative research is still challenging. Everyone wants NIH research to pay off, but highly innovative research is often high-risk research. If everything you fund pays off, you're probably not funding enough innovative research. So review panels need to take a balanced approach about enthusiasm for highly innovative vs. more incremental science, and NIH similarly needs to take a balanced approach when making funding decisions. For both reviewers and NIH, we must see that spark of innovation and get fired up about an application that might dramatically propel science forward.

Another tricky thing about innovation is that it often comes from a compilation of projects that together have a great impact. Any single project might seem derivative or incremental but when you put them all together they make science leap forward. So sometimes it is hard to tease out the innovation that will come.

Despite these challenges, I believe reviewers are thinking more about innovation and thus giving us even more input about this, which in turn increases our confidence that the research NIH supports will advance biomedical science, technology and health.

What do you think about [data](#) showing preliminary “approach” scores are the number one driver for overall impact scores?



Reviewers may concentrate most on approach because it often will determine for them whether or not a research project is feasible -- an important consideration. Of course, we have a long history of applications with extensive approach and methodology sections, and some reviewers can find it easier to assign an overall impact score by honing in on the approach and picking it apart.

It's important to know that the second and third factors that drive overall impact scores are “significance” and “innovation,” and they come close together. So the emphasis on approach is probably not as dramatic as what we saw in the old days with 25-page applications. I think reviewers are looking at projects in their totality, and this is very helpful in determining the potential overall impact of the projects.

Have increased competition and lower paylines made it more difficult for NIH to identify and fund innovative research?

I know this may be the thinking out there -- that it is easy to become conservative when funding is tight -- so I believe one of the best things reviewers can do is to stay focused on our goal, which is to identify innovative and high-impact science. Without their input, it will be very difficult for NIH to make funding decisions that support innovation. We also can't lose sight of the fact that innovative research includes basic research, and NIH continues to strongly support the fundamental sciences because they will lead to the innovative solutions down the road.

NIH does have difficult choices to make in deciding how to fund research. I think sustained funding for new and otherwise promising investigators will foster innovative research and keep the pipeline of talented next generation scientists strong. Often if funding for your lab is covered, you have the freedom to do even more things outside the box. This also sets up the question, does NIH fund totally as a meritocracy and continue to add more to well-funded investigators or do we award funds more broadly to a larger cadre of investigators, and how will that impact innovation? As we do this balancing act, I think we are doing the best we can given our circumstances. I believe we have elevated the conversation enough to have innovation at the forefront of everything we do.

Is there anything more NIH can do to improve the way it funds and advances innovative research?

We certainly can always do more. This is a time never before seen in our history where technological advances and our understanding of biology have come together with such a force that we can advance science more rapidly than we ever imagined.

We have a number of programs that target innovative research, such as the [NIH Director's Transformative Research Awards](#) program, and the [Pioneer](#) and [New Innovator](#) award programs. There are other exciting efforts underway and planned at the [National Center for Advancing Translational Sciences](#) and at other NIH Institutes and Centers.

Are there ways to improve the review process to advance innovative research?

When we looked at the data, we found that individuals who got discussed but didn't get funded tended to do better in the long term than those who didn't get discussed at all. One reason for this may be the feedback they get when their applications are discussed in review meetings helps them submit more competitive applications in the future. However, we can't practically discuss every application. So we continue to look for ways to provide more constructive criticism without increasing burdens. We'd like to see scientists spend less time writing and reviewing applications and more time doing innovative, high-impact research.

What do you say to new applicants who tell you their mentors advised them to hold back their innovative ideas and only send NIH their most solid research applications?

The most important thing for a new investigator is a slam-bang, creative, innovative idea. We want a review committee to feel that not being enthusiastic about such an application would be a travesty. And young investigators are probably at the most creative points in their lives, so they should put forth their great ideas! However, new investigators shouldn't be unrealistic and load their applications with too many objectives. They should have a manageable number of objectives and concentrate on explaining how important they are and how they can be accomplished.

Making their cases may be difficult, particularly if they are proposing something innovative where they don't have a lot of experience. So I would advise new investigators to find collaborators that can bolster their application's gravitas. And importantly, new investigators should ask others at their institutions to pre-review their applications well before submitting them to NIH. This is probably the most beneficial thing applicants can do to make sure they are conveying their ideas in the way they intend.

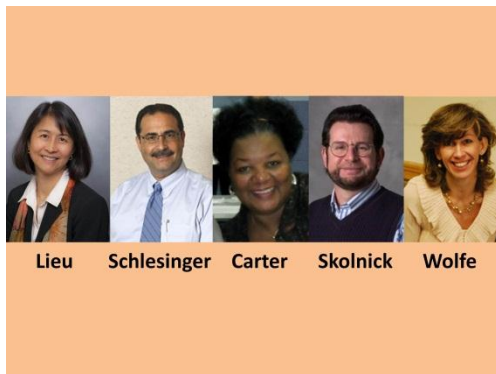
If you attended a study section meeting, what would be your final words to the reviewers on innovation?

Don't lose sight of it. You need to balance the different types of applications you have in front of you. But be open to that really innovative idea that captures your fancy. You'll know it when you see it, and then make the case to your fellow reviewers about why the application is so compelling.

Finally, I would say thank you. You are the ones who keep this big ship afloat. I really admire you and all NIH reviewers for what you do. You are the foundation of the good we do at NIH.

Learn more and share your thoughts by visiting Dr. Rockey's blog: [Rock Talk](#).

Former Study Section Chairs Share Advice for New Reviewers



With many new reviewers coming on board this round, we asked five retired study section chairs to tell us the advice they would give to new reviewers. The nuggets below come from many years of combined experience as reviewers and chairs.

Advice for New Reviewers

Get started right away to discover if you have a conflict with an application. It is cumbersome to reassign the application late in the game. You want to make sure every application gets due diligence.

Don't be overwhelmed by the number of applications. Just start reading as soon as you get your application assignments. Give each application adequate time for a full and comprehensive review.

Remember you are not alone: you can clarify any uncertainties about the review process with your SRO or chair prior to writing your reviews.

You're not expected to know everything: Peer review is a group process with multiple individuals providing special expertise. So when you get to the meeting . . . other people might pick up things that they see from a different latitude.

Don't be too critical: Some people just come to the table and put their hat on to criticize. But an application doesn't have to be totally perfect for you to give it a good score.

Recognize that applicants can't provide all the details in the new NIH format. Consider if the PI has sufficient command of the material to make it likely the project will succeed.

Focus on the big picture and not the little details. Is the application transformative? Or does the proposed research address an important need, even if it is not necessarily transformative?

Be receptive to high risk/high yield projects, because NIH wants to fund a balanced amount of this kind of research.

Applicants are just like you: They are excited about the science and often it is their life's work. You really want to respect that.

Prepare the notes for your assigned applications well so you can be conversational at your meeting. You don't want to read your critiques.

Prioritize what's important to bring up in discussion: Say what the big picture issues are, what is modifiable, what is not fixable and what needs to be discussed more.

Know the review guidelines may be different for different groups of applications: For example, small business owners may not have prior NIH grants, or prior work and studies. This is not required. The other unique piece is commercialization. SBIRs are designed to bring products to the market that make a difference.

Don't just express your opinions: Be prepared to explain your opinion as objectively as possible.

Don't be unsettled if someone disagrees with you: You were asked to be on the study section for a reason. You should feel comfortable sharing your expertise and knowledge. And it is OK to disagree.

Don't be intimidated by a senior reviewer who comes down on an application you feel is terrific: You should be sure your opinion is stated, and it will be respected.

Be flexible: Listen and be open to changing your mind if new and compelling perspectives come on the table.

Keep your reviews in sync: Make sure that your comments and what you say are calibrated to the score that you're giving.

Meet new friends and colleagues: You will spend a lot of time with colleagues who are well-known in the field, and you have an opportunity to develop a community of science network through these relationships.

Enjoy the experience: You have the opportunity to see firsthand cutting-edge science and where a field might be going, you're going to learn a lot about your field of science you wouldn't otherwise learn, and you're going to become a better grant writer as a result.

Thanks to the Former Chairs Who Helped Develop these Tips

Dr. Laverne M. Carter: President/Chief Project Director, Research and Evaluation Solutions, Inc. Former Chair of the Health of Populations SBIR Study Section.

Dr. Tracy Lieu: Director, Division of Research, Kaiser Permanente Northern California. Former Chair of the Health Services Organization and Delivery Study Section.

Dr. Larry S. Schlesinger: Chair, Department of Microbial Infection & Immunity at Ohio State University. Former Chair of the Clinical Research and Field Studies in Infectious Diseases Study Section.

Dr. Jeffrey Skolnick: Director, Center for the Study of Systems Biology Georgia Institute of Technology. Former Chair of the Macromolecular Structure and Function B Study Section.

Dr. Barbara Wolfe: Associate Dean for Research William F. Connell School of Nursing at Boston College. Former Chair of the Nursing and Related Clinical Sciences Study Section.

Make the Best Use of the "Additional Comments to Applicant" Box



NIH reviewers are advised not to help the applicant rewrite an application through their written critiques, which should stay focused on evaluating the application's scientific and technical merit. Thus, many reviewers and applicants are perplexed by the last section of the reviewer critique templates: The Additional Comments to Applicant section.

This section was developed during the [Enhancing Peer Review](#) initiative to allow reviewers to provide additional information or advice to the applicant. These comments need not relate directly to the scientific or technical merit of the application, do not factor into the final impact score, are not binding, and do not represent a consensus of the review panel. In fact, other reviewers may not agree with them. Finally, applicants are not obligated

to address these comments when writing an introduction to a resubmission application.

We offer the following examples to help reviewers see how they may use this opportunity:

Information that Might Be Useful for New or Early Stage Investigators

The application creates the impression that the New Investigator is rather isolated intellectually. It appears that s/he would benefit from mentorship and interactions outside of his/her institution. These should be available locally.

This application is overly ambitious . . . a common mistake for junior investigators. This investigator would be wise to develop fewer aims more thoroughly. It's always risky to base subsequent aims on the outcome of the first one.

Comments that Might Help Applicants with Non-Discussed Applications

For such a talented investigator, his/her time would be better spent on a more compelling research question. I do not recommend revising and resubmitting this application.

The applicant should write a smaller grant focused on gathering sufficient preliminary data.

Notes That Alert an Applicant to Grant-Writing Issues

This application is frustrating to read because of extensive jargon that is not defined and experiments that aren't connected to specific aims. A thorough rewrite with the help of an experienced grant writer is suggested before this application is resubmitted.

Ideas that Might Be Helpful for an Applicant to Consider

It would be interesting to see the investigator try the new technique of XYZ et al. on their samples. One might expect much better resolution.

The abc mutant phenotype is remarkably similar to that described for these new loss of function strains. Has the investigator thought about whether these mutations are in the abc pathway?

Because such comments could be very helpful to applicants, reviewers are encouraged to take advantage of this opportunity to use the Additional Comments box. We hope that this feature of the reviewer critique template will help applicants in deciding on appropriate [Next Steps](#).

Who Are the Other People in Your Review Meetings?

Study section members may have noticed quiet visitors who sit on the sidelines and take notes at their meetings. They may be senior CSR staff members, who attend meetings to see how well the reviews are going. They also may be other Scientific Review Officers, who may come to learn from the way others run their meetings.

Other very important visitors who may come to your meetings are often program staff from the NIH institutes and centers.

Why Are Program Staff Members There?



The main reason they come is to *listen*. Although program staff members receive the summary statement with reviewer critiques and a summary of the review discussion, they want a thorough understanding of the reviews so their institutes or centers can make informed, wise funding decisions and advise applicants about their next steps.

So program staffers listen carefully to capture information that may not be in the summary statement or easily conveyed in a written document. Do the reviewers reach consensus about the overall merit of an application or do differences of opinion persist? If differences exist, do they suggest that a project is on the cutting edge, that a reviewer did not understand the science, or something else?

The presence of program staff is thus a reminder that reviewers' work really matters. It's not just about the numerical score; it's also about what you say and how you say it.

What If Program Staff Can't Be in the Room?

Program staff often are assigned applications reviewed at multiple meetings on the same day, so the only way to listen to the discussions is to phone into the meeting. Using the microphones in the room is essential for program staff to hear what you have to say!

What Else Do Program Staff Members Do at Review Meetings?

Program staff may confer with the Scientific Review Officer during the review when more information is needed or a correction is required. But what program staff absolutely must not do is influence or comment on the panel proceedings themselves (e.g., no eye rolling or grimaces or inappropriate comments during the breaks).

Institutes do not all have the same processes and priorities so program staff on occasion can provide context at the invitation of the Scientific Review Officer.

What Are Program Staff Members Listening for Most?

As a reviewer, you may wonder what information is most helpful to program staff members as they make decisions and advise applicants. Reviewers' assessments of an application's strengths and weaknesses, feasibility, and any fatal flaws are important. But program staff need to know more than that. A succinct summary that addresses the impact of an application on its field and, when it is appropriate, on broader scientific questions is compelling.

If you think a project is terrific, say so. Let your excitement come through in your written review. Program staff want to know your thoughts on the possible impact of the project. And speak up if you think the proposed research is not salvageable or it is unlikely to have impact without major and substantial revisions. Applicants frequently ask to know this. Of course, if the flaws are not fatal, applicants want to know this.

Institutes and Centers depend on the integrity, transparency, and excellence of the review system. Your reviews are fundamental to our ability to make judicious decisions and give pragmatic advice.

So don't forget that the quiet visitor in the room, on the phone, or online is listening -- very carefully.

New CSR Reviews for the NIH-FDA Collaboration on Tobacco Control Regulatory Research



NIH and FDA have established a collaboration to support research that will provide scientific evidence to guide the actions of the FDA Center for Tobacco Products Research.

The partnership benefits both agencies, as several NIH Institutes and Centers [have long supported](#) tobacco-related research as part of their mission, and scientific evidence will help FDA better understand tobacco and its ingredients and constituents, tobacco addiction, tobacco marketing and labeling, and childhood tobacco use.

FDA has identified 56 research priorities in 7 research areas (see collaboration [Web site](#) for details), and there are a number of ongoing funding opportunities that may be of interest to investigators in this field. These include a scientific conference grant program ([R13](#)), a research center program ([P50](#)), and an ongoing program for supporting research project grants ([R01](#), [R03](#), and [R21](#)). Visit the Office of Extramural Research's "[Rock Talk](#)" [blog](#) to learn more.

CSR's Role

The research center program (P50) and research project grant applications (R01, R03, and R21) will be reviewed in CSR, using [review criteria](#) that have been adapted to meet the goals of the Tobacco Control Regulatory Research Program. Another unusual feature of this collaboration is that NIH Intramural scientists also may submit and compete for these funds.

CSR's Review Schedule

This past summer, CSR helped review competitive supplements for these funds. CSR will be busier this winter reviewing P-50 and R01 applications for this program.

More reviews are expected in the coming years since this is an ongoing NIH/FDA collaboration.

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