**TRANSCRIPT**

**Webinar:** NIH Simplified Review Framework for Research Project Grants (RPGs)

**Event Date**: Wednesday, April 17, 2024

**Event Time**: 1:00 – 2:00 PM ET

Megan Columbus: Welcome to our webinar on a Simplified Review Framework for Research Project Grants. Today we're going to be focusing on implementation and the impact on new and existing funding opportunities. This is the second webinar that we have had on the Simplified Review Framework. And so today you'll be having me as a moderator. My name is Megan Columbus. I'm from NIH's Office of Extramural Research. Joining me is Dr. Erica Brown, the Director of the Division of Extramural Activities at the National Institute on General Medical Sciences. She is a member of the executive committee who's implementing the simplified review framework. And I have Mark Caprara, who's the Chief of Molecular and Cellular Sciences and Technologies Branch at CSR, who's co-chair of the implementation team. We have a lot of people who are working in the background who will be answering questions as they're put into the Q&A. We'll be pulling out and answering as many questions as we can live, and those that are commonly asked we'll add to our FAQs and make sure that there's resources online for you. Today, we're going to be going over a couple of things. We're going to be doing a background of the changes just to make sure we're all on the same page. I know we had a webinar on the changes, but let's make sure that we're on the same page. So, the whole overview and then we're going to talk about what the changes mean for our funding opportunities and for the application packages and provide some tips for applicants and talk about where to find some more information and then answer questions. All right. With that, let me go ahead and pass the baton to Dr. Cabrara, Mark.

Dr. Mark Caprara: Thank you, Megan, and welcome to everybody attending. I'm going to give a brief overview, as Megan said, of the simplifying review framework. So, review of grant proposals to NIH go through a two-stage process, the first of which is performed by scientists who volunteer their time to evaluate the technical and the scientific and technical merit of the applications. I'll introduce the simplified review framework that is expected to improve how peer reviewers evaluate research project grants. The review framework will be implemented for most RPGs, as we call them, including the well-known R01s and R21s. The full list of the impacted mechanisms are shown below. And this will be in effect for applications received on or after January 2025. January 25th, 2025.

I want to point out that the framework was published via guide notice this past Fall. That was followed by our first public webinar that Megan mentioned. The information presented there was in much more depth than I'm going to go into here, since the main topics here are really about the application, the impacts on applications and applicants. But I do encourage everyone to read over the notice and watch a recording of the November webinar for more information.

How do we get here? So, as pointed out in those references and I mentioned, this framework was developed with significant input from the extramural scientific community. So, over the years, NIH has received complaints regarding complexity of peer review as well as concerns regarding reputational bias. Community input on these issues was solicited via a blog posted in February of 2020. Received about 1200 comments, and this provided foundational data for us to work with. The next step was the formation of a working group, including scientists who are familiar with peer review, and NIH staff, who developed a set of formal recommendations to address these issues.

These recommendations were then discussed and refined somewhat by NIH working groups, and then went through a formal approval process that was completed in September of 2022.

NIH reached out to the community again for their input via a request for information and other outreach efforts between December 2022 and early into 2023. We received 800 responses from individuals and societies, and the big take home was that the majority were supportive of this new framework, and that's likely a reflection of how much input the scientific community had and motivating and developing the framework. And as we've mentioned, the final the final simplified review framework was published last October.

So, let me give you a brief overview of the framework.

Start first with the goals are shown here with links to additional relevant information. Again, these goals were driven by issues raised by the community. So, first, we want to enable peer reviewers to better focus on answering the key questions necessary to assess scientific and technical merit, mitigate the effects of reputational bias, and reduce reviewer burden.

These next two slides show the major aspects of the new framework, including the underlying rationale for the changes. So one, we wanted to enable reviewers who improve review by first focusing their attention on three main questions. Should it be done? Should the project be done. Can it be done? And will it be done? And this was done by reorganizing the five review criteria, into three factors that align with these questions. So, the first factor being defined as the importance of research, ask the question, should it be done, rigor and responsibility or feasibility aligns with cannot be done. And expertise and resources will it be done?

We also wanted to simplify and strengthen the review criteria by using conceptual definitions rather than lists of questions. So, the working group felt that shifting away from extensive sets of complex questions encourages thoughtful integration of concepts rather than checklist or yes no thinking.

In terms of the second goal, I wanted to modify the criterion definitions for investigator environment and factor three to reduce reputational bias. We did this by having, going to have reviewers assess the adequacy of investigators expertise and institutional resources with respect to the work proposed as a binary choice, either appropriate or additional resources or expertise needed.

And then finally we relieve reviewer burden, but not requiring peer review of select additional considerations. So, any of those considerations that aren't directly related to scientific merit will shift to NIH administrative staff review.

So, let's look at the reorganization a little bit more detail. At the left shows how the criteria are currently organized. Each receives a score and major score driving points are provided by the reviewers. On the right is the new framework, the criteria organized into factors as I mentioned. So, we have factor one the importance of the research. And this incorporates or encompasses the significance and innovation criteria. This receives a score and also comments by reviewers. Factor two is rigor and feasibility. This incorporates approach as well as inclusions for human subjects and clinical trials study timeline. Again, this will receive a score and comments by the reviewers, and factor three is expertise and resources. This encompasses investigators and environment. This factor won't be scored but evaluated as appropriate or additional expertise resources required and if additions are thought to be required, reviewers will provide an explanation.

Reviewers will still provide an overall impact score, reflecting the reviewer's overall judgment of scientific merit based on an integration of the evaluations of each factor, as well as the additional review criteria such as human subject protections, vertebrate animals, biohazards. As with existing scoring methods, reviewers will weigh these factors as they see fit when arriving at an overall score.

This slide shows the additional changes to review criteria that will help reduce reviewer burden. Most of the additional review considerations shown here on the left side, will be shifted to who's responsibility to review will be shifted to the Institute Center. So, these considerations do not affect overall impact score, and reviewers will be asked only to comment on two out of the five considerations.

So, that was my short introduction to the simplifying review framework. But I did want to address take a few minutes to address some of the questions we've been receiving. First, what are the expectations of this framework? So, the various working groups and NIH leadership expect that the framework will improve review. And by that we mean clearer evaluations of the proposed research importance and the rigor and feasibility of the approach, and also more consistently appropriate evaluations of investigator and environment.

There have been questions about how we'll evaluate review or the framework, and the simple answer is that we monitor review all the time and we will continue to do so. I show a couple of ways here. This isn't exhaustive, but some things we do include monitoring, review or critiques, monitoring some study section discussions, and scoring behavior. When we detect any problems, we address them promptly. Reviewers and staff are also surveyed regarding review, the quality of the review, experience and effectiveness. And we have a, and we can benchmark these new surveys against a large database we have of previous surveys to detect any changes. There have been questions about our plans for training. We have an experienced training committee that's bringing program and review staff up to speed via guide documents, FAQs, webinars and workshops. These are ongoing and will continue through 2025. For reviewers, we're developing training slides, videos, guides to writing critiques. These are all in development for our 2025 review meetings, which will be the first review meetings for the Spring. And with that, I'm going to virtually step aside and hand it over to Erica.

Dr. Erica Brown: Thanks, Mark. Now we're going to transition to information that you can use for preparing for and tracking changes to notices of funding opportunities, which are abbreviated NOFOs. There's two definitions I want to cover before we jump into this part of the talk. And the first is I'll be using the term NOFO throughout, and it will refer to the impacted RPG NOFOs. Since that is the point of this presentation is to talk about those that are, impacted by the simplified review framework. And the second is I will often use the term implementation date just to succinctly state due dates on or after January 25th, 2025. So, since we're going to be talking about implementation in this part of the presentation, we'll want to simplify that sometimes. But I will also say the date as we go as well, just to help sediment that in folk's mind. Okay, so with that being said, the first thing to note is that all impacted RPG NOFOs will be updated with the simplify review framework for due dates on or after the implementation date, which is January 25th, 2025, and you're going to find all of that information in section five of the NOFO, which is called Application Review Information. So, what will implementation look like? Some of our NOFOs are set to expire this calendar year, so in 2024, before the implementation date. And some of these NOFOs will just be extended through the implementation date to make it easier for everyone. However, there are also some NOFOs with due dates that will come after that implementation date, and so these NOFOs are going to need to be expired. Most of these will be reissued with the new simplified review framework. For those that are being reissued, you can expect to start seeing these as soon as this Summer and up to a minimum of 30 days before the first due date after our implementation date. So, note that for most NOFOs, these are going to be published actually well in advance, so more like up to 60 days in advance, but the minimum will be 30 days before that first due date. So, you'll expect to start seeing them maybe 60 days or even more in advance. And so, for example, all of our parent funding opportunities, which are the RO1, R21, RO3, you can expect to start seeing these reissued this fall.

Concurrent with the implementation of the Simplified Review Framework, NIH is also transitioning, transitioning to updated application forms from Forms-H to Forms-I with the same implementation due date, and that is for applications with due dates on or after January 25th, 2025. The updated forms and instructions will be made available this Fall, and you can see the notice referenced on this slide. I'll read it out. NOT-OD-24-086. This is where you can find some information on a summary of the key changes for Forms-I, as well as some details on the implementation plan for that rollout.

Now to merge the implementation plans for these two initiatives together. So, as I mentioned, you're going to start seeing NOFOs with the simplified review framework as early as this Summer. However, since the forms and the application instructions will not be available until the Fall, some of the NOFOs are initially going to be posted without an application forms package. However, just like our NOFOs, you can expect to see these posted at least 30 days before the first due date and oftentimes 60 days or more. With that being said, you do not need to wait for the updated forms to be posted. Applicants can start drafting their application attachments using the NOFO as well as the current Forms-H instructions, and then just adjust as necessary once Forms -I is released. But if you take a look at the notice I referred to on the previous slide, you're going to see that there are few to no changes that are actually going to impact the SRF activity codes.

Okay, so some tips on how you can track changes to NOFOs. You'll primarily do this through the NIH Guide to Grants and Contracts, and more specifically through Notices of Intent to publish, Notices of extension, Related notices that will be updated and current NOFOs, and information that will be updated in our reissued NOFOs. I'll provide a little bit more information and examples on each of these. Okay, so you can stay up to date with all of these changes through the NIH Guide to Grants and Contracts, which is the web page where NIH publishes all of our NOFOs and our notices. And a great tip is to subscribe to the weekly Guide update, so you'll receive a summary of all of the NOFOs and notices that were published that week right to your mailbox.

Some of our Institutes and Centers may issue notices of intent to publish, otherwise known as NOITPs, you'll see on the slide, to indicate that there are some NOFOs that they plan to reissue. Note that this will be used rather sparingly, likely at NIH, so just some of the NOFOs will be associated with the notice of intent to publish when it's necessary. So, this is one tool in the tool kit, but you'll be able to follow these quite easily. As you can see on this slide, the title will clearly note these as Notices of Intent to publish, and we'll have a very descriptive title, often the same title as the NOFO that it's referring to that is being reissued. You'll also be able to track all of these in your current NOFOs. So, when a note when a notice is published to say, hey, we plan to reissue this this notice through an NOITP, that will be added to the current NOFO under the related notices section. And I'll elaborate on this related notices section just about two slides I think it is. Okay, so I also mentioned that some of our NOFOs that were set to expire this calendar year, so, in 2024, before the implementation date may be extended up to that implementation date. And so certainly keep an eye out for notices of extension. And this will just make life easier for everybody in many of these cases. So, NOFOs will not have to be reissued twice within the same year. So, what will this look like? Here's an example of a notice of extension and what you'll find in the notice is that there's a new expiration date provided, as well as additional application due dates. And in a related notices section, you'll be able to see the NOFO that this is the notice is referring to.

Okay. And here's an example of what the NOFO will look like. So, that was the notice. And here's what a NOFO that has been extended will look like. I mentioned on the notice of intent to publish slide related notices. And so, here's the example of an a NOFO where you can see all of the related notices that have been published that are relevant to that NOFO. And in this example, you'll see that there was a notice to extend a NOFO. And then when you look in the Key Dates section, you will see again that notice referred to and also additional application due dates populated in the due dates table. And an updated expiration date. So, this is how you'll track notices of to extend a NOFO.

Okay, so we've covered, notices of intent to publish and notices of extension. And so, I also mentioned that we're going to have many NOFOs that will need to be expired and reissued. And so, what will these look like? What you'll see in the expiring NOFO is again in the related notices section, you'll see a note regarding that the NOFO has been reissued, and you'll see a link to the new NOFO. And then in the key dates table, you're going to see a new expiration date. And in this example, you can see this NOFO was expired early. However, it is very important to note that the application due dates are not updated. So, there may be due dates that extend beyond the expiration date. So, it is very important to pay close attention to the expiration date.

And then what will this look like for the newly reissued NOFOs? So, that was what the expired NOFO will look like. Here's what the new reissued NOFO will look like. You'll see in the announcement type section that the NOFO will clearly be labeled as a Reissuance, and we will be providing a link back to its predecessor, so you can link back and forth between the two NOFOs. And importantly, we mentioned that the new forms and application instructions will not be available until the Fall, so some NOFOs will be published without an application package. And in these situations, the NOFOs will have a temporary message included in place of the submission options, indicating that the forms are not yet available and that they'll be posted at least 30 days before the first due date. Sorry. There we go.

Okay. We want to help you avoid any submission issues. So, as always, we encourage you to submit early in case you need to correct any submission errors. Also, if you apply through ASSIST, which is a system that we use to prepare and submit grant applications to the NIH, you will see a splash screen that reminds you of which applications to use, for which of the due dates, and you'll also be able to take advantage of some pre-submission validation tools to help you check for errors before you actually have to submit the application. We encourage you to follow NIH communications for funding updates and other applicant guidance, and to view our recently posted applicant guidance on the Simplified Review Framework page.

Okay, So, some final tips. Remember, the simplified review framework affects how reviewers evaluate applications with the goal of a better focus on scientific and technical merit. It is not expected to change the application materials that you submit. With that being said, applicants should always be responsive to both the application instructions in the NOFO as well as the review criteria when preparing applications. Remember, we are telling you exactly how we're going to evaluate your application, so you should take advantage of that and make sure you're being responsive to the review criteria. Also, it's important to remember that applications are evaluated with the review criteria that is in the NOFO. So, this means that resubmissions to NOFOs with the simplified review framework will be evaluated with that new framework. Again, this should not impact how resubmission applications are written. And last but not least, we encourage you to take advantage of features and ASSIST, Grants.gov, Workspace, and many institution systems that allow you to copy an existing application draft to a different NOFO so that you don't end up having to recreate the wheel, as these NOFOs are reissued over the next year or so. Okay with that, I will turn it over to Megan. Thank you.

Megan Columbus: Thanks so much, Erica. I have a problem that my mouse isn't actually working. So, can someone advance a slide for me, please?

Technical Assistant: I can do that. Megan. Thank you. Maybe Eric is doing it.

Megan Columbus: So, over the next year, we are doing a lot in the, in the back end here. So, there's lots of changes that we need to make to our systems to be sure that we're being able to capture the reviews appropriately. We're continuing to pull together, you know, resources and guidance for applicants and reviewers. We'll be updating and publishing the funding opportunities, as Erica described. We'll be releasing the new application forms in the Fall, we'll be planning for reviewer training to make sure that everyone's on the same page and we know what's coming up and there's no surprises.

So, so in April, we already issued a notice on the changes to funding opportunities and our approach. And so that's the approach that Erica went over just a few moments ago. And you'll see those, as she said, start to appear on Grants.gov and in the NIH Guide very soon. The new application packages will get added to those opportunities, that have due dates, on or after January 25th, beginning in November. So, there will be that break in time where there won't be an application forms. Right. Come January, the new framework is going to apply to those applications and the reviews that happen after that and then reviewer training is going to happen. All right. So, I'm going to start with some questions. And then I'm actually going to have to tag after the first few questions because my mouse isn't working. I'm going to have to tag Erica to start reading questions after that. All right. And I can jump in and answer, okay. So, does a simplified review framework apply to Fs or Ks?

Dr. Mark Caprara: It does not. Fellowships are undergoing their own changes that you might have heard about, and Ks are not part of the discussion. So, I know, Megan, if we can link them to the fellowship thing, maybe.

Megan Columbus: Yeah. So, we'll have somebody put in the chat the link to, to our Fellowship website, because we have a website which I kind of blew by for, the simplified review framework and, we have another website for fellowships, but we also have a website that's encompassing all of the changes for January 2025. And so, we'll put those in the chat so that you will have them. You also have them in the presentation. What about the R35s the MIRAs?

Dr. Mark Caprara: So, there are also not part of this. The R35s are, an investigator sort of focused, mechanism. And they really wouldn't fit into the simplified review framework. And so that's why they were left out.

Erica, I don't know.

Megan Columbus: Erica, you use that, you use that mechanism a lot at NIGMS, right?

Dr. Erica Brown: That's right. That's the exact right answer. And I did mean to say during my talk to, to reiterate this point about what are the applicable activity codes, because I know folks get confused and think it's all of the activity codes at NIH and it's not and it's not even all of the research project grant activity codes. It is a subset of those activity codes. So, that does not include the R35.

Megan Columbus: All right. Erica, my screen is completely frozen now, so let me just have you keep going.

Dr. Erica Brown: Okay. We'll do. And so, we did cover the next question, Mark with the answer I just gave. And it was does this apply to the SBIR STTR activity codes. And again, it does not. It is a subset of the RPG activity codes that I think Mark covered on maybe slide five or so. And I know we're put into the chat as well. Okay, so the next question is with the plans to change to the common form biographical sketch format, which does not include personal statements nor contributions to science, rather just a list of positions, honors and publications, how will investigators be able to represent themselves for the new framework?

Megan Columbus: Yeah. You know, that's an excellent question, Erica. And we haven't released details yet because we're working through and finalizing and, you know, crossing the last T on the details for implementing those common forms. But NIH will be using other means to collect the personal statement, the contributions to science and honors. And so that will get factored in. So, people won't be losing that.

Dr. Erica Brown: Great answer.

More on that will come this Summer. Sorry, so, that will be soon.

Dr. Erica Brown: Okay. The next question is these seem like mainly cosmetic changes, that while combining categories, does not alter the burden on reviewers nor the number of factors, reviewers must consider whether for overall impact scored criteria or simply the identification of gaps in expertise and resources. How is this fundamentally reducing burden?

Dr. Mark Caprara: I guess that's me. So, I think it's really important to look at, the, the work that the working group did in terms of coming up with, the evaluative, instructions under each of the criteria that are under the factors, I think they did a really good job of focusing reviewer's attention on what's important. And I think that it does simplify their job and reduce their burden that way. Also, the thing that we heard from the community was they were incredibly distracted by these additional considerations that they had to fill out. And I know that they that taking those away was really applauded by a number of what we heard were responses, really applauding, that were taking those distracted things away from them.

Dr. Erica Brown: Mark. This next one will also be for you. We're sticking in the same zone here. What about questions on sex as a biological variable? Are those now administrative too?

Dr. Mark Caprara: No. That's still under review criteria.

Dr. Erica Brown: Right. And Mark, can you provide a clear way to come up with Impact Score? This is still not clear.

Dr. Mark Caprara: It's an art form, I think, you know. So, we instruct reviewers to think about what overall impact is. Right. So, it's defined as the likely is their assessment of the likelihood of the project to exert a sustained and powerful influence on the field. And I would say that I think we've done a really good job over the last few years, probably more than a few years, really getting reviewers to focus on significance to like, sometimes there's too much talk about approach and things like that, and we want to make sure that they're weighing all of the criteria, factors now. In a way that, they're thinking ahead about what kind of impact will this really have? Right. And that's being redundant because I'm using the word in the answer. But again, it's an art form and we rely on the scientists to make that judgment. Actually, the panel, I should say, make that kind of judgment.

Dr. Erica Brown: Mark sticking with you for a little bit here. These, questions are all related, but Megan and I are happy to jump in if you need a break. So, I think you may have answered it, but I'll still ask it. How will reviewers weigh the scores for factor one and two to arrive at overall impact?

Dr. Mark Caprara: Again, it's up to them. And just to remind everybody, even now, the overall impact score is not an average of all the criterion scores, and it won't be an average of factor one. And the scores for factor one and factor two.

Dr. Erica Brown: Will there be a section to comment on ESI and NI applications?

Dr. Mark Caprara: No.

Dr. Erica Brown: Yeah. My sense is that maybe this. I don't know if this is what the questioner was getting towards, but they're always, is a, some nuance provided under investigators, which is still something that is evaluated but is evaluated differently in the framework.

Dr. Mark Caprara: Yeah. So, I'll just say that the instructions under Factor three still include the idea that reviewers should take into account the career stage of the applicant when they're assessing factor three. So, new investigators will still be, you know, emphasizing their training. As opposed to what they've actually done. Published in things like that.

Dr. Erica Brown: Okay, sorry. So, that was a bunch of related questions. Mark, I can help with this next one to give you a break. And it's how would the simplified review process apply to a resubmission where the initial submission occurs this year, so, in 2024 and then is resubmitted next year in 2025. And so, as I mentioned we evaluate applications according to the review criteria that are in the NOFO that the application is submitted to. So, naturally, any application that is resubmitted to a NOFO that uses the simplified review framework will be evaluated using that framework.

Megan Columbus: So, you know, Erica, my mouse is back. Do you want me to jump in so that I can ask, and you answer?

Dr. Erica Brown: Yep.

Megan Columbus: Because the next one is also about resubmissions. And so, you know, if a new NOFO is issued and the applicant needs to resubmit an application in response to a NOFO before the change.

Dr. Erica Brown: Okay. So, before the change again. So, if you just think about that, look at the review criteria in the NOFO that you're applying to. So, if it's before the change you if I'm understanding the question correctly, you would be submitting to a NOFO that uses our current review criteria and you will be evaluated with those.

Megan Columbus: Yeah. Okay.

Okay. So, when applying for a grant, should we write our grant with three sections or factors, so, it's easy to review? It's a good question.

Dr. Mark Caprara: So, the way the so the way grants most applications, RPG applications are submitted as the applicants typically write their specific aims page, and then they have a section on significance followed by innovation followed by approach. And when you think about it, that actually aligns perfectly with the way the factors are now organized. So, I think, staying the same is not, is probably the best advice, although I don't think I should be giving advice. But, Erica, I don't know if you have some insights into that.

Dr. Erica Brown: Yeah. I mean, I would certainly say we know that the application guide instructions aren't changing, and they're currently structured in that way with significance, innovation and approach. And so, I would think that folks would continue to follow that format. Our message here is you don't really have to change the way you're, developing your applications. Again, the questions in the review framework are similar to the ones before. They're just adjusted a bit to get a better focus for the reviewers on scientific and technical merit. So, I would think that you would continue to follow the application instructions.

Megan Columbus: Yeah.

Megan Columbus: And we have another question I think is pretty duplicative of the one that you just answered. And so, there's a question about, how will the NIH Biosketches be affected? And from the simplified review framework perspective, they're not impacted at all. But there is a separate initiative which is to implement common forms across the research agencies for Biosketches that will impact the Biosketch. And so, the Biosketch will after, I think that's going to get implemented a little bit later than January. So, I think it's going to be implemented in about the May time frame next year. So, at that point, the Biosketches will be a little bit different than they are now. But the good news is that most of the Biosketch will then align with what the other agencies are doing, and there will just be a little bit of extra information collection, specific to NIH.

Okay, so this one's from a reviewer. As a reviewer, I've often felt that the order of the final proposal build is inconsistent with one, the order of the scored criteria, and two, the order of importance of the scored criteria. For example, information about investigators and environments, slash resources as well as the budget, comes much earlier in the proposal than the research strategy that contains a significance, innovation and approach. This fact itself encourages some bias. Has there been any thought given to changing the order in which the documents are packaged to be consistent with the new, elevated importance of the scored criteria versus unscored items?

Dr. Mark Caprara: So, I can answer that. I know, so we've heard that before, and we recognize the sort of inconsistency between the application package and the review and, we're discussing this. Megan, I don't know if you have information about it. I heard that it might be difficult to do at the moment. But it's something that we are discussing and it's definitely on the table.

Megan Columbus: Yeah, I know the discussions been happening, but I don't know if you know what the outcome of that will be.

Dr. Mark Caprara: Yeah.

Megan Columbus: Will there be a survey? Will there be surveys of both applicants and reviewers to evaluate the effectiveness of the new framework for future improvement and refinement? And I know, Mark, you had addressed, evaluation in your part of the presentation.

Dr. Mark Caprara: Yeah. So, it would definitely be surveying reviewers, as well as review officers. Applicants we hear from all the time as well. So, and reach out to us. We listen.

Megan Columbus: Okay, so here's a question that gets to things that I think you guys have already touched a little bit on, but it bears repeating. So, could you please detail how the new simplified scored criteria will impact the final score? Will the final overall score still be independent of the main three? In other words, the summary statement will contain three critiques with three scores for each project. Then overall score can still be a number independent of this average.

There's a few different things to parse out there, I think, actually.

Megan Columbus: So, let's talk about the scored factors. So, do you want to remind them which are scored factors and what are not scored.

Dr. Mark Caprara: So, factor one and factor two will receive a factor score. Factor three will be evaluated as either adequate or resources expertise needed. So, again, the overall score that the reviewer puts in as their preliminary overall impact score, will not be an average of the two factor scores.

Megan Columbus: Just like it's not now.

Dr. Mark Caprara: Just like it's not now.

Dr. Mark Caprara: And...

Dr. Erica Brown: And then the overall score.

Dr. Mark Caprara: Well, yeah. Summary statement. Yeah. And the summary statement was still contain three critiques. You'll see what you'll see on the summary statement, okay, so, you will see an overall score from the panel. It's scored. For each of the critiques, you'll see factor one, factor two scoring scores, and whether factor three was judged to be adequate or something required, and then their critique. Repeated three times.

Megan Columbus: I think that's very clear. Thank you.

Dr. Mark Caprara: Yeah.

Dr. Mark Caprara: I hope I answered that there was a lot in that question.

Megan Columbus: There was a lot in that question, but I think you got to all of it. Will reviewers be required to take the training regarding the new criteria, or will it only be a suggestion?

Dr. Mark Caprara: Oh, gosh no. So yeah, everybody will be required to take training before they review their applications.

Megan Columbus: Yeah. And so, they're asking, you know...

Dr. Mark Caprara: There will be lots of resources.

Megan Columbus: How will the SROs be empowered to ensure that reviewers are following the new criteria?

Dr. Mark Caprara: They will be empowered.

Megan Columbus: So, there's no question about this.

Dr. Mark Caprara: There's no question. And, you know, even if, yeah, we'll get involved, Chiefs will get involved.

Megan Columbus: And yeah, people are. Watching this closely on our side to make sure this this happens. Right.

Dr. Erica Brown: Well and it's also worth noting that we will be doing training for SROs. So, there will be training that will help them help reviewers. With the implementation.

Megan Columbus: For project demonstrates high significance but lacks novelty in its approach, how will such an application be scored within the first category of the simplified approach?

If it demonstrates high significance but lacks novelty in its approach.

Dr. Mark Caprara: Yeah. So, this speaks to an old question of how innovation fits into how applications are reviewed. And I think the part, the way the criteria are written now, I think it really makes clear, explicitly clear that, a project that's worth doing, even though it may not be innovative, you know, should still, can still receive a high score in factor one. And so that's going to be a big part of our training, reviewer training as well. How to parse these two things out under factor one? Sometimes, the innovation, for instance, if you're developing a new way of measuring something, sometimes that's why the project is so important, right? Because of the technology that you're developing. At the same time, if you're developing a technology that measures something in a new way but doesn't give you any advantage over existing methods, you know, might not score as well under, factor one.

Megan Columbus: That's a good example.

Dr. Mark Caprara: Those are all the kind of things one considers, looking at innovation and how it relates to the importance of the project.

Megan Columbus: Can you talk about percentiling and what this actually means for percentiling? So, will applications be percentiled? What will that mean? Will there be a change because of all this?

Dr. Mark Caprara: So, applications will still be percentiled. The new, so how percentiling works, which is very complex, but basically, we take scores from previous two review rounds. This is for standing panels. Previous two review panels. Previous two review rounds and the existing round. And that's used in a complicated scheme to come up with a percentile on how a particular score ranks in relation to all the other scores. The new, once the new framework is implemented, there will still be percentile scores. We're monitoring this. If we see any strange deviations from scoring from the new round to the previous round, we do have the flexibility of resetting the percentile base. But we're actually don't think that we'll need to do that. But we will be watching.

Megan Columbus: Good. All right. So, we're monitoring. So, here's a question that's I think that's it's fundamental to all of peer review. You know, what happens if the reviewers can't reach agreement about the investigator environment?

Dr. Mark Caprara: If there's no expectation of, what's the word when we all come to an agreement?

Dr. Erica Brown: Consensus?

Dr. Mark Caprara: Consensus. Right. Again, this is this is the beauty of peer review. We pull together a panel of people and while there are three people, usually, assigned to an application and they discuss things, the panel teases things out as well. And everybody votes, as they see fit. So, there's no reason to come to an agreement about the investigator involvement.

Megan Columbus: All right. Thank you.

Megan Columbus: We have lots of questions for you here, Mark.

Dr. Mark Caprara: I was just saying. I mean, everything that Erica had talked about was like. I mean, I was just thinking about, oh, my goodness, I have to look for what and where. And she did a great job explaining it. I guess.

Megan Columbus: That's right.

Megan Columbus: Can you talk about, what aspects of the new framework actually reduce this reputational bias?

Dr. Mark Caprarar: So, mostly it would be factor three. So, again, what we're trying to do is focus reviewers on the question of whether or not the investigative team has the right expertise and experience to carry out the proposed work. Not necessarily how? What your general impression of them is, you know, as, quote unquote leader in the field and things like that, those kinds of things don't, we're trying to reduce that type of reputational bias. Reduce statements that we hear sometimes in review where somebody says, well, you know, there's many holes in this approach, you know, but this team will be able to figure it out. You know, we want to really get away from that kind of thing. And that way. Have equal competition amongst all applicants and applications as we review them.

Megan Columbus: Good. Just in case the reviewers do not follow well the simplified review guidelines, what will the Scientific Review Officers do on those outliers?

Dr. Mark Caprara: A general question. just like now, if there are critiques, or reviewers that go outside of the review criteria such that the review, we feel the review is not fair, we review them. So, I mean, we will counsel reviewers, we will train them, we will give feedback on their critiques. Sometimes all of that doesn't work and so we rereview them.

Megan Columbus: So, I think we've kind of covered this question, but since it continues to come up and it's, you know, it's getting voted for...

Dr. Mark Caprara: Is it about SBIRs?

Megan Columbus: This one's not about SBIRs. This one's about, will factor three have a smaller effect on overall impact score than factor one or two?

Dr. Mark Caprara: I want to be careful how I answer this. It depends. I would say it depends. I think one of the, the examples I gave, in the previous webinar was suppose you have a situation where you have an application where somebody is, using NMR to study a protein structure. And the application looks just perfect, but the investigators don't have access to an NMR machine. Right. So, in that kind of extreme context, I probably would have a, you know, a big impact on the filing.

Megan Columbus: Right.

Okay, so back to the question of I think people are very concerned that reviewers aren't going to get the message that they need to look at these applications differently. And so, if a reviewer doesn't follow the guidelines, can an applicant report it? And I think you addressed that right.

Dr. Mark Caprara: Oh, absolutely. I mean that I mean we hear from applicants all the time. They feel that the review was unfair. And we look at it, examine it. And if a rereview is warranted, we will do it. But I want to say something, you know.

The response that we've gotten to this has been overwhelmingly positive. And reviewers, we do chair training once a year, for incoming chairs of study sections. And they've all been applauding this. So, I think the community is really, you know, welcoming these changes. And I don't think that there's going to be, a large population of reviewers out there, resisting these changes. I think they're going to be welcomed and they're going to follow, you know, reviewers want to do a good job. I mean, that's sort of the secret of study sections. If you've never served on one. Reviewers really just want to do a good job, and they really eat up the training that we give them. And so, I really expect it to be relatively smooth from that point of view. But as always, if you feel that the review was unfair in some way, you should always report it back to your program officer and they will get back to us in review.

Megan Columbus: It sounds good. I see another question come in here about asking a back to the Biosketch question. And I know that we're not talking about Biosketches here, but it is related, and it's asking about whether Science CV will be updated to make this transition to Biosketches easier. And that is indeed the intent. And so again, more information is coming. But that's the intent of that. Is it recommended to contact a program official or a scientific review official prior to application? Erica, why don't you take that one?

Dr. Erica Brown: Sure, I'll take that.

Megan Columbus: You haven't talked in while.

Dr. Erica Brown: I'll give Mark a break. Yes, before, if you look at the end of a NOFO, there will be contacts for a particular NOFO. If you'd like to contact somebody and it will tell you who to contact and when. So, you will contact a program officer, if you want to talk about the science you're submitting. about what NOFO is right for you. Questions about a NOFO. You will direct all those to the program officer prior to submission. You only will start contacting the SRO after application submission or anything about the peer related to the peer review process. But it's very, POs are the folks that you interact with about, you know, certain topics, science, NOFOs, questions about NOFOs prior to submission.

Megan Columbus: Great. Thank you.

Megan Columbus: People seem concerned about this factor three and so this one asks, you know, what does it mean by no individual score in factor three? And you talked about this Mark, but maybe you can reiterate, you know what that kind of, approach is.

Dr. Mark Caprara: So, factor three instead of getting a score is going to the reviewers are going to give a binary assessment, whether it's adequate. And if it's adequate, there'll be no reason or there'll be no requirement to give any other types of comments under it. It's adequate. If it's not adequate. then the reviewer, the reviewers will be asked to provide comments. Why isn't it adequate? What's needed in this case?

Megan Columbus: Right.

Megan Columbus: I see that we're getting some questions still about fellowships and career development awards. And I just want to reiterate that, you know, we're just about to release the additional details on the changes to the fellowship applications and awards, and we will be having a webinar just like this one to talk about that. And so, no, don't worry about that at the moment. And, and there aren't plans right now, that we're rolling out this year for changes to career development awards.

Megan Columbus: And we have another question here about whether there are significant changes to Forms- I and Forms- I is really addressing the changes. There's a notice out there already that was released, I think, on April 4th about Forms- I and we also included it in what we're calling that Uber notice that when over all the changes that are being implemented for January 2025, and beyond. And so, I encourage you to look, but it's, we're, it's implementation of the things that we've been talking about and the changes that are upcoming. And I think we're getting very close to the end time here. I want to, go back a little bit without showing it to you, but the slide that I kind of blew past about, the website, we have all kinds of resources available there, right? We have presentation materials. If you want to take things back to your institution and talk to people about the changes. We have, you know, one-page overviews or for what this means for applicants, we have, all kinds of things there that's worth exploring. And you can find all the policy documents and you can find what we've been saying, and you'll be able to find recordings such as the last webinar we did. And by the end of next week, you should be able to find this webinar. Thank you to the tech team who was able to find the slides so quickly. But there really is so much there that you can dig into. And I encourage you to keep looking at those FAQs, because we will continue to be populating them as we get questions. Yeah. And so, I encourage you to stay tuned. And I thank you so much for joining us all today.

Megan Columbus: Thank you all.