TRANSCRIPT

Webinar: NIH's Simplified Peer Review Framework for NIH Research Project Grant (RPG) Applications: for Applicants and Reviewers

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>> Megan Columbus: All right, welcome and thank you for joining us today. Today we're going to be talking about how NIH is simplifying the NIH Peer Review framework for most Research Project Grants starting with applications with due dates on or after January 25th, 2025. This Webinar is the first of what will be a number of events that we have planned to help ensure that applicants, reviewers and NIH staff understand the new framework. My name is Megan Columbus. I'm the Communications Director at NIH's Office of Extramural Research I'll be your Moderator. We're kicking off today's event with a video introduction from Dr. Mike Lauer, NIH Deputy Director for Extramural Research, and following that video, we'll have a presentation, by Dr. Mark Caprara, one of the co-chairs of the implementation team for this initiative. After that we'll bring on the other co-chairs on screen for a panel, and we have plenty of time that we can address questions. Please note that the chat feature we've turned off, and you should be using the Q and A feature for questions. We'll be answering as many as we can following this event. So now let's go ahead and hear from Dr. Lauer.

>> Mike Lauer, M.D.: Hello, I'm Mike Lauer, I'm the NIH Deputy Director for Extramural Research. I want to thank you very much for joining us today. We're going to be discussing the rollout and implementation of the NIH Simplified Review Framework, sometimes we call it SRF for Research Project Grants, and this is going to be implemented for applications coming in January 25th, 2025 and later. Now I like to think of the NIH as being a learning organization that we are, and we have learned from many people, we have learned from peer reviewers, we've learned from staff, and we've learned from many of you who have responded to our calls for input, and we were very grateful to that about ways in which we could improve peer review. Peer review obviously is a bedrock, it's a pillar of what we do, every year we receive about 80,000 applications, and every single one of them undergoes some form of rigorous peer review, and that peer review obviously is critical and helping us make the best well-informed funding decisions. So, what did we learn? What have we learned from reviewers, from staff, and from many of you? It is that there are ways in which we can improve peer review. We can make it less complicated, simplify it, focus more on the scientific and technical merit of proposals as opposed to other items which are important, but which are probably more appropriate for the agency to deal with, and we can also mitigate problems related to reputational bias, and by doing these two things by focusing and simplifying review so that the focus is on scientific and technical merit, and by taking steps to mitigate the problem of reputational bias. We can improve peer review, and that can help the agency be more successful in its mission. So my colleagues are going to work with you and explain with you exactly what we're going to be doing in order to implement this again, the implementation will be effective for applications coming in January 25th, 2025 and later. I'd like to take this opportunity again to thank those of you who participated in our various groups, and who responded to our RFI, because through that this has helped our learning and help make things better. So thank you very much, and I hope you find this event to be interesting, informative, and helpful.

>> Megan Columbus: Great. Thank you Mike, for setting the stage for us so well. Now, I'd like to introduce our presenter, Dr. Mark Caprara. Mark is a review branch chief at NIH's Center for Scientific Review, and, as I mentioned previously he is one of the chairs of the implementation team for this initiative. So go ahead and take it away, Mark.

>> Mark Caprara, Ph.D: Thank you, Megan. I'm going to share my screen. Okay, I would like to welcome everybody who is attending today as we go over the Simplified Review Framework. So, we'll start with an overview, 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 scientific and technical merit of applications. Today we'll introduce the Simplified Review Framework for research project grants that are expected to improve and help your reviewers evaluate these grants. These grants are called RPGs, they include the well-known RO1s and R21s and as Mike stated his will go into effect for applications due for January 25th, 2025. For this Webinar we'll be introducing, including background on how and why this was developed, and then I'll introduce the framework. So, as Mike pointed out in his introductory remarks, the framework has been developed with significant input from the extramural community. So over the years NIH has received concerns regarding complexity of peer review. A formal request for community input was issued by a blog that was published in February 2020 and we received over 400 comments and emails and content analysis of these comments provided the foundational data for a working group that was formed to tackle these issues. So what were the issues with regards to review that needed to be addressed? So this slide shows that the issues come to two broad categories, and some representative comments are shared. So first, the complexity of peer-review criteria has grown over the years, including asking reviewers to comment on administrative and compliance issues. Comments mentioned that this detracts from reviewers attention away from the critical primary role to evaluate scientific merit. We also received a lot of comments about reputational bias, and this was a concern where whereby well-known places and people are given a pass while others are treated with more scrutiny. The next step was the formation of a working group, including extramural scientists familiar with the peer review system and NIH staff, and they developed a set of formal recommendations to address these issues, and this report was completed in April of 2021. The recommendations were then discussed and refined somewhat by NIH working groups, and this went through a formal approval process that was completed about a year ago. We then reached out to the community again for their input versus a request for information and other outreach efforts between December of 2022 and early 2023. The analysis from these responses can be found in the link in this slide. We received 800 responses from individuals, societies, and institutions. And the big take-home message was that the majority of them were supportive, and this is likely a reflection of how much input the scientific community had in developing the framework. One recommendation that came up many times related to implementation was the call for developing strong training resources and this is certainly a focus as we implement this framework. So, what is the framework? So the goals of the framework are 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. The next two slides show the four major aspects of the new framework, including the underlying rationale for them. So first simplify and improve review by focusing the reviewer attention on three main questions. Should it be done? Can it be done? And will it be done? And this was done by reorganizing the five core review criteria into three factors that align with these questions to the

importance of the research. Should it be done? Rigor and feasibility? Can it be done? Expertise and resources? Will it be done? Next. Modify the criterion, definitions for investigator and environment to reduce reputational bias. This was done by having reviewers assess the adequacy of investigator expertise, and institutional resources, with respect to the work proposed as a binary choice, so appropriate for gaps identified. Third, simplify and strengthen the review criteria by using conceptual definitions rather than long lists of questions shifting away from extensive sets of questions of complex questions, encourages more thoughtful integration of concepts rather than yes, no, or checklist thinking. And finally relieved reviewer burden by not requiring peer review of select additional considerations. So consideration is not directly related to scientific merit shift and NIH staff administrative review. The next few slides show these changes, so on the left, this is the current criteria as they are currently organized, each receives a criterion score, and major score driving points are provided by the reviewer. On the right is the new framework, the criteria organized in three factors. As I mentioned before, factor one is the importance of the research, this encompasses significance and innovation. This will receive a criterion factor score and reviewer comments. Factor two is rigor and feasibility, its incompetent's approach and also will include the inclusions for human subjects and clinical trials study timeline. Again, this will receive a factor score and comments from the reviewers. And finally, there's reviewer factor three which is expertise and resources, this encompasses investigators and environment. This does not receive a score, but is evaluated as appropriate or gaps identified; and if there are gaps identified, reviewers will provide an explanation. Reviewers will still provide an overall impact score that reflects their overall judgment of scientific merit based on an integration of the evaluations for each of these factors, as well as additional review criteria, human subjects, protections, vertebrate animals, and biohazards. As with existing score methods, reviewers will weigh these factors as they see fit, and arriving at an overall impact score. This slide shows a couple of examples of how reviewer review definitions modify from complex questions into more conceptual definitions. These aren't the only definitions under factor one, I just chose two for simplicity and the other factors have similar types of definitions. So it was felt that these definitions are clear, then the current questions will help to focus reviewers the guidance to the reviewers is more direct, and this should also lend to easier reviewer training, Finally to reduce reviewer burden, most additional review considerations will be removed from first-level, peer review, and shift to the awarding instant to your center. Currently, there's five additional review considerations that don't affect the overall score. In the simplified framework reviewers will only have to review two out of the five. It can be easier to visualize this framework in a familiar way, such as what your summary statement will look like in the new framework. And so this is shown in the next couple of sides for a standard RO1. So I'll discuss proposals. We'll get an impact score and percentile. It will also include a resume and summary of discussion that's prepared by the SRO, and then it'll be followed by three sets of critiques, each organized in the following way. Factor one of Factor two, you'll see a score, a score will be displayed, followed by strengths and weaknesses, followed by an overall impact paragraph and then factor one strengths and weaknesses. Factor two, again, strengths and weaknesses, and again, as I mentioned in this example, it will include inclusion plans for human subjects research, if appropriate. Factor three will be organized in this way, it will either be value, it will either have an appropriate selection, or if gaps were identified, it will include reviewer text to explain that and then this, then that you'll be followed by protections for you, and subjects for different animals, biohazards, authentication and budget and period of support. So what are the expectations, and how will NIH monitor progress? So, by simplifying, reducing burden, and addressing reputational bias, the expectation is that the quality of review improves, and what we mean by that is, we'll have clear

evaluations of the importance of the research. Should have been done? The rigor and feasibility of the approach. Can it be done? And the appropriateness of investigator environment. Will it be done? So some of the measures that we actually pursue in a valuing peer review are going to be shown on the rest of the side, and this will be used to evaluate the new framework. So, SROs and leadership will continue to monitor critiques and meeting discussions, trends, positive or negative, will be discussed, and problems addressed promptly. We'll be monitoring and benchmarking, scoring distributions against an existing extensive database. We collect reports of bias from reviewers and applicants, and investigate and act upon them. This also gives us an opportunity to compare this data through different review rounds and years. We frequently survey reviewers and NIH staff regarding the perceived quality of review and review experience, and we'll be able to benchmark new surveys against previous survey data, and we will engage with the applicant community for feedback. As I said, we expect peer review to improve but attributing improvement to this initiative solely will be difficult, and the reason for that is NIH is committed, for example, NIH is committed to addressing reputational bias on multiple fronts, you can go to this link here to see that. After implementation, if we see positive changes in the range of institutions or investigators that receive funding, for example, this will need to be taken in the context of these other complementary efforts. So, what's happening between now and January 2025? We'll be making changes to our NIH peer review systems developing training resources and updating and publishing funding opportunities, because each funding announcement needs to have an updated version of a section on review. They'll be lots of training and outreach to socialize this change for reviewers, chairs, applicants, and staff. And then, finally, we have a public-facing website for this initiative, this has a lot of information on it now, and we will continue to populate it as the implementation of this framework progresses. And with that I'm going to thank you for your attention and echo Mike's thanks to members of the scientific community who contributed to their thoughts and hard work in developing this framework.

>> Megan Columbus: Thank you ….. for that helpful overview of Mark. So now let's have our other chairs join us for a Q and A panel. Dr. Brian Hoshaw, who is chief of the Scientific Review branch at the National Eye Institute and Dr. Lisa Steele, a review branch chief at NIHs Center for Scientific Review. Now many of the submitted questions when you registered with this event, and while many of those questions were likely answered by Mark's presentation, I thought we could go ahead and start with a few of those before moving on to those that we're receiving in real time. Are there anticipated changes to the SF 424 (R&R) application to reflect the changes in the review process.

>> Mark Caprara, Ph.D: So we don't anticipate any changes on how you need to prepare your application. But we also always encourage applicants to be aware of the review criteria, and keep these in mind when you're crafting your application. Since that's what is guiding reviewers

>> Megan Columbus: Good advice. What about factor three, how will that affect the overall score when it's being rated as sufficient or not?

>> Lisa Steele, Ph.D: First let's take a step back, and just remember that the overall impact score is not an average of the criterion score, some complicated mathematical formula. It is the result of way, the major strengths and weaknesses that have been identified in the review criteria to come up with that score. There are elements that don't receive scores presently, like protection of human subjects that still have ability to be factored into the overall impact. So, even though factor three doesn't get a score if it is a major score driving factor, it can be included. But you know, if it's not, then it doesn't affect the overall assessment.

>> Megan Columbus: Okay. So just to play off of that a little bit more. I see somebody just came in with a question. In factor three, then if gaps are identified, how would that affect the success of the proposal?

>> Lisa Steele, Ph.D: So that, just like any other strengths or weaknesses in the review criteria identified by reviewers, it's up to the reviewer's discretion to decide if that weaknesses, or in this case a gap will actually affect the overall scientific merit of the application, and they will explain that in their overall impact paragraph those major score driving issues.

>> Megan Columbus: Thank you for driving that home. So how will the simplified review framework improve the chances of funding of PIs for resource-limited or research-limited.

>> Brian Hoshaw, Ph.D: I can address that one. So, as Mark pointed out in his presentation, one of the goals of the simplified review framework is to address reputational bias and peer review, not only with investigators, but also with the institutions. So we're doing this by changing the review of this investigator and environment to it, and changing it from a detailed discussion with criterion scores and strengths, weaknesses to a binary assessment of appropriate or gaps identified. And this is in terms of the signs of it. So, we're hoping this will level the playing field. For example, when a research limited institution, if they have the resources needed for that application, they will be able to compete with a larger institution which might have a wealth of resources that aren't related to it. We're hoping this will level the playing field when the focus is on factor one and factor two, and that NIH would be providing specific training of reviewers and chairs to really reinforce this point.

>> Megan Columbus: Great. Yeah, Thank you, Brian. I think this one's probably going back to Mark. I know we talked about the application forms themselves are not changing. But there's still a question regarding whether the application will change, whether it'll change the structure or the order or the assembled information that's seen by reviewers.

>> Mark Caprara, Ph.D: No, I mean we've talked about doing that because it that suggestion has come in before, and technically it's feasible but very difficult to do, so at this time we're not going to do that, but I will note that what's interesting is that most research strategy sections are organized now, there is a section on significance and innovation, and then the approach. And actually, this aligns quite nicely with how factor one, factor two are organized.

>> Megan Columbus: Great. Thank you. A question related to masked review. Could you eliminate the name and institution of the PI to eliminate bias, or make the review even more efficient and effective.

>> Brian Hoshaw, Ph.D: So this has also come up a lot throughout this process. So Federal regulations require us to assess investigator environment and to assess You know, all five of the criteria as part of the Review, so the best we could do would be a two stage review, where the first part is masked, the second Part Isn't. And we're actually doing that now, CSR is doing that with the transformative RO1s, and they've also done this before with their CSR anonymization study, hopefully a lot of you have heard about that. And two points, one they found in both the transformative RO1s and then the anonymization study that about 20% of the reviewers can figure out just from the research and approach can figure out who the PI is. You know there's a small field with the expertise, they know the players, they know the research so they can figure it out. And then, secondly, we review about 80,000 applications a year, so logistically to do a two-stage review for everything, what would really be a burden on the community and the reviewers and I think would affect the level of review, where we have thought about this throughout the process.

>> Megan Columbus: There's some questions about other mechanisms. We talked about this impacting most research project grants, there are some exceptions like small business. This question is about, if small business, career development, and Ps are not, which are program projects are not impacted by these changes, will they stay with the same five standard review criteria, or will those undergo changes soon as well?

>> Mark Caprara, Ph.D: I'm sorry. Is it S,P,R,I,F,K's as in Ps, at the at the moment, no, they're going to stay same.

>> Brian Hoshaw, Ph.D: There are changes of time. There are changes coming for F so stay tuned for those, but the other ones will stay the same.

>> Megan Columbus: Yeah, and those F changes will be different than what we're talking about.

>> Mark Caprara, Ph.D: Yeah.

>> Lisa Steele, Ph.D: I would say, just as a note to people that every funding announcement contains that section five that tells you the review criteria. So you know, even if you missed all of this, you know communications and all the notices. Whenever you apply, look at that section five, and you will see exactly what you will be evaluated on.

>> Megan Columbus: Absolutely. Following up on the masked review. Is there a discussion on possible two-state reviews?

>> Brian Hoshaw, Ph.D: So that I mentioned those are being used to transform RO1s, but logistically, for all 80,000 applications, hat wouldn't be, it might be expanded a little bit, but logistically it's already, we're already trying to condense the timeline between submission, review, and counsel, so adding another step would really go against that whole movement.

>> Megan Columbus: A follow-up question about this overall impact score, it's not clear to me how providing an overall impact score reduces reputational bias when in the end the reviewer has the option to highly weight factor three in their overall score.

>> Lisa Steele, Ph.D: Well, I think that you have to remember that if it is a review criteria they reviewers can use it to determine their overall impact score. So we can't eliminate that ever being a score driving factor, and it would be inappropriate to do so. It is an evaluation for these grants, and it should factor in according to the importance determined by a reviewer. As Mark said, this isn't the only thing we're doing to reduce reputational bias. We have a great training module that is currently being used, and will soon be mandatory to alert reviewers about. You know the problems of reputational bias as SROs are reading these critiques and providing feedbacks, as well as being very attentive during the meeting, and reviewers themselves have noted that after the training they felt more comfortable, interrupting or asking questions themselves in the meeting. So it's everybody you know together working on this issue. I think that will make real headway. This isn't going to be like a one chat. It can totally prevent that.

>> Brian Hoshaw, Ph.D: And just to follow up on that. As I said, there are a lot of things we have in place to address this, and it's not one review, or we use the application that gives the final score the whole panel votes. And we're hoping to really change the culture of the review meeting, and we're already starting to see that in some of the meeting where they've taken the training where reviewers will point out like, well, okay, you know, we just you shouldn't give that much weight just because of their seniority or that much weight because the university, we should assess everything. So having culture, change training, not just for reviewers, but chairs, and also SRO's To really address this.

>> Megan Columbus: Yeah good answer. So we have more questions about this factor three, right? So I'm going to combine a couple of these questions. One is well, how will factor three be quantified? And I

know we've already touched on these things. But if factor one and two are exceptional and three is not appropriate. How will that affect the score?

>> Mark Caprara, Ph.D: So again, it's not, not appropriate it's if some gaps are there. So let's say, for example, you propose to do a wonderful study, structural study on a protein using an NMR you know, and everything looks great. And then, when it gets to the resources, you find out that you don't have access to an NMR machine, so can it be done that way. But it those things are never that extreme right. So sometimes you'll have gaps and expertise for a small part of the application, and the reviewer was just going to have to weigh that in terms of, well, is this project, you know, if it should be done, can it be done, you know, even without this expertise? And we'll just weigh those things.

>> Lisa Steele, Ph.D: And I do want to add on to that. Yeah, it's not absolute, and it's also. You may identify. Gaps may identify weaknesses, but the question is, are they addressable? If they're easily addressable gaps, or you know deficiencies that reviewers may decide that it's easily addressable, so it doesn't really affect the score. So it's not just the presence of these concerns, but are they addressable, are they major?

>> Megan Columbus: Thank you. We have a question about when the exact language for the simplified review is coming out, and you know, before I throw anything to the panel, I just want to let people know that we did put out a guide notice that has the language there. If you do a search on NIH Simplified Review, you'll also find websites that detail our new simplified review framework. Certainly we will be providing additional information for reviewers and our scientific review officers and other things, and those will be coming at a time that's closer to the time they'll actually need it to do what they need to do. Anybody on the panel want to add anything to that? Should we anticipate instructions for the facilities and other resources documents based on the new review criteria.

>> Brian Hoshaw, Ph.D: So, as we've said before, the application won't change, it's still the same information, if you're proposing this research, you should have, you know, information on the bio sketch, the expertise, the resources, we're not requiring any changes in reviewers. Won't be looking for anything different. It's just a little bit different on how it's assessed. So that's sort of the takeaway from that is, we're making sure that community is aware of it, so you know your summary statement will look different, as Mark pointed out, but your application itself is in no require changing.

>> Lisa Steele, Ph.D: right, so like you can, in terms of you know, facilities and resources, you can really make sure that you're targeting it toward the science that you're proposing, because now, you know, reviewers are just focusing on that. Not your general kind of expertise, but what is needed for this project. So reading those review criteria hopefully will help you to write a better, more focused application, knowing what you're being evaluated on. But, as we said many times, the actual structure of the application isn't changing.

>> Megan Columbus: So a question about the factors and the scoring for those factors. For asking whether significance and innovation are each going to be scored one to nine, or is there one combined score?

>> Mark Caprara, Ph.D: It was just one combined score. So a little bit of history. So the working group recognize that innovation is a complex criteria in evaluating a proposal's importance or impact. So in some contexts, innovation, you know, maybe the focus and primary driver of the research and sort of the importance of the research. And in other contexts, you know an application that's not very innovative, may still be addressing very important question, and shouldn't be downgraded by a lack of innovation and so the language in the new framework takes this into account. I think I'm trying to find the words, I think the exact languages evaluate, the extent to which innovation influences the importance of undertaking the proposed research.

>> Megan Columbus: Thank you, Mark. Regarding the PI and institutional bias. Should the PI consider reworking their personal statement on the bio sketch or the role description in the budget justification, or should they continue to stress their expertise and experience.

>> Mark Caprara, Ph.D: I think Lisa answered that you know nicely before, in the sense that you probably want to tailor it to the research that you're being that you're proposing in that particular application that you're submitting.

>> Megan Columbus: And I think the application instructions already lead you in that direction. So how does this have any effect? Or does this have any effect on the calculation of percentile for payline?

>> Brian Hoshaw, Ph.D: So the percentile of payline are determined by overall impact score of percentile, and they're still giving an overall impact for one to nine, so that will not change. Just sort of how they get to that number might be changed a little bit. So those weren't changed. But I know that CSR calculates the percentiles, and they will keep an eye on it. If there are any changes or major issues, they do have opportunities to reset it or address it. But no, we're not anticipating any changes, since the same overall impact score one to nine will still be used.

>> Megan Columbus: People have, you know, are talking about this third factor. Not surprisingly, will there be further sub criteria within the third factor to determine the gaps objective?

>> Lisa Steele, Ph.D: Yeah, the blanket answer is no, there's definitely, you know, again, guidance in the language for evaluating that factor three but we're not going into sub criteria because one of the things that we want to do is trust reviewers, and recognize the very wide variety of both science and

approaches, and different ways of doing it, so that every time we try to make it more specific. There's exception, you know. So we try to start that balance of giving, you know, reviewers guidance, but also letting them use their experience and the specific question that application in determining the evaluation of these factors. So we don't want to get more specific, and then inadvertently end up, you know, hurting one field that that particular guidance doesn't apply to.

>> Megan Columbus: Yes, absolutely.

>> Mark Caprara, Ph.D: It also goes against the whole simplifying the criteria that we're trying to get to.

>> Megan Columbus: Has the new framework have been piloted, and if not, why

>> Brian Hoshaw, Ph.D: So, this has also come up a few times, so we're not piloting this. Piloting that wouldn't change, you know, designing a multi-year study with a subset of RO1s or RPGs carved out for reviewing, using this different set of criteria, and this would really result in an uneven playing field across these applications over years. So again, logistically, we wouldn't want these two sets of our RO1s being reviewed different ways, and then still having to be, you know, having the second level of review make funding decisions for those. So it's much easier just to implement the changes and make sure we've allowed plenty of time for training and outreach to let everyone know about it. But that's why we're not doing a pilot.

>> Megan Columbus: Thank you. You know, I know Mark mentioned in his slide some information about evaluation, but we do have a question here about how NIH is going to evaluate this change.

>> Mark Caprara, Ph.D: So again we're going to be collecting information. Again, it's going to come from, you know both SROs and leadership will be monitoring critiques, and the discussions will be looking at scoring and the demographics of success. We'll also be looking at reports of bias, whether increase decrease, and also engaging the PI. One thing I guess that's maybe under appreciated by the community is how much effort we put into analyzing peer review on a round to round basis, a meeting-to-meeting basis. And so we do a lot of it. We have an office for it. And so, if there are any problems that creep in, we're able to address them rapidly.

>> Megan Columbus: Thank you. How will this affect the process, or the criteria by which applications are separated into kind of discussed and not discussed by the review panel? Will there be any impact there.

>> Brian Hoshaw, Ph.D: So that is still determined by the preliminary overall scores from the assigned reviewers, and that's not changing. They're still submitting overall scores the same way that it before, and then, when they come in, they'll not discuss. Preliminary list is based on that and then at the end the review committee still has final say on whether an application is discussed or not, beginning of a meeting, they can rescue applications as they did before. But, in short, that process will not change since the overall impact score process is still the same.

>> Megan Columbus: And then, on a related note, will this new system have an impact on early stage investigator or new investigator applicants. And what happens to them in the peer review?

>> Mark Caprara, Ph.D: No. So that'll be the same. The instructions are when judging the investigator who's a new investigator or early stage investigator, will still be asking the reviewers to when you're assessing them to assess their training, as opposed to whether or not they have hundreds of papers published because they probably haven't had the time to do that.

>> Lisa Steele, Ph.D: But again, hopefully, by you know, focusing on their accomplishments and the resources they gather to do their application. This will work toward kind of evening, the playing field for people who are just starting out their career and have the expertise and resources to do it without necessarily the track record. So, we're hoping this actually improves their chances of receiving great impact scores.

>> Megan Columbus: Training of peer reviewers on this it's super important. How will this be structured? And can you share any information at this point in time.

>> Lisa Steele, Ph.D: Yeah. We definitely consider training a large part of our job. And you know this is like kind of communication starting the training process. But the specifics are going to come. But, definitely looking at multiple ways of training, developing things like a mock study section eventually to kind of show people how this is actually working out after we have some experience in these meetings. So yeah, there will be a lot of training resources, and we'll definitely watch the website, and it'll start getting populated.

>> Megan Columbus: Right, and your SROs will certainly be reaching out, Scientific Review Officers, will be reaching out to reviewers and training.

>> Mark Caprara, Ph.D: And so Lisa's being a little modest because she's chairing the subcommittee, we have a whole subcommittee on training that's developing these materials and lots of work ahead, but we anticipate them being ready by next, early, mid next year, late next year.

>> Lisa Steele, Ph.D: Yeah, Yeah.

>> Megan Columbus: How would this affect a resubmission under the new framework.

>> Lisa Steele, Ph.D: So a resubmission will be evaluated under the framework that is present for when it's submitted, so if it's after for an NOFO after funding announcement after January 25th, 2025. Then it will be evaluated under this simplified review framework. We will not just, and again like, I would say, look at section five, you know, when you're applying, and you will see exactly how it's evaluated, so the resubmission, if it comes after the state will be evaluated under the simplified review framework.

>> Megan Columbus: Will we be publishing our critique of this new system after six months or a year?

>> Mark Caprara, Ph.D: I've already talked to leadership about this, and yes, we'll be keeping the public informed about how this is going. I don't know it'll be six months out, it'll take some time for us to gather that to draw conclusions. But we will certainly, and it's part of engaging with the applicant community.

>> Megan Columbus: All right. We have somebody out there who is um an early career reviewer, preparing to serve on the first review panel, and they're asking if it if they need to learn the old way of reviewing and scoring applications now and then the new simplified way later? The answer would be yes. And are there training materials still available to learn how applications are currently scored. Yep, because when we have multiple review rounds before that happens, and so absolutely, there's lots out there, and your scientific review officer will be providing you the information that you need. Can strategies now be organized as two sections, one significance and innovation and two approach, past NIH communication encourages using three sections. Strategies now be organized. Oh, so I guess the research strategy. I guess we're talking about how they organize a research strategy of the application? I guess I mean It's up to an applicant how they want to structure the application right? I mean, you want to make sure you're answering the questions that the reviewers are going to be evaluating against.

>> Brian Hoshaw, Ph.D: Yeah. And the way Mark pointed out, the way applications are set up now you know it's all you see, significance, innovation, you have your specific gains, you go into your approach within the page limit, so those should look the same.

>> Megan Columbus: Will data management and sharing plans to be evaluated differently with the new framework?

>> Brian Hoshaw, Ph.D: That's a trick question, because review doesn't affect those? No, those will still be evaluated by program officers and the IC Staff, so they will not be evaluated by a peer review.

>> Megan Columbus: Right, and that could be inspired by the question, because, we said, resource sharing, is shifting. Does this change the emphasis on productivity as an important criterion for renewal of RPGs given the Yes/No assessment of the PI.

>> Lisa Steele, Ph.D: So the evaluation of the renewal remains evaluate the progress made in the last funding period, so the productivity is still evaluated as part of the criteria.

>> Megan Columbus: It looks like the budget will come under more scrutiny than it currently does. Is that correct?

>> Brian Hoshaw, Ph.D: No.

>> Megan Columbus: No, I don't know why it would look that way. So right, there's nothing changing there.

>> Brian Hoshaw, Ph.D: Yeah, and that doesn't the evaluation, that doesn't affect the overalls.

>> Megan Columbus: Good point. In the past reviewers have been guided to note the significance of a prior and proposed research to help gauge significance, innovation, and approach. It sounds like reviewers will now be guided to note, should it be done, could it be done, rather than the rigor of prior and proposed research? Or will the latter still be emphasized in review?

>> Mark Caprara, Ph.D: So the rigor of prior research, which is usually the foundational data that the project is based on is still an important component of review.

>> Brian Hoshaw, Ph.D: If you look at the text in the guide notice for section five under factor one, it's still in there, if anything, it's emphasized more.

>> Mark Caprara, Ph.D: Yep, yep.

>> Megan Columbus: Does this new plan reduce the likelihood of having our resubmitted grants be reviewed by new reviewers instead of previous reviewers. Should it?

>> Lisa Steele, Ph.D: No. This is, you know, slightly off topic, but we do look at resubmissions as a current application, although you know, responsiveness to prior critique can sometimes be factored in. The real. emphasis is on the evaluation of the present application, and therefore the expertise for that application is evaluated at the time of submission. So we don't have the identity of previous reviewers in our database, so that we could use them, but just reminding you sometimes that wouldn't even be appropriate, because if we're looking at the application fresh, the expertise may change because you have changed the application in response to the previous critique, or just because of time. So we really do focus on each application when it comes in, and we don't keep the identity of previous reviewers.

>> Mark Caprara, Ph.D: And that's the policy now, and we'll be in the future. Right?

>> Megan Columbus: So how did or does the new simplified model consider or address issues of the bias that affect foreign applications,

>> Brian Hoshaw, Ph.D: So those will be reviewed the same way, it doesn't, I don't think it'll affected one way or the other. It's the same sort of level playing field for everyone, so they'll still have to have an extra section about resources going to a foreign university doesn't affect the score, and that'll actually be reviewed, not a part of peer review, but that'll be preferred if an application is going to the council for that institute. So, in short, it doesn't directly affect that I mean the changes will affect the application as a whole the way it does other ones, but it's not affecting review of applications for a foreign university.

>> Mark Caprara, Ph.D: And again, we're just focusing the reviewers on the significance impact, etc. of the application, not taking into consideration where it's coming from necessarily, if it's not a US application.

>> Megan Columbus: So we're still we're still working on scoring here. If Factor three has some weaknesses, but is acceptable will it affect the overall impact score? I think you've addressed this a couple of times, it's worth mentioning again.

>> Brian Hoshaw, Ph.D: And I'll just say, on a different note, there's no mathematical formula for how a criterion or factor score goes into your overall index score. We give the reviewers a lot of leeway on how they weigh them, and I think Lisa pointed out earlier, if it's identified gaps that are easily addressed, that would have less of an impact on the overall score as opposed to things that just, you know, cannot be

addressed by the application. So there's not, there isn't a formula on how you determine it. Reviewers, we rely on them with their expertise in any field, there are too many caveats in every field to kind of give more specific instructions, so they are able to, those criteria will still affect the overall score, and they determine how much based on the significance of the strains or weaknesses, or the gaps that are identified.

>> Megan Columbus: So is this truly only impacting, scoring?

>> Mark Caprara, Ph.D: No. So again, you know, we're changing how things are organized, we're changing the review definitions. Again, what we're expecting is the quality of the review will improve. Hopefully, the output of this are content-rich critiques and summary statements that are focused on sort of those three key questions you know of should it be done? Can it be done? And will it be done? So we're hoping that this improves things, and it's not just something that's affecting scoring.

>> Megan Columbus: You know, so, from the applicant perspective, you're not changing your application in terms of how it's submitted, and what's in your application, it's going to change just even how reviewers are conceptualizing the review, and it'll change how they're coming up with this score. But in the end the impact score will still be one to nine, and you're still submitting your application in the same way.

>> Brian Hoshaw, Ph.D: You know a lot of the focus, you know, and the questions obviously has been on the role of reputational bias in chapter three, but remember the other reason we're doing this is burden on the reviewers, so less burden on them, more time to focus on the significance innovation approach. You know the overall potential impact of the application. There are two forces driving this, so we should keep both of them in mind, and I think it'll be a better quality review because they're not taking time to assess these administrative aspects.

>> Megan Columbus: Yeah, I think those are important points. I'm an early career reviewer, will it be possible to serve as the early career reviewer again under the new framework?

>> Lisa Steele, Ph.D: No, sorry, you're ready for the big time. You're ready to be a full reviewer, sorry, you had your special attention. Now you're ready.

>> Mark Caprara, Ph.D: I would say, I wouldn't hesitate to accept, you know, being an early career reviewer. Now if asked, there's lots of benefits to serving, and there's a lot of good things to take away from it. And even though it won't prepare you for the new simplifying review framework, it's still a good idea to serve.

>> Megan Columbus: I agree. Since resubmissions are basically considered new applications, are there plans to eliminate the introduction section?

>> Brian Hoshaw, Ph.D: You still had, you know, when you submit, you still had the option of submitting it as new or as a resubmission. But as of now, this project itself they're working on is not addressing that topic at all. They still allow, you know, a one resubmission for an application, you'll still have the introduction, and reviewers will still have access to the previous summary state, so that won't be affected by this project.

>> Megan Columbus: Okay. So if a proposal had high significance, but low innovation, would those two sub-factors be averaged for factor one? Or if one sub-factor is rated as high, is factor one rate is high, so I think there's a little bit of confusion, because there's only one score for factor, one right? There's not two separate scores for factor one. But do you want to talk about significance and innovation, and how a reviewer might think about that, as it relates to factor one when coming up with a score?

>> Mark Caprara, Ph.D: So I think I addressed this in my answer earlier. You know this was made up so, yes, so that's just one score. And to take into account, you know, sometimes innovation is dry, and remember, the factor is the importance of the research, it's not significance. It's the importance of the research. And so, in some cases innovation is really driving that if you're making a new tool that can be distributed broadly to answer new questions. You know, that might be driving the and the score for the important of the research. Other times you may have a research question, that's very, very important, but low innovation in terms of how you're going to get it done. Again, the working group didn't want them to be to those types of applications to be downgraded. So, that language is in the description for that factor.

>> Megan Columbus: Thank you.

>> Mark Caprara, Ph.D: So I guess I should say it like this, maybe this will get the answer. You know it's an integrative type of review, right? We're not taking one and the other, and then trying to mesh them together and average them when we're coming up with a great factors for them.

>> Megan Columbus: All right last question. And I think we've touched it, but it's a good drive home question. Is there a single key takeaway emphasis that should be related to PIs and future applicants? The short like elevator-ride speech is what they're looking for. What do they need to know?

>> Brian Hoshaw, Ph.D: I think Lisa said it earlier, I would say, for any notice of funding opportunity announced or NOFO you're applying for, look at section five. You should always do this because that is

what the reviewers are going to use to guide their review. So whether it's the current version or new version, I would say, always, look at that because you'll know what the reviewers, what they'll be addressing.

>> Megan Columbus: Yeah, and I guess I would add to that, that if you are a potential applicant that's been concerned that you're not from a big named school, or you don't have the track record. Maybe now is the time to think about applying, right.

>> Brian Hoshaw, Ph.D: That's a good point.

>> Megan Columbus: Okay, so thank you all, panelists for your answers and thank you to our audience for their questions and for the engagement, we're going to be using the questions that we received today to continue to flush out the FAQs that are on the simplifying review website. We have quite a number there already that you're welcome to take advantage of. We'll be developing a plethora of resources to support the community in the next year, to you know, for this change, and we'll be having an additional events like this webinar, to answer additional questions. So thank you for joining us today. We'll make the recording available on the event web page as soon as we can, you'll see the URL for our website, right here on this slide. And if you have questions that have gone unanswered, certainly you can reach out to us at simplifiedreview@nih.gov. Thank you.