Demyth-defying Review: Submission to Score

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Stephanie Fertig: Thank you for joining us today for this session on "Demyth-defying Review: Submission to Score." I'm pleased to present our panel for today's discussion. We have several individuals from the Center for Scientific Review, and for those who don't know, the Center for Scientific Review is where the vast majority of our SBIR and STTR grants are reviewed. We have Elia Ortenberg, David Pollio and Vonda Smith. Elia and David are both Scientific Review Officers, and Vonda is the Assistant Director for the Division of Receipt and Referral. Now I'm Stephanie Fertig. I'm the HHS Small Business Program Lead, and I'm your moderator for today's session, so let's get started! Looking at the next slide, what are our session's objectives today? Well, we're hoping to help demyth-defy review. What happens after your SBIR application? How is the peer review managed? And, of course, how to put your best foot forward, so with that, I'm going to turn it over to Vonda.

Vonda Smith: Thank you, Stephanie. As Stephanie said, my name is Vonda Smith, and I'm an Assistant Director, one of many, in the Division of Receipt and Referral, and we are essentially the funnel for the majority of applications that come into the NIH, and we are the people who make the assignments. And this first slide that you see here is how we do this. You can see it's broken down for the Institute Centers, the Integrated Review Group and Special Emphasis Panel. The central theme here amongst all of these, especially for the assignee to the IC and the Integrated Review Group, and you'll hear me also abbreviate it as IRG, are based on for the IC the overall mission guidelines and/or specific programmatic mandates in interest of the IC. For the IRG, the theme here, review guidelines that are specific for each IRG, and from there, they go to Special Emphasis Panels for small business applications, also fellowships, and keep in mind that reviewers are recruited as needed for these Special Emphasis Panels. Next slide. Now small business applications are reviewed across all four of the divisions that you see here. I'm not going to read them all. But there are approximately 40 small business Study Sections in CSR that review about 6,500 applications per year, and to help you learn where to get your application assigned, we have several tools, and we encourage you to use those tools. The one you can use .. . The top two for CSR are the Assisted Referral Tool that we refer to as ART, and you can see it at this link, and this is a useful tool because it allows you to cut-paste your specific aims and the title of your application into the system, hit go, and it'll come back and give you top 10 or so Study Sections that may apply for you to submit your application. You can also just go and browse the CSR small business Study Sections at the link shown here. You can type in key words, and it'll come back and give you a list, and from there, you're encouraged to click on those links, read the descriptions and make your choices, and if you've looked at the Assignment Request Form, which is part of the application package .. . We lovingly refer to it as ARF. You get three choices for ICs, and you get three choices for potential Study Sections. Don't worry if you make a mistake and choose or request an IC or a Study Section that isn't appropriate because we will make sure your application gets assigned to the most appropriate IC and Study Section. Next slide. All right. So I know this is what everybody is here for. It's what are the mistakes that can happen. So next click. First is FOA inappropriateness, and here FOA means funding opportunity announcement. These are the things that you use to decide, "Oh, here's an opportunity for me to send my application to NIH because they are looking for A, B or C research, and I think my application is going to fit." But the problem comes when you find a FOA that is appropriate, but you submit information or an application that's appropriate for an IC that does not support that FOA. In other words, that IC is not listed in the FOA, and if we cannot find an alternate IC, then we will sent .. . We have to withdraw the application. For this, another way of having an inappropriate FOA is you picked a FOA that is no longer active. Again, if we can't find an alternative, your application will be withdrawn. So how do you address this? Always, always, always, no matter when you are submitting an application, please contact a program officer before you write that application, and then read the entire FOA to make sure you're submitting to an IC that supports it. You know the due dates, et cetera, et cetera, and any special things that are in that FOA. Next three common mistakes are submitting an application before the submission deadline, submitting an application too early for the due date. This happens if an applicant decides to submit about 60 days before the due date. Those will be returned unless you include a cover letter that say, "Please accept this application early." The reason we return those applications is because about 30 days before the due date is the time that any notices of any changes with respect to that FOA come out, and as a result of anything that's in that notice, it may make your application unapplicable, and we have to withdraw it. Also, submitting an application that's incomplete or with errors. Can you click the next thing? This happens when applicants think, "Oh, I have submitted by the deadline. I am in. Yay, yay," but it comes back and says, "You have errors." Now you are late. Applications must be submitted complete and error-free by the due date. I'll say it again: complete and error-free by the due date. So how do you address that? Make sure you complete all the appropriate registrations that you're needed for your small business, including DUNS and SAM. Again, read the FOA for due date information. Submit early, no later than 2 days before the due date so you can have time to address any errors and still get your application in on time, and please check that sections are correctly included. For instance, for small business let's say you have a Phase II, and this is for the Phase II that's a continuation of a Phase I or a Direct Phase II or a Fast-Track, but you forgot to include the commercialization plan. Your application is incomplete. It will be returned to you. The last section is noncompliant. This means that it violates NIH policies. I'm going to talk .. . got a couple of these because misclassified clinical trial is pretty clear, and a new application that refers to prior review is pretty clear. That essentially means if you submitted it as new, but you said, "I am addressing the previous reviewer questions," or you include the previous application number, that is saying that the application really isn't new, so that will get you returned. Overstuffed, which can also come with font, format and page limit violations means you put information that should have been in a page-limited section, for instance the research section, in an area that isn't page limited, like let's say human subjects or your authentication of key biologicals. You are not allowed to do that. That information is supposed to be in that section. If it's not, it will be withdrawn. The same thing can happen if you use a font that's too small or if you use .. . You have more than six lines per inch. We will check that, correct the proper font of being 11 point and having six lines per inch, and if that puts it outside of the page limitation, the application will be withdrawn. Next click, please. How do we fix that? Read and follow the SBIR/STTR SF424 Instructions, so take-home is contact program officer, read the entire FOA, read and follow the instructions for submitting your application, and one more thing. If you talk to a program officer, and they say, "Yeah, seems like your application may fit for us," you go and write it, but you changed something. Go back to the program officer to let them know because what you changed may have now made that application inappropriate for that particular IC. Another thing to remember is when you are contacting us because you are in a panic because you don't see your application in the system, if you can't see it, we can't see it. Remember, 2 days after you submit it sits in grants.gov. Then it gets passed to the ERA Commons. Again, it's going to sit there for a couple of days for validations because that's where it's going to look at the completely assembled application, and then from there, it gets passed to us at DRR, and then we can make the assignments, okay? Next slide. Now who can I talk to? Who are the key people? There are three. First is your program officer. Remember from the previous slide because they can answer questions about IC priorities, let you know yes or no. This may be appropriate for us. Let you know, "Hey, here is a FOA that may be appropriate," or, "No, this isn't appropriate for us. Maybe you should try another IC." Next is my office for DRR staff. We can answer general submission questions such as, "Does the FOA that I want to submit to allow late applications? When is the due date for this FOA?" things like that, that are general. We will answer your question but also take the moment to teach you about where you can find this information to help you in the future. The next person is the SRO who can answer questions about Study Sections, scope and review. You're encouraged not to send your SRO your specific aims or your full application because they cannot say with any certainty an application fits their Study Section until the completely assigned and assembled application is received by DRR. And, with that, I will kick it over to Elia. Thank you.

Elia Ortenberg: All right. Thank you so much, Vonda. And Vonda is a very important person, so I highly suggest that you listen and pay attention to everything that she just said. I'm Elia Ortenberg, and I am one of about 35 Scientific Review Officers that oversee review of the SBIR and STTR applications, and I would like to think very much that I have a very important role in the process of peer review, and probably the most important responsibility that I have is to identify and recruit and assemble reviewers to join these Special Emphasis Panels. So, as Vonda mentioned, SBIR and STTR applications are reviewed in special Study Sections that are assembled specifically for this review. We recruit approximately 20 to 40 members from both the scientific and the business community, so just keep that in mind, that these are diverse panels that represent multiple types of backgrounds and expertise. We review them de novo, which means that we review reviewers new every single round, so one Study Section for one round will not be identical to a Study Section for a subsequent round, okay? And these review panels then review approximately 60, maybe less, to 100, maybe more, applications assigned to that Study Section in that particular round, so it is a very important role for the Scientific Review Officer to make sure that the reviewers recruited are both not in conflict, right, with the application or with any of the applications in the meeting that would make them not eligible to join review, so that's one of our key roles. And another role of ours is to, once these reviewers are recruited and the panel is assembled, to assign applications to these reviewers, okay? So, on average, a reviewer might be assigned to eight or so, eight to 10 applications, and each application is assigned to about three reviewers, a minimum of three reviewers, maybe, possibly more depending on the specific aims of your application. And then, finally, my role here is to produce summary statements, and I produce them for all applications regardless of whether the application is discussed or not discussed, and I'll talk about that here on the next slide. Okay, so an important consideration for the work that the Center for Scientific Review as well as the National Institutes of Health does is we really abide by the core values that you see on this slide. And I also wanted to point to this wonderful, wonderful picture pre-COVID when we handled SBIR and STTR review in person in a cramped hotel room where reviewers are sitting shoulder by shoulder. You see an SRO. You see the meeting chairs, and we are active in discussing the applications, okay, but we do so in a way that abides by these seven core values. We want to conduct review in an expert way. We ask reviewers to be impartial and fair and review with integrity and review with confidentiality, so it would be a clear violation of NIH policy for you to reach out to anybody on the review panel or for the review panel to mention anything to applicants or to PIs about any of the review. The review meetings are closed. However, CSR abides by a transparent process, so while the meetings are closed to the general public, the information about how review is conducted is standardized across review panels, and the process is not invisible. You can learn about this, and this is a great opportunity at this conference to learn more. Okay, let me talk a little bit about the review panel and what the reviewer's responsibilities are. So the review panel scores each application according to five core review criteria, plus they assign the application a single overall impact score, and that score is along a one to nine scale, okay, and Dr. Pollio will mention a little bit more about this in just a few minutes, but based on the overall impact score, the top half of applications will be determined, so the strongest applications will be determined based on the three reviewer scores. And it is those top half of applications that are going to make it to discussion on meeting day, okay? Now one thing I want to mention is that the applications are clustered, so the top half of the Phase I applications are considered differently than the Phase II types, so Phase II applications, Direct to Phase II applications and Fast-Track applications are all clustered together, and it's the top half of those applications that will be reviewed separately from the Phase I applications. So reviewers .. . The whole entire review panel during the course of the discussion will discuss the discussed applications and give and assign final scores to those, okay? So at the end of the review meeting, we have a set of applications that are discussed and receive final scores, and then we have a set of applications that did not make it to discussion, and those applications are considered not discussed. They do not receive final scores, but you still will be provided a summary statement showing the three assigned reviewers' critiques. All right. So let me turn to some of the common misperceptions about SBIR and STTR review. All right. So there's about six that I want to review here, and certainly, at the end of our presentation more than happy to answer any questions, but first, after seeing the roster, can you as a PI request specific reviewers to review or perhaps not to review your application? And the answer to this question is no, okay? So you may request expertise. You may identify competitor conflicts, but that all should be done at the time that your application is submitted. So Vonda mentioned the PHS Assignment Request Form. On that form, you can also make requests about specific types of expertise that are required to review your application. So, second, for your discussed application, does the score that you get, does that reflect a mean of all those reviewer criteria, and as we discussed, the answer to this question is no, okay? So the final score that you get if you're fortunate to have your application discussed, that score is the mean of all of the members' scores who are not in conflict with your application, okay? So those reviewers that are in conflict with your application step out of the meeting. They do not participate in the discussion and the scoring of your application if they are in conflict. All right. So, third, since your application unfortunately was not discussed, will you receive any scores, or you will not receive scores. That, I guess, is the misperception. The answer is no, so while nondiscussed applications will not receive a final score, as I mentioned, you will still receive full critiques from the three assigned reviewers, and you will receive those criteria scores. And now, fourth, that critique is very important because it gives you the opportunity .. . if you do decide to resubmit your application, gives you the opportunity to address those reviewers' concerns, so the fourth misperception here is that if you address all of the prior reviewers' concerns in your resubmitted application, does that mean that you're going to automatically get a better score the next time around? And, unfortunately, the answer here is no, all right? So resubmitted applications are assigned to new reviewers, as I mentioned. Every review panel that reviews SBIR applications are recruited de novo, new round, so it's going to be a new set of reviewers, and so the chances that any reviewer from a prior review panel will review this application is zero, so it's going to be that new reviewers are going to see your application, and they may identify continuing concerns or new concerns based on their read of the application, okay? Now does that mean that you shouldn't address the concerns from prior review? And the answer to that is no. Of course you should address the prior reviewers' concerns because that is a score-driving criteria for the review of your application, and the extent to which you can address them and address them in a way that makes your application more rigorous, the better off you are. Okay, fifth, that none of the reviewers on the panel has the expertise to review your application, no. So the answer to that also is not, all right? It's entirely possible that no one reviewer may be 100 percent fit to the specific aims of your application, but please be reassured that the panel has the collective experience, the collective expertise to review all of the applications assigned to that panel. And now, finally, that I can talk with you after review is over. Unfortunately not. So the role of the Scientific Review Officer, the journey of your application is complete when .. . once level one review is completed, okay? So after the review, after you receive the summary statement, you should discuss next steps for your application with your program officer. It is their role to help you as the journey of your application continues. All right. So I think now I can turn it over to my esteemed colleague, Dr. David Pollio. Thank you so much, everyone.

David Pollio: Good afternoon. I was very pleased to be asked to be on this panel. I've been an SRO for less than a year, but I was asked because for the 6 years prior to that, I was a member of an SBIR committee, and for the final 2 years, I was a chair, so I'm speaking to you with two hats, one as someone who has read and evaluated, I don't know, hundreds of SBIR applications and one who has gone over to the dark side and now organizes these. So I'm going to talk about this both as someone who has done it and someone who is now organizing it. So, congratulations! You have written an SBIR or STTR, and it has gotten scores that put it in the top half for your committee, and it is about to be discussed. That's an important step, but what's part of the .. . what Elia has already mentioned as part of the process is understanding that all of the grants, all of the applications that get discussed very much have a similar set of issues and a similar process, so your application is up. Three people will have reviewed it, given it close attention, and they will present in the order of their review -- there's a reviewer one, two and three -- all of the elements on this slide. When you are preparing your SBIR application or STTR application, you'll want to pay attention to all of the bullets on this page because all of these will drive the score, so have a look. We review efficiently but in-depth so that if you have gone very great depth into one and not into the other, it's going impact your review, so you want to be clear to address all of these because the overall impact of your application and your overall impact score is a summation of what you've written, how it's been evaluated and the discussion in the review section. Next slide, please. So a competitive application is one that is well-prepared, that is rigorous and reproducible, and what we mean by that is that it is scientifically addresses the review criteria. It is .. . It explains the literature correctly. It doesn't move beyond, but it acknowledges the strengths and weaknesses. It documents this. The problem that it addresses is a significant one, and this is very important. You may believe that your issue is incredibly significant, but if you don't make that case, your reviewers don't know what you know, so you have to be clear on the significance. It also needs to be realistic. There are a number of mechanisms and groups, what they call what we said clustered, and you need to make sure that your application is realistic within that cluster. Do what the instructions say. Don't do more, and be very clear to say, "This is what we're doing." If it's not realistic, these reviewers are going to know this, and that will be a problem. Next slide, please. So here are some hints to help you to put in the application that you want to put in. First, you need to plan your writing time wisely. Letters of support often take a while to get. You have to gather your team together. You have to think about what you're going to do. You have to give yourself time to make sure that you are submitting the best application you can. I don't know of too many, if any, applicants who can put together any size SBIR, STTR in a few days. It requires work. Next. Please do not use jargon or acronyms. The reviewers are going to have knowledge in your general area, but not all of them will have all of the knowledge. Jargon without explanation does not help. It is frustrating, and it can often be unclear. So, remember, you are speaking to an expert lay audience. Remember, SBIRs are not all researchers, and they are not all businesspersons. Make sure that you are speaking to both audiences using concepts and words that they will understand. Next. You need to provide a strong rationale for your product. It's not just that your issue is significant but that your solution addresses the issue well, so it's not just something that affects half the population. If your product doesn't do very much or replicates what's out there or doesn't make sense to the layperson, you're going to have problems. Next. Remember, although they are not all scientists, there are scientists. Make sure that when you review your research, you review it correctly. One study in one chapter of a book does not mean that it is established. Rigor is not just demonstrating that the knowledge is there and is well-studied. It is acknowledging the limitations and the strengths. Scientists want to know what we don't know, not just what we do know and why what you're doing addresses this gap. Next, please. The approach is very important. All of the issues that I talked about in slide 11 are important, but the approach is the way you're going to demonstrate your aims, so you need to make sure that there are enough methodological details. This is not an R01, but you do have to have enough details for the committee to understand what you're doing and why your approach meets your aims. This is very important. Oftentimes, committees will focus on the approach, and since there are many who are scientists who have been funded, going too vague or saying, "We're going to do --" I think my favorite example is when someone says they're going to do a qualitative study, and they say, "We're going to analyze the transcripts." The committee will say, "And? What does that mean?" You don't need to write a method section of an article, but you do have to be clear and give enough detail. Next, please. Finally, this is the realistic. Your aims and your time line have to be realistic. Many of the folks on the committee will have had experience both as reviewers and as recipients of SBIRs. They know when you're making stuff up. They understand that issues take time. So if you cannot get all of your aims into the time period, you need to go back and look at your aims and your approach. It's not against the rules, but the committee and as a reviewer, I found it enormously annoying when I was reading through and saying, "They've got a year. How are they going to do this? It's not possible." That will affect how people review you. So these are just a handful of the myths that we were talking about. The thing to do is keep these in mind, but perhaps the best way to sum it up is, keep in mind that your applications are being evaluated, that you are speaking to a group of lay with some expertise. Do not make the mistake of pretending that they don't know science or thinking that they know everything that you do. Think about that in advance as you put this together. Next slide, please. So you want to become an SBIR/STTR reviewer. We have not scared you away in this presentation or at this meeting. There are a number of ways to become this, but the best overall is do not be shy. We are always looking for reviewers. Think about 20 to 40 reviewers per panel three times a year, and they're all ad hoc. Feel free to introduce yourself. Look at the panels that are available. Figure out which ones you have expertise or knowledge, and contact your SRO. One of the nice things is, we share. Everyone has the same issue, so if you're not quite right, we'll send you to the right place. We're always looking to build a bank of qualified reviewers, so do not be shy. If you think you want to be a reviewer, contact us. The other thing is if you're interested, you can go to our website. There's a nice link that will explain all of this. Like I said, we are always recruiting. We are always interested in finding new talent, and if you are a particular type like me, you could start as a reviewer, end up a chair and then have a chief or an SRO say, "Hey, we have a job opening. Are you interested in doing this full-time?" And I will say, it is a very interesting career direction if you're interested because you get to read all of these interesting applications and have a part in the creation of the next generation of science. Here are some slides with .. . Here are some links for you to give you more information on peer review, policies, how to do electronic submissions. I strongly recommend you look at the Study Section descriptions if you are putting together an application. You do not necessarily have to do exactly what's in them. DRR, Vonda and her crew, will get it to the right place, but it might be nice to know what the places are you're looking at, and also, all of our rosters and meeting dates are available. I believe it's 30 days in advance for the rosters and further for the meeting dates, so you can see once you know what committee you're assigned to who the reviewers are going to be. I really liked to do that. It doesn't help anything, but it's comforting to know who the people who are sitting on your committee .. . And that's the conclusion of our presentation, and we're now available for questions.

Stephanie Fertig: Great. So we've gotten a number of questions that have come in, and I'm going to start with one that has come in, in different forms, and so it's about conflict of interest and bias, and really, I'm getting a lot of concerns about conflict of interest, bias, and how do you make sure that there isn't conflict of interest, that there isn't bias that's occurring? How do you make sure those reviews are fair?

Elia Ortenberg: That's an excellent question, and it is an issue that CSR takes very, very seriously, so before reviewers are recruited for the panel, we do do some background investigative work. Nothing to the level of FBI, but we do make sure that there aren't any obvious conflicts from the start, right, so there could be a reviewer who could join the panel, who would want to join the panel, but unfortunately, they're not eligible to serve on the panel itself due to either a personal conflict of interest, a professional conflict of interest or no applicant is allowed to serve on a panel for that round. They would be out of meeting conflict. In terms of assigning applications to reviewers and managing that conflict, all of the reviewers go through very specific steps to make sure that they are not in conflict by institution or by .. . through direct competition with a reviewer, and as I mentioned, those situations are identified by the .. . can be identified by you when you are first submitting your application. You can give us any potential conflicts in terms of direct competitors, but we also then invite reviewers to do the same kind of check, and it is .. . I wanted to say that it is never too late for any reviewer to declare a conflict or for a conflict to be identified any time throughout the review process. It is something that we take very seriously and manage throughout, including during the course of the discussion. If something is identified even at that point, it's still not too late to address it.

Stephanie Fertig: So I am going to .. . And I'm going to do these as a little bit of a lightning round since we only have 5 minutes or so to go, but there was a question about how the panel members can all score an application if they weren't assigned to it, so only three reviewers are assigned. How is everybody scoring the application?

Elia Ortenberg: David?

David Pollio: All of the members of the committee who are not in conflict listen to presentations by the three reviewers, which talks about what is driving the scores they make. After they do that, there is a discussion time when all of the members have the opportunity to bring up points that they want addressed, nuances on how the information was created, and one thing: We do not reach consensus in our meetings. Individuals score based on what's been presented, and they do have access to the grants while they're being discussed, and they may score basically within the range of the three reviewers, or if they really disagree, they can score outside of it, and probably the most lively parts of this discussion is when the other members say, "You weren't clear on that," or, "Are you aware of this?" or, "This is not the method of choice for this answer," so there are three that have given deep dives into it, and the rest have had it presented and had an opportunity to both understand what's there and discuss opinions and then give their score influenced by but not controlled by the scores of the other reviewers.

Stephanie Fertig: So you said they don't do consensus, but what about not discussed? Does everybody have to agree to not discuss something?

David Pollio: No, the not discussed is the lower half of the scores.

Elia Ortenberg: But the committee does come to agreement on that. All of the applications are eligible to be discussed, and so there needs to be full consensus of the panel of the applications that are presented for discussion and the applications presented not to be discussed. There does need to be consensus there.

David Pollio: And in some cases where there's a large range of scores, where one of the reviewers really likes it and two don't, we will discuss it anyway because that indicates the potential that something has an influence that needs to be addressed in the discussion.

Stephanie Fertig: How can someone, once they see which Study Section they've been assigned to, is there a way for them to request for a change? And, Vonda, this may go to you.

Vonda Smith: Yes, there is. They can send an e-mail to DRR Central e-mail, and we will tell them that what they should do is either wait for the chief that the application is completely assigned to, already assigned to, sends them an e-mail explaining why it was assigned there, or they can say, "Ooh, I see that it's not there where I want it to. What do I do?" and it's, again, contact the chief of where the application is assigned, and they will tell you why it's assigned there, but if you disagree, we can still make a change if the new chief agrees to accept the application, but you can make that change. Also for ICs, as well.

Stephanie Fertig: Well, I'm going to sneak one oe last question, and I know some of our organizers on the back end are waving their hands here, but one last quick question. Are reviews given guidelines that they have to follow about the merit of the application? What about subjective versus nonspecific? How does that work? If there's a lot of question of opinion versus scientific opinion versus fact, we get a lot of questions about that, so are there guidelines for reviewers?

Elia Ortenberg: There are very, very strict guidelines for reviewers. Every reviewer goes through a SRO-led reviewer training. There are additional resources that also reviewers are given, and I think the basic answer to that question would be to go to the CSR website. There is a section that directs you towards review, right, so there's a section on the CSR website for applicants, but there is also a CSR section for reviewers, and I would highly encourage any applicant out there to consult those resources, too, so that you know what these very strict criteria are for the review of the overall technical merit of your application.

Stephanie Fertig: Great. Well, I know we are over time now, so I want to thank everyone for joining us today. We hope you found this session useful. I'd encourage you for more information about review, and we're going to walk through some summary statements. Please come to the resubmission session that's going to be later today. If you have any additional questions, take the opportunity to meet with small business program experts in the 15-minute appointments that are available this week. You can visit the HHS and NIH Hub on the conference site to get started. If you have any issues, please click the information tab, and feel free to get help there, and don't forget to share your feedback about this session, other sessions and the overall conference. Thank you, all.