**TRANSCRIPT**

**NIH Grants Process Primer: Application to Award Part 1**

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MEGAN COLUMBUS: Welcome today to NIH's two-part webinar. It's on the grants process primer from application to award. Today is day one, and we'll be looking at tomorrow afternoon for day two for a more interactive session for day two and a little bit of a deeper dive. My name is Megan Columbus and I'm from the NIH Office of Extramural Research, and I'm So, pleased to be here today co-hosting an event with the Center of Scientific Review. Before we go too far, I want to have a quick video that's a message to you all from our leadership.

NONI BYRNES: Hello, I'm Noni Byrnes, Director of the NIH Center for Scientific Review.

MICHAEL LAUER: And I'm Mike Lauer, the NIH Deputy Director for Extramural Research, and the Director of the Office of Extramural Research at NIH. Welcome to the webinar entitled, "NIH Grants Process Primer: Application to Award. The purpose of this event is to share key information about the process of applying for a grant from NIH to support biomedical or behavioral research. NIH is the largest single public funder of this type of research in the world, investing more than $40 billion annually. Over 80% of NIH's funding goes to extramural research supporting nearly 300,000 investigators at more than 2,500 research organizations across the United States. Our goal is to fund research proposals with the greatest potential to increase our scientific understanding and ultimately improve human health.

NONI BYRNES: NIH has a vested interest in receiving applications from a wide range of investigators and institutions to allow us to capitalize on the wealth of ideas, talent, and creativity from across the country. We are making significant efforts to broaden the applicant pool and to ensure that all applications receive fair, independent, expert, and timely scientific reviews to identify the most promising research for NIH support.

MICHAEL LAUER: Our recent efforts include simplifying the peer review criteria for the majority of research project grant applications, beginning with the applications due on or after January 25th, 2025. This initiative aims to focus reviewers on the key questions needed to assess the scientific and technical merit of the research proposals. Simply put, should and can the proposed research be conducted? This simplified framework changes the evaluation of investigator and institution to a binary choice of either appropriate or additional expertise resources needed for the proposed research. The objective is to help reduce the undue influence of the reputation of the institution or investigator in the scientific peer review process, again, with the aim of identifying the most meritorious projects.

NONI BYRNES: In addition to these changes to the peer review process, we have also implemented other approaches to strengthen the quality of peer review. First, we have broadened the pool of qualified expert scientists who serve as peer reviewers to ensure that NIH study sections are frequently revitalized with fresh perspectives. In addition, CSR-implemented training for reviewers on bias and review integrity, which is now mandatory for all NIH reviewers. We have also established a direct reporting mechanism to allow any applicant to report potential bias in the review process or breaches of review integrity directly to us at CSR. You can find more information about this on CSR's website. One last thing I'd like to share is that NIH is also restructuring the review criteria for fellowship applications. These changes will allow peer reviewers to better evaluate the trainee's potential and the quality of the scientific training plan without the undue influence of the reputation of either the sponsor or the institution.

MICHAEL LAUER: So, if you or your institution has submitted few, or perhaps no NIH grant applications before, now is a great time to do so. While applying for an NIH grant support remains a highly competitive process, if you don't apply, there's no chance for funding by NIH.

NONI BYRNES: We hope that this webinar will provide you with important information to help you navigate the grant application process, and most importantly, encourage a broader range of investigators and institutions to submit applications to the NIH. Thank you.

MICHAEL LAUER: We hope you enjoy the webinar.

MEGAN COLUMBUS: Yes, isn't that great advice, right? What we're looking for is we want you to apply, we want a broad range of people, even those who don't think they might be someone that we might traditionally fund. So, thank you to our leaders for that introduction. Okay, so today we're going to be going through the grant basics, right? Orienting you to NIH, planning to apply, writing your application, submit, review, and monitor, and reporting and getting you some resources. We will be taking Q&As. Remember those are the ones that have been submitted in advance between the first and second segment, and there will be a brief intermission so that people can go do what they need to do for a couple of minutes. All right. Okay. So, let's get started. As we go through today, we're going to be walking through these steps. Remember, this is a primer. If you've been working with NIH for a lot of years, this is fundamentals and so recognize it for what it is. Okay. With that, I'd love to turn it over to our first speaker, Sheri Cummins.

SHERI CUMMINS: Thank you, Megan. All right, so for the next 20 minutes or so, we're going to start with some of those basics, those real fundamentals, and build a common understanding of some key concepts that you need to know when you're working with NIH. And then we'll step through the full grants process from planning to apply all the way through to closeout, as Megan mentioned. But it's really important to understand some of the lingo that we talk about, you're going to hear lots of acronyms and so forth. So, let's get started with that. There we go. All right. So, some of the questions we want to answer in this particular segment is, what do we do, where do we start, where's the money, how do we actually announce the opportunities that you might be able to apply for? Who's eligible, who you'd be talking with at NIH? We'll touch a little bit on registration and then we'll talk about just some wrap up and some key resources. Slides are a little slow to go forward. There we go. All right, so what do we do? As Dr. Lauer mentioned, we are the largest public funder of biomedical research in the world. Okay. The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

NIH provides financial assistance in support of that mission in a number of ways, and we use these broad funding categories to kind of categorize that different types of funding. We're going to be talking today mostly about grants and cooperative agreements. In that arena, we cover research and training and career development grants. That includes things like individual fellowships, individual career development, institutional training. And you'll notice that there's some little three letter codes there, those are called activity codes. You may hear us refer to things like RO1 and F31 and K01. These are actually called activity codes, and it's a way for us to differentiate the wide variety of programs that we have at NIH. And they do fall under these broad categories. So, for example in individual fellowship we have an F series of codes, so things like F30. In the career development, we have a K series, so you'll hear things like KO1. Institutional training is a T series with T32. And of course, with our research and development, we have an R series. Those are the ones you most commonly hear of things like RO1 and RO3, and R15.

We also do construction modernization grants, small business, and we provide some competitive and administrative supplemental funding to those awards. So that's all kind of in that grant space, though we won't be talking about them through today's and tomorrow's events. We also provide financial assistance in the areas of loan repayment programs, contracts, other transactions and challenges and prizes. And you can find information on all of these funding categories on our grants and funding website at grants.nih.gov in the funding tab. Dr. Lauer touched on this a little bit, but for fiscal year 2023, NIH issued over 34.9 billion. So nearly $35 billion in grant awards to over 58,000, we made over 58,000 awards to almost 2,800 universities, hospitals, small businesses and organizations across the globe. So where do we start? So, I recommend starting with the NIH grants and funding website. Again, that's at grants.nih.gov. This is where you're going to find all the information you need to understand grants policies and to work through our processes. It has things like how to apply application guide and our grants policy statement. Basically, everything you need to know to apply, you can find on the site.

I want to touch on just one little utility link in the upper right-hand corner, and that is our glossary. Again, we use lots of acronyms and lots of terms that may or may not be familiar to you, and you can always go to that glossary and look them up. So, we don't want you to be lost. We'll do our best to expand them, but if you ever get caught that is a handy resource to keep right there at your fingertips. So, where's the money? And to understand this question, you really do need to understand a little bit about how the National Institutes of Health is structured. NIH is comprised of 27 institutes and centers, and we're going to use ICs. So, you're going to hear IC all today and all tomorrow. That means institutes and centers. Each IC has its own mission priorities, budget and funding strategy. NIH also has an office of the director. I happen to work in the Office of Extramural Research, as does Megan, right? So extramural research would be outside of NIH and intramural research would be internal to NIH. Okay? But within the Office of the Director, we set NIH policy that is applied across all of the institutes and centers, and we plan and manage and coordinate some programs and activities that go across NIH. All right. 24 of those ICs and several offices within the OD post funding opportunities and fund or co-fund awards. Okay. That's a really important point. So, all of our funding is done through these institute centers and offices.

With that said, it's really important for you to understand where your research may fit within those NIH Institutes and Centers. To that end, we provide a resource called Find a Fit for your research, aptly named, NIH Institute Centers and Offices. And on this page, again, it's on the grants.nih.gov site. On this page, we can describe how you can use Matchmaker, which is a tool that we have that allows you to explore funded grants. You can actually put in some text from your specific aims or your abstract and feed it into this tool, and it will kick back a report of all of the things we've awarded that are similar. And will show you which institutes and centers have actually funded research in the past in those areas. There's a little Matchmaker tool video that you can look, that'll walk you through the process and what that looks like. And I encourage you to check that out. And we'll also have a session tomorrow on our RePORTER tools. So, in addition to some tips about how to use that Matchmaker tool, we also have compiled a central list of all of our institutes and centers, their mission statements, their funding pages, their funding strategies, all that information so that you can go off and do your homework and find that IC of interest.

So how do we announce these funding opportunities? And here's another term for you, notices of funding opportunities are NOFOs, okay. And that's really just a broad term for funding opportunity. Within that broad term, we have things called centrally managed parent announcements. All right. These are broad announcements that we can use to accept certain types of applications. We also have ICO-issued program announcements or PAs, okay? So, it's just a special type of NOFO. And within our program announcements, we have some that we have set aside funds. So set aside funds would be money that's literally set aside to make awards to a particular funding opportunity. And those funding opportunities specify how many awards and how much money they intend to spend on that program. So those have set aside funds. And we have PARs. So, the R there is for special receipt, referral, or review considerations. So those are just special kinds of PAs. So, under this NOFO umbrella, we've got some parent announcements, we've got some PAs, a couple of flavors of them, and we also have ICO-issued requests for applications or RFAs. Okay. So, these are all terms that you're going hear. Now, it's important to understand that NOFO is kind of a new term to us. We haven't been using it for very long. We used to use something called funding opportunity announcements or FOAs or FOAs. Just know that when you see the term FOA, it's equivalent to NOFO. Okay? So, you'll hear us talking about funding opportunities and NOFOs and FOAs and so forth. They're all equivalent terms.

All right. So where do we put these funding opportunities? How can you find them? We have a system called the NIH Guide for Grants and Contracts. Okay? And we will refer to that for short, we just say NIH Guide. Okay? So, NIH Guide for grants and contracts equals NIH Guide. And within there NIH and some of our federal partners, like HRQ, FDA, CDC, post opportunities, okay? Those NOFOs, those notices of funding opportunities get posted in the NIH Guide. Okay. In the NIH Guide, we also post other types of notices. We post notices of special interest, which was referred to as NOSIs, all sorts of terms I'm throwing at you. Remember there's a glossary. Okay? So, we have these notices of special interest, we have policy updates, we have changes to notices. We don't always get it right, sometimes we have to make corrections, and we have to tell you about it, right? So those would be change notices. We also have notices out there about events you may have learned about this event today from a notice that was posted in the NIH Guide. So, all sorts of types of notices are posted there, in addition to our funding opportunities.

We also post all of our funding opportunities at grants.gov. Now, grants.gov is a federal wide system. So, it's used by all the federal grant making agencies to post opportunities and to provide a way to apply for them. So, all of the NIH applications go through grants.gov, okay? So, we post all of our opportunities there in addition to the guide and all of our applications. And you'll learn more about this throughout today and tomorrow, actually route through grants.gov. So, we post all of them in these two systems. In addition, you can find our funding opportunities on institute and center websites, topic specific websites. For example, we have a website dedicated to small business opportunities. So, you'll find that subset of opportunities on that site. All right. So, these opportunities that we're posting kind of have two flavors. We have this investigator-initiated and we have targeted research. So, what do we mean by investigator-initiated? So that is research where the focus originates from your research idea or training need. It has to fall within the NIH mission, but it's your idea that you want to put forward. Okay? And to do that, you would apply through those broad parent announcements or ICO-issued funding broad announcements. Okay? So, these would be investigator-initiated.

We also have targeted, or NIH requested research. And this would be for opportunities where we want to get applications in response to for example, an understudied area of research or we want to take care-- we want to address a high scientific program priority, something like that. So, we're actually putting the science within that funding opportunity and saying, this is what we're looking for. Okay? And we're asking you to submit applications for that. These are the ones that we're going to be your RFAs in your PAs' with set aside funds, okay? So, we are specifically laying out the type of science we want you to put in your applications there, right? So, two flavors, investigator-initiated and targeted.

Once you find a funding opportunity that's of interest, it's going to have everything you need to apply in it, or it's going to link out to some additional information like our application guide. Okay? But a NOFO has the opportunity description, the participating institutes and centers. You have to be submitting an application that fits within the mission of one of those participating institutes and centers. It's going to have your due dates and other key dates. When does it expire? When does it go to review? What's your earliest start date? All of those key dates, it'll have award information, it'll have eligibility information. In fact, for our foreign friends out there, we have a section on foreign eligibility. And it will clearly state whether or not foreign organizations are allowed to apply. It has all your submission requirements, your review criteria, award administration, and agency points of contact. Okay? So, it has everything you need. And then it links out to our application guide for those step-by-step instructions to complete your application. Okay. So, it's all there.

All right. Who's eligible? Now here's a really important point. NIH recognizes the applicant organization as the recipient, not the principal investigator. Okay? The applicant organization is the applicant. In general, that applicant organization can be domestic or foreign, public or private, nonprofit or for-profit. All right? In that funding opportunity announcement, there is an eligibility section that gives any restrictions for that particular announcement. Okay. So, in general, it's pretty wide open, but on a specific announcement, you need to be very careful to check the eligibility. Let's talk a little bit about foreign eligibility. There are certain programs with NIH that foreign organizations are not allowed to apply to. That includes institutional training, program project, center, resource, small business and construction grants. Okay? So those are just off the table for foreign organizations. For the opportunities where foreign organizations are allowed to apply, they were going to be held to the same research criteria as any other applicant with a few additions.

And I'm just going to go ahead and read these verbatim because I think the wording is important. Whether the project presents special opportunities for furthering research programs using unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing US resources. Okay? And the second is whether the proposed project has specific relevance to the mission and objectives of the ICO and has the potential for significantly advancing the health sciences in the United States. All right? So basically, we're saying these are federal programs, they're paid with US tax money. And so, we're saying it has to be within the mission of the NIH, there has to be some special circumstance that says we need this particular population or this particular area or organization, and that it's going to in some way advance the health in the United States. Okay?

A little ahead of myself there. Okay. So, let's talk a minute about early-stage investigators. An early-stage investigator is a principal investigator who has completed their terminal research degree or end of postgraduate clinical training within 10 years and has not previously competed successfully as the PI on a substantial award. Okay? Now we use that phrase, competed successfully on purpose. If for some reason you have to assume the responsibility of a principal investigator on an award that you didn't actually start out as the principal investigator on, that does not remove your ESI status. Okay? So early-stage investigators are within 10 years of their terminal degree or training and have not competed successfully for that substantial research award. NIH is committed to supporting these individuals that hold this status. So, what does that look like? On certain programs, specifically RO1s and some of the equivalent programs to RO1s reviewers give early-stage investigators some special consideration. The applications with meritorious scores may be prioritized for funding. And we do have a few programs that are geared specifically to ESIs. ESI does not come into play for all of our programs, it is just some of our larger, more substantial programs like the RO1.

You're going to hear more about ESIs as we go through today and tomorrow, we want you to just kind of get some basic understanding of what that is. All right. Now we talked earlier about the importance of identifying an IC that might be interested in your research. Most of your contact with NIH is going to be with staff at that IC. So, if I have identified the National Cancer Institute, I'm going to be mostly working with folks at the National Cancer Institute, and they're going to fall into one of these three roles, Program Official or PO, Scientific Review Officer, or SRO, and Grants Management Officer or GMO. Okay? So, the Program Official is responsible for those technical programmatic scientific aspects of the award. So you're going to contact a PO if you need-- if you've questions on a funding opportunity, about what we're really looking for, if you want to check with the fit of your project within the mission of the IC, if you want to talk about progress on an award, or to review the outcome of a review, once that summary statement is out, those are things you would call your PO for.

A Scientific Review Officer is going to be your contact from application through to the outcome of the review. So once that summary statement's out, the PO takes over. But before that, from the time your application goes in until the outcome of review, it's your scientific review officer. So, you would contact them to discuss review assignments, if you had any questions or concerns about review, or if you wanted to submit some post submission materials. There's a limited a number of things that we will allow after submission to come through, and we have a whole policy on that. You would work with your SRO, if you kind of fell into needing to do that. And then finally, that Grants Management Officer. Now this is the administrative aspects of your grant and award. So, your Grants Management Officer is going to work with you on financial and grants administration issues, they can help you interpret grants policies. The GMOs work very closely with the POs. In fact, you'll find in many cases the principal investigators will be working very closely with their POs and the administrators are working very closely with the GMO. Not in all cases, but that tends to be how that works out.

All right. If you have not worked with NIH yet, you are going to have to get through some organization registrations. And these registrations can take up to six weeks or more, so if you're attending this webinar and you have never worked with NIH before, you need to get started on those registrations. Those registrations will be with systems like the System for Award Management, and that is needed to do business with the government, period. And that particular registration, it's a one-time thing, but every year you need to do a renewal of that registration. Grants.gov, again, we talked about that being required to submit grant applications. Remember, all of our applications flow through grants.gov. eRA Commons, which is required to do business with NIH. That's how we transfer information between NIH staff and our applicants and recipients. And then if you are a small business and you are applying to one of our small business programs, you get a bonus registration. And that is with the Small Business Administration. All right. And in addition, some individuals will need accounts in those systems as well. And for example, in grants.gov, if you are authorized to submit an application to NIH on behalf of your organization, you will need an account in grants.gov with an AOR or signature authority role.

Similarly, if you are working in eRA Commons and you are responsible for those submission of those applications, and for signing off on reports and such, you will need an account in eRA Commons with a signing official role. Any senior key that are noted within a grant application, also need eRA Commons credentials. And in May of 2025, we will also be requiring those senior key to have ORCID IDs, and to prepare biosketches within SciENcv. So, you'll need to be able to get into those systems as well. And there's more information about that on our grant.nih.gov website. All right, so that's a lot. I just threw a lot of concepts at you, a lot of lingo. So, let's just kind of wrap this up. Key takeaways. NIH, largest public funder of biomedical research. We provide a variety of federal systems in lots of different areas. In support of the NIH mission, funding is made through the NIH Institutes and Centers and Offices. ICOs post notices of funding opportunities or NOFOs in the NIH Guide for grants and contracts. NOFOs include all the information you need to apply. Your NIH team is going to be Program Officials, POs, Scientific Review Officers, SROs, and Grants Management Officers, GMOs within the ICs. And to do business with NIH, organizations must register in multiple federal systems and certain individuals also need accounts. Okay? So hopefully with that, you have a foundation that you can use throughout the rest of this webinar today and tomorrow. And with that, I will turn it over to my colleague, Dr. Lanay Mudd, and she will start us walking through that grants process with plan to apply.

LANAY MUDD: Thank you, Sheri. And I think we're going to try to fix the slide advancing. So, I'll just go ahead and introduce myself while we're waiting for that. My name is Lanay Mudd. I am the Deputy Chief of the Clinical Research Branch at the National Center for Complementary and Integrative Health. And I'm going to be talking today about really the first step in this process, which is planning to apply. And as scientists, I think we can all get behind the idea of planning and planning well in advance in order to avoid the need to try to squeeze things in and make it work at the end. And so, I'm going to go through planning within your organization, considering your idea, resources, and collaborators, finding that notice of funding opportunity along with the contacts and due dates for that, following NIH application policies and requirements, and knowing what those are. And finally, really thinking about organizing your time to complete all of these steps.

So, I know that NIH can be a little scary when you're first starting to apply. Understanding and applying to NIH funding opportunities can be confusing and it can feel like a very rough and steep uphill climb. I want to reassure you that there are multiple paths to NIH funding and there are a lot of resources to help guide you through the process. So, the first step really is planning within your organization. And you need to realize that applying to the NIH takes a village. No one person can do all of these steps on their own, and so it's very important to connect with the resources that are available to you within your organization and that includes getting to know your Office of Sponsored Research or your Office of Sponsored Programs. These are individuals that really know all the ins and outs of applying to different funding agencies. And so, they can help with understanding all of the internal processes for grant applications, including understanding your institutional deadlines for different steps along the way. They can also help with getting those registrations and setting up within NIH system accounts, providing guidance on how NIH works, importantly, connecting you to experienced investigators and administrators who have done this before, and providing technical assistance for completing different aspects of your application, such as the budget and other types of application parts.

Now, I want to emphasize that many of you are at institutions that have a lot of experience applying to the NIH and they have very experienced offices of sponsored research. Some of you are at institutions who may not have applied to NIH before and may need some additional assistance. And so, I want to share some additional resources that can help you navigate the NIH as well. And these are a couple that I talked to about a lot of constituents about. So, the first is the All About Grants Podcast, and this is a great resource that provides episodes on ins and outs of NIH funding from different perspectives, including Program Officers, Review Officers, and Grants Management Officers. So, they cover a lot of different topics and regularly post new episodes. The other resource I want to talk to you about is the NIH Grants YouTube channel. This is a fabulous resource. You can see all of the different categories of videos from NIH fundamentals, applying for grant funding, early career scientists to peer review and special funding programs and others. Basically, any question you might have about how does this work at the NIH? There's likely to be a video about that question that's posted on this channel. And this content is regularly updated so that it reflects the latest NIH policies.

In addition, if you are an early career researcher or a student, a pre-doc or a post-doc, I also want to point you to our researchtraining.nih.gov website. This is really a one-stop shop for all funding opportunities that are specific to these career stages. And so, there's lots of resources on this page, including an overview of all of these different funding opportunities, the contact information and links to training information for each institute and center and several other resources. All right, so once you've connected to your Office of sponsored programs, the next step in planning your research application is to consider your idea. You want to start with the science. What is it that you are interested in that you want to study? And you want to ask yourself, is this unique? Has this been done before or am I proposing something new? So, to do that, you want to do a literature search, and we also highly recommend that you use the NIH RePORTER system, which is pictured here. There's going to be an interactive activity on this tomorrow, so I'm not going to go into details about how to use RePORTER. This is a publicly available database of every award that NIH has made. So, you can put in search terms related to your science and see all listing of grants that have been funded that are related to that science. You want to look through and make sure that the exact thing that you're proposing isn't already funded and that what you are proposing is building on the science that is underway or has been completed. If you are doing clinical trial research, another great resource to search is clinicaltrials.gov. So, you can see other related trials that have been done or are ongoing.

The other thing to think about in terms of your idea is, is this something that you've already submitted for funding somewhere else? One note is to realize that you cannot submit duplicate proposals to the NIH at the same time. We consider this a waste of our resources, and really, we want to value our reviewers time and make sure that they're not reviewing duplicate proposals at the same time. In addition, NIH will not fund research another organization is already funding. So, with that, the other aspects in terms of your scientific idea to think through is what do you need to complete your research? What equipment or facilities, access to human research participants, or animals, or existing data sets do you need? Are there other resources that you need such as software for your methods, and do you have access to those resources at your institution or is that something that you need to incorporate into your grant application? In addition, what expertise is needed for your research? Most science at this point in time is team science. And so, you want to think through, do I need statistical expertise, methods expertise, human subjects research expertise? Are these collaborators that I already know and have worked with before or do I need to go out and find new collaborators? If you need to find new collaborators, that Matchmaker aspect of RePORTER that was just talked about can be a great way to find other people who are doing similar science that you might want to collaborate with.

Another aspect to think about in terms of collaborators are, are these individuals inside your institution already or are you going to be collaborating with people who are at different institutions? And if that's the case, you may need longer to prepare your application as you're going to need to think through things like subcontracts. And finally, do you need to be connecting to community organizations in order to get access to particular human research participants or just as collaborators in your research? And again, you may need to start early to develop those relationships. We do recommend starting very early on letters of support as these can take a long time and you don't want to get to the end of developing a complete application only to find out that the community organization you were planning to work with is unwilling to provide a letter of support. So, make sure that you talk about this early in the process and start working on it. All right. So, after thinking through your idea, the next step of planning is to find that notice of funding opportunity that fits the research that you want to do. And as has already been described, there are many ways to find different notices of funding opportunity. You can certainly search the guide in grants.nih.gov, or you could utilize a parent funding opportunity for investigator-initiated research. It is critically important for you to think about which institute, centers, and offices fit your research and make sure that the IC that you're interested in actually participates in the funding opportunity that you decide to apply for. In addition to participating, you also want to know do they have any specific funding policies for that funding opportunity? So, it's important to become familiar with that.

And then finally, making sure that that selected funding opportunity allows the type of application you plan to submit. This can include things like a revision or a renewal application, or a resubmission. It can also include things like whether or not you are including a clinical trial in your research. So, I want to circle back to this idea of finding a home for your research, and we've already talked about this a couple of times. And I think that just highlights how important it is. You really increase your chance of being funded if your research is well aligned with the strategic plan and scientific priorities of the specific institute, center, or office that you are applying to. So, to do that, you want to review the strategic plans and priorities of several different institutes and centers and think about which one best fits your science. And the reality is that you might come away thinking, oh, I think I could fit in with two or three or maybe more of these different institutes and centers. At that point, you want to explore their websites a little bit more to get a better understanding of how they operate, what funding opportunities they use and don't use, what their interests are as stated on their website, if they have specific funding strategies that they employ. And several times these institutes and centers have specific resources posted on their website, including blogs that provide more explanation about how they use different funding opportunities. You can even sign up to get email updates about different blogs and new funding opportunities from different institutes and centers that you're interested in.

All right, so the other thing to realize is that Program Directors are a resource for you as you try to navigate this. So, like I said, if you come up with two or three or maybe more institutes and centers that you're thinking about, don't be shy. Reach out to a program director and run your idea by them and say, hey, does this fit with the type of science that your IC funds? We can provide insight into that funding process and explain how our institute and center operates and provide that feedback about whether your idea is a good fit with our priorities or not. So, you can find Program Directors to contact by looking at the scientific contacts and the funding opportunity that you're interested in applying to. These are typically listed towards the bottom of the funding opportunity or again, by using that Matchmaker function that we've already talked about. Now, once you've found a funding opportunity that you're interested in, you do really want to check your eligibility to make sure that both your institution fits the eligibility criteria and that you as the PI fit any eligibility criteria. Highlighting foreign involvement as we've already said, some notices of funding opportunity do not allow foreign institutions or components as specifically small business, and fellowship and training grants also have US citizenship requirements for the PI. And as we've already said as well, funding of a foreign award is unlikely if comparable research can be conducted in the US.

The other aspect that you want to look at in that notice of funding opportunity is key dates. And this is really important when you're in the planning mode to make sure first, that the funding opportunity is not expired. And then secondly, making sure that you can make the application due date considering any institutional due dates that might be in place ahead of that. And so, this is just an example table that you might see within a notice of funding opportunity. You can see the application due dates depending on your application type. For new applications, renewals, resubmissions, or revisions, and then if you have AIDS-related research. And then depending on your application due date, it will also list the approximate timeframe when scientific merit review will take place, and then advisory council review, and the earliest start date. And just note that it's about an eight-month lag from the due date to the earliest start date should your application get funded. Once you've selected the funding opportunity, it is important to know and play by the rules. So, you have to follow all NIH application policies and requirements. And these policies may vary slightly by the area of science that you are applying to and the award type. So, for example, there are policies on application submission, there are scientific data sharing requirements and financial conflict of interest, as well as potential foreign interference policies, and scientific reproducibility policies. This is not an exhaustive list, so you want to, again, work with your office of sponsored programs to make sure you're aware of the policies that apply to your application. Also, NIH publishes policy changes in the NIH Guide and any changes in policy will be listed in the related notice and section in part one of every notice of funding opportunity.

Additional requirements may apply depending on your type of science. For example, human subjects' requirements for pre and post award, and inclusion policies, and IRB, clinical trial requirements, and animal research requirements. And I just want to emphasize that the NIH has a very broad definition of clinical trials. So, your research may qualify at the NIH as a clinical trial even if you would not define it that way. So, make sure that you review that closely because that actually determines the different funding opportunities you're allowed to apply for. Every funding opportunity will note whether or not a clinical trial is allowed. In addition, some applications do require NIH prior approval before you submit. This can include large budget requests, support for scientific conferences and ICO opportunities. The last thing I want to emphasize as part of planning your application is organizing your time. And we recommend creating two separate timelines. The first is thinking through the scientific timeline for the research that you want to conduct. The second is organizing a writing timeline with all the different aspects of the application and what they'll require. And these are just a few example bullet points that might be on those timelines, make sure that you incorporate a lot of time to write and revise and write and revise and have others review and then revise and so forth. And make sure that you incorporate time to talk to the NIH well in advance of the application due date.

So just to sum up my key messages here, first, it takes a village. You want to make sure you get to know all of the folks at your institution who can help you with your application. Secondly, focus on the science. Let that drive all of the decisions that you make, find the right fit in terms of the funding opportunity and the institute or center at the NIH that best fits your science. Know and play by the rules and realize that this takes a lot of time and make sure to plan that in advance. Thank you so much and I'm going to now hand it over to my colleague LeShawndra Price to talk through the next steps.

LESHAWNDRA PRICE: Hello and good afternoon, everyone. Or whatever time it is around the world where you are, it's great to see you. So, you have been introduced to the NIH, you've heard about completing the required registrations. We've discussed how to prepare, to apply, and who can help you at your organization or institution, and who can help you at the NIH. Now you are ready to write your application. So today I am going to share with you a few pointers about the application process from the view of how to apply. So, we will talk about how to apply, the forms, the forms directory, and general grant writing tips and advice as you draft your application. So where do you get started? Well, the NIH Application Guide is your how-to manual. The Application Guide and the NOFO, the Notice of Funding Opportunity, provide the forms, the application information, and instructions for your application. So be sure to read the general instructions and then also read the instructions for your specific activity code. For example, you'll remember the activity codes are things like the RO1, the research project grants, the K22, for example, or the G11. So, you'll recall those from the earlier discussion of activity codes. Now, the forms directory is a searchable, consolidated listing of forms, format pages, and instructions. And this is an excellent tool to help you as you apply.

As you're drafting your application, you'll find several kinds of fields in the application forms. Sometimes you'll see check boxes, dates, there'll be fillable entry fields and attachments. And the NIH has very specific attachment formatting requirements. Failure to follow these requirements may lead to application errors or even worse potential withdrawal of your application from funding consideration. So, a keyway to ensure that you are setting yourself up to be successful is to ensure that you're paying close attention to the formatting. Now, the link at the bottom of this slide titled Learn more: Format Attachments, provides specific guidance, it leads you to specific guidance on formatting, including guidance on documents that are prepared outside of the grant application. So whatever software that you're using, the editing software you're using, something like Microsoft Word, whatever you use that you eventually will convert to a PDF and then upload to your application. So be sure to take a look at that link.

Now, as I mentioned previously, there are several kinds of fields in our applications. The How to Guide provides rules for text fields and specific information about page limits that are key to preparing your application. Be sure to always follow the policies related to text fields, which also help applicants ensure that their applications are well organized. And make sure that you follow the page limits to ensure that your application is error-free and meets the application requirements. Now, Sheri and Lanay already discussed how you can make sure that you or the investigators that you work with are ready to apply. So, let's talk about tips for grant writing. These are three tips that I think are absolutely key. First, a well written application, a well formatted application is your key to being successful. Applications that are organized, that are clear, concise, and realistic, fare well. As a writer, you want to make it easy for readers to follow your ideas in your application. And specifically, when I say readers, I'm thinking about the reviewers that will review your application. So, you want to establish a clear structure for your application. Use headings, use lists, use bullets or short paragraphs and make sure that your sentences are not overly complex. You want to communicate your ideas clearly and succinctly. That is key to the process. You want to make your points as direct as possible.

And as you dive into your writing, start with your specific aims. You want to write and revise, Lanay, I think just said this. Write and revise, write and revise, write and revise, and build in time to even take a break so that you can come back to your application to write and revise some more and ensure that your application can be well understood and that it's realistic and not overly ambitious. Now I want to talk about this term, overly ambitious. Well, overly ambitious is not a compliment. In fact, it's actually just the opposite. Overly ambitious applications indicate that you're trying to do too much, and the potential result of that is a lack of feasibility. So overly ambitious applications promise more than is actually feasible during the project period. So, you never want to see overly ambitious in a summary statement or a description about your application. So be sure to pay attention to your terminology also. Be sure that your consistent with your terms, with your formatting, the way that you cite information, and your writing style.

Now as you're writing, remember that reviewers are your primary audience. So, you want to stress the significance of your work, don't make your reader, the reviewer, don't make them guess. Include enough background information to enable them to understand your work. Use figures, and diagrams, and charts, or other graphics to summarize and elaborate on your plan. So, when you're talking about your project, those are keyways to help you explain what you're planning to do. And make sure that you edit. Writing Your application will likely involve drafting your application, as I mentioned, reading it, revising it, coming back to it, and reading it again with fresh eyes. Enlisting help is a great way to improve your application. So, reach out to more experienced investigators and even investigators who have very little experience or don't know about what you're proposing. Junior colleagues on your team can be great at reviewing your application because if it's something that they're unable to understand or they're not able to follow, then that might tell you that you need to edit and revise some more. Some organizations and institutions even have editors or funds for editors, so you may want to inquire at your institution about whether those services are available.

Now I'll share information about specific areas within your application, starting with the specific aims section. Now the specific aims will ideally address and collectively answer your overall scientific question and address any gaps in your field or interesting or significant issues. The goal with your specific aims is to grab the attention of your reader and to focus on what can be accomplished in that four-to-five-year grant. And most of the time, typically research project grants, focus on three related aims. Again, make sure that you're telling your reviewers what the results will mean and be clear and concise and explicit. The research strategy is the largest narrative section in most application. The three main sections are the significance, innovation, and approach. Significance answers the so what, question. Innovation is where you present a strong case for how the research will be paradigm shifting. And the approach is how you're going to do it. Now, the link at the bottom of this page titled Learn more, offers more specific guidance in the how-to application guide specific to the research content strategy section.

Now many investigators find the budget section to be very time consuming. So as Lanay mentioned earlier, start early, make sure that you know what the budget requirements are for the particular NOFO, and work with your office of sponsored programs or your departmental administrators on the components of the budget. When you have questions, don't hesitate to reach out to the financial or grants management contact that is listed in the NOFO. Especially, if you have questions about allowability or other budget kinds of concerns. And then make sure if you need to request prior approval for an application because the budget exceeds more than $500,000 in any single year of the proposed project, you want to make sure that you're reaching out early, at least six weeks before the submission date. And I encourage you to plan ahead. Now, I'm going to quickly talk about the characteristics of outstanding applications. Those include applications that have impact, that address very important public health problems, they have an excellent, well-qualified group of investigators that are leading the work, there's clear rationale for the project, the applications are very focused. You want your application to be a joy to read. So that also means things like there are no typos and problems, et cetera.

Now, the other thing is what are the characteristics of weak applications? Well, these are some of them, remember, weak applications are often overly ambitious. They may only make incremental progress, they're not innovative, the team lacks the experience needed to conduct the research, the work is not feasible, it's messy, there are typos. You don't want your application to be the one where a reviewer says, "There were so many mistakes. It angered me to read this." Remember, your goal is to be a joy to read the application. And I believe last but not least, a lot of times people often ask about sample applications. So, on this slide and at the links that are presented here, are sample applications and summary statements from across the NIH and there are lots of different formats, there are also formatting examples, language examples, and other examples there as well. So, I encourage you to take a look at that. Now, I'll turn things back over to Megan to lead us in, I think a little bit of Q&A.

MEGAN COLUMBUS: Thank you so much, LeShawndra. If I could get my fellow speakers up here with us. All right, there we go. We've got Sheri and we have Lanay. All right. I'm not there yet, but that's okay. I could be headed from beyond. Okay, so Sheri, why don't we go ahead and begin with you. Can you give everyone a general idea of how long the process is from the time you actually apply to peer review and then to funding?

SHERI CUMMINS: Sure. And I'm certainly hoping the slides are going to cooperate with me now. Oh, do we have control? Here we go. All right, so the NIH grants process, and we've already gotten a start on it, we've started with write and submit, but let's take a peek at this timeline. Okay, so the writing phase, so we just talked about all the things you need to do in that writing phase. You're going to start this three to six months before the due date at least, right? So that's leading up to the submission of your application. And then you're going to move into that submit phase. Now, we're going to talk about submit, review, and award later, but just at a very high-level let's kind of walk through the timeline. So, for submit, at least two days before the due date. So, we always say submit early, and we mean days, not minutes or hours. So at least, two days before the due date, you're going to submit your application. Okay? And then on the due date, you're going to have a nice big sigh of relief, you're going to pat yourself on the back and be thankful you didn't wait until the last minute. All right? But two days before the due date you submit, and then it goes into review. So about two weeks after the due date, okay? You're going to be able to go into eRA Commons and you're going to check for your IC and review assignments. Then about four to five months after the due date, that's when we're going to go through peer review. So that's going to take place.

You can check eRA Commons for scores about two to three days after your peer review meeting and the summary statement about a month after your meeting. Okay? So now we're already four to five months after that due date. After the peer review, it's going to go through a second phase of review, which is advisory council. And again, you're going to hear about that more this afternoon. And then finally, we're going to go into the next phase, which is your award. And that's going to be about seven months after the due date. You're going to start getting-- if you're within a favorable range, your scores fall within a favorable range. You may be asked for some just in time information, and then somewhere around eight to nine months after the due date that's when you're going to get a notice of award if selected. All right? So, we're talking about an eight-to-nine-month timeframe between that submission of your application and due date until that award comes through.

MEGAN COLUMBUS: Great. That's super helpful, Sheri. Thank you.

SHERI CUMMINS: You bet.

MEGAN COLUMBUS: All right. LeShawndra, let's move to you. We have a lot of people here from all over the world, and our international investigators and often sponsored research are wondering whether non-US citizens or international scholars are eligible for NIH grants. And just so you know, we do have entire webinars that are dedicated to that. But LeShawndra, how about a quick answer here.

LESHAWNDRA PRICE: Sure. Yes, non-US citizens and international scholars are generally eligible to apply for NIH grants, although there are some specific NIH programs that do require citizenship and permanent residency. And I recall that either Sheri or Lanay mentioned some of those. Most funding opportunities, however, are open to non-US citizens for most research project grants. And the principal investigator does not need to be a US citizen to apply. Foreign organizations are able to apply for NIH grants, but there are certain limitations in some cases. So, it's always very important to check the NOFO for the specific requirements, always review the NOFO to see if there are citizenship restrictions. And I believe, I think, we may have a slide that talks a little bit about some of the key information here. Megan, can you walk us through this slide?

MEGAN COLUMBUS: Yes, absolutely. I just wanted to provide some of the resources that we provide on the NIH grants and funding site. We have an information for page specifically for foreign grants. It'll talk to you all about foreign grants, what it means to be a foreign prime, what it means to be a sub-awardee, and we actually have a webinar. There's a whole series of webinars actually, that you'll find on this page. But I pulled out just one on Understanding International Collaborations because I think that's a great place to start. Right? And so, no, we're not going to be able to answer your questions all about these things in the primer today. But lots of questions have already been answered and information is out there for you. All right, thank you so much, LeShawndra. Lanay, turning to you. So, we've got lots of early career researchers out there, and so what funding programs are appropriate for them or for clinicians even?

LANAY MUDD: Sure, thanks for that question. So, I'm actually also the Training Officer for NCCIH. So, I often give talks to early career audiences. And as I mentioned in my talk, I strongly recommend that early career researchers and clinicians consider funding mechanisms that are restricted to other applicants that are at the same career stage as you. So, this can include the F mechanisms which support individual fellowships for pre-docs and post-docs and dual degree MD/PhD students. There are also NIH supported institutional training programs like T32s and T35s that also support pre-doc and post-doc students. And then RK mechanisms that support mentored career development. And there are early career Ks as well as mid-career Ks. So, there are a lot of different FTs and Ks that are described in detail on the researchtraining.nih.gov website. So, I highly recommend exploring the career path links and the kiosks on that website. Another important program to be aware of is the NIH Loan Repayment program. This can help researchers pay off educational loans and help them stay in scientific careers. So, you can also check out more information about the loan repayment program on their website, which is lrp.nih.gov.

MEGAN COLUMBUS: Great answer, Lanay. And that was a lot of information. If you want to explore, we have the research training website that Lanay mentioned. We also have the new grants site; our funding information has evolved. And so, I highly recommend that you explore this research training career development link here because I think you'll find a lot of information about what might be good for you, and lists of funding opportunities, and those kinds of things as well. Wonderful. Let's see. Lanay, I think this one's for you as well. Can you talk to us about what NIH takes into account when making funding decisions?

LANAY MUDD: Sure. This is another great question as practices can really vary between different institutes and centers. So, this is a good topic to discuss with a Program Officer when you are preparing to apply to make sure you understand the practice at that institute or center. So, some of the items that get taken into account include the outcome of initial peer review, which is your score or your percentile. Then the recommendation of the advisory council, which you'll hear more about later today, and the fit of your science with the mission of the institute or center that you're applying to, and particularly if you're filling a particular gap that they're looking to fill. There are also program priorities as well as congressional band-aids that can come into effect. And of course, the availability of funds. And so, for example, right now we're operating under continuing resolution. And so that can impact our funding decisions as well. And just it's important to know that it's actually the IC Director that makes final funding decision and it's never peer review. So, peer review does not make funding decisions, they only review the application. So those are a few of the things that can come into play.

MEGAN COLUMBUS: Thank you so much. LeShawndra, can I come back to you about what is an early-stage investigator? I know we talked about it a little bit already but we're getting lots of questions about it, and what's the benefits of applying as one?

LESHAWNDRA PRICE: Sure, Megan. So, an NIH early-stage investigator is a researcher who has completed their terminal research degree or medical residency within the past 10 years, and that individual has not yet secured a substantial independent NIH research grant. So, the benefit to applying as an ESI is that grant applications from early-stage investigators receive special consideration during the peer review process and funding. Now, when applying for an NIH grant as an ESI, the applications are prioritized during review, meaning that reviewers will place more emphasis on the potential of the research idea rather than the established publication record, for example. And the other thing to keep in mind is that some institutes have separate higher pay lines for ESI applications compared to established investigators. Now, to claim your ESI status, it's very important that the individual, principal investigator or the researcher ensures that the date of their terminal degree completion or the date of their completion of medical residency is accurately updated in their eRA Commons system. Megan, I believe that at OER you all are responsible for the ESI webpage. Is that correct?

MEGAN COLUMBUS: We are, indeed. And so, I love your advice about making sure that your Commons profile is up to date because all you need to do to make sure that we understand that you're ESI eligible is have those dates in there and then we'll know. We have the ESI website which also has a chatbot there that can help answer questions and get you to the right answer in an FAQ. And so, I encourage people to explore that because I see we have lots of questions coming in about ESIs. All right. LeShawndra, how can an applicant decide which institute to apply to and which funding mechanism or activity code would be best?

LESHAWNDRA PRICE: That is an excellent question and one I receive quite often. And I believe earlier, maybe Sheri showed the NIH Matchmaker tool which can help find potential matches for an application. That will break down the results by institute or center, as well as by activity code like RO1, R21 or RO3. And as well as for study section, so you know where an application might be reviewed and Program Officers. So, it gives you a lot of information. And if you want to see how RePORTER really works, join us tomorrow afternoon where we will walk through all of the fantastic things that RePORTER does. As you're thinking about finding a fit for your research at NIH, another way to find information other than the tools that were mentioned earlier today, is to contact a Program Official. We are also called Program Directors, Health Scientists Administrators. Bottom line, contact someone at the NIH. And we can advise you on whether your research is a good fit for the funding priorities at our institute or center. Another way to consider it, and I think that Lanay talked about this, is sending a concept paper to a Program Official if they will accept it. Sometimes people are too busy, and they don't want to disappoint you knowing that you're in a timed process and focusing on a specific submission deadline. But if a Program Official will accept a concept paper, send one because it can help you ensure that your proposed project is appropriate and on target with the interests at that institute. I also suggest talking with your mentors and more established investigators that work with you and your office of sponsored programs or departmental officials because they can also help you with navigating the grants process and selecting the right activity code for your work.

MEGAN COLUMBUS: Great. Lanay, did you have anything to add to that? You're also a Program Official.

LANAY MUDD: Sure. I mean, I think that's a great response and maybe I'll just add a little bit in terms of what to say when you're contacting a Program Officer. I know there's a lot of hesitancy and a lot of people just get scared about it, and so they don't send that email or try to have that phone call. And I want to emphasize that we actually do like to talk to scientists, and we like to talk about your research. And so, when you are contacting a Program Officer, I recommend starting with an email and as LeShawndra said, please send us a summary of your idea, whether that is your draft aims page or a brief paragraph that summarizes your research idea. It's helpful to include that as an attachment in your initial email to us along with the specific funding opportunity that you're interested in if you've identified one, maybe that's one of your questions and that's fine too. And any specific questions that you might have, just in a few bullet points. That helps us determine whether I'm the best person for you to talk to. So, I might get an email and say, oh, this is not science that I oversee, but my colleague Dr. Chen does. So, I'm going to forward this to Dr. Chen, and she'll respond instead of me. Or it might be that you send me an email and the science, I say, oh, NCCIH is not the right home for you, and I can send you back an email that immediately says, I think you need to talk to the National Institute of Aging or the National Institute of Mental Health instead. We're trying to find the best home for your science, and so anything you can do to help us make that determination prior to setting up a call. So, you need to realize that while we love to talk to you, we are also very busy, so it might take us a few weeks before we have availability for a call. So that's why it's important to reach out to us early.

The other thing I would say is, please, don't spam POs by sending the same message to a large group of us at the same time. It's true you might want to speak to more than one Program Officer, but you want to tailor your message and get feedback from one person before trying to reach out to another.

MEGAN COLUMBUS: Great. Thank you so much. I think one more question. Sheri, circling back to you. How could potential applicants and recipients keep up with the latest changes and resources on the grants process, like what's the best way for that to happen?

SHERI CUMMINS: All right, so we talked about the NIH Guide for grants and contracts, right? And that is our official publication of changes and notices and policy updates and such. So, I highly recommend that if you have not done yet done so that you subscribe to our weekly emails that give you a listing of all of the postings we've done for the week. You can find the subscribe link on the NIH Guide for grants and contracts itself. Also, on the news and events section of the grants.nih.gov site, you're going to find links to all sorts of materials. All of our social media, you'll find links to our blogs, the open mic blog our Extramural Nexus newsletter. If you want updates on eRA Commons, there's a list there for that. So, spend a little time in that news and events section. We also have a distribution list for events like the one we're in right now. So, there's lots of places that you can go and sign up to get more information. CSR also, on their site has some places that you can sign up for information there. And if you're working with a particular institute and center check out their site, a lot of them have blogs and newsletters specific to those communities, so check those out as well.

MEGAN COLUMBUS: That sounds like a lot.

SHERI CUMMINS: It's a lot, right?

MEGAN COLUMBUS: It's a lot. It is a lot. But better to over-communicate than not. Now for the second part of today, we're going to be talking about submission and the review process, understanding award and the processes associated with that, what it means once you've got the award, just a little bit on monitoring and reporting and making sure that we're reinforcing those resources and answering some of those questions that you submitted ahead of time. All right. So, let's go ahead and get started with Dr. Michelle Timmerman.

MICHELLE TIMMERMAN: Hi everyone, I am Dr. Michelle Timmerman. I am an Associate Director and the Guide Liaison Officer in CSRs Division of Receipt and Referral. So, I am one of the first human beings at NIH that will see your application after submission. Okay, so are the slides advancing?

MEGAN COLUMBUS: Yes.

MICHELLE TIMMERMAN: Great. And so, we are at the submit portion in your idea to funding timeline, and what I'm going to be talking about is the way that you submit in your systems and then what happens after submission. How things are checked for completeness and compliance and your relevant submission policies. So, the first thing with submission is to be sure you submit on time, and that's a little more detailed than simply the term on time. What we mean by on time submission is that your final error-free submission is submitted by five o'clock your local time on the due date. So, when I say your final error-free submission, I mean the last time you click submit on your computer. That is because we have no error correction window to fix things like submitting the wrong attachment or forgetting to put a name on it after the due date. So, it's very important that you submit early so you can use your two-day viewing window to correct problems before the due date. We do have a late submission policy, NOT-OD-15-039, however it applies in a few situations. Think of it more as humanitarian situations rather than an extension of the due date.

Now, if there are problems with our federal systems, that is something we will take into consideration but there's a process for that. The first thing that you have to do is document those issues with our eRA service desk before the due date, and that's even if the problem isn't with eRA itself. And I will warn you, federal systems issues are rare, but frustrations with your computer, that is a lot less rare, and those things do not qualify for late submission. So, this is why it's important to submit early. And submission doesn't end when you click the submit button. We actually use the phrase submit, track, and view. So, you would submit through assistgrants.gov workspace or your own organization system to system solution. And again, I will say this many times, submit early. It's so important, we created a hashtag, #SubmitEarly, and we created a slogan measure early on a calendar, not a clock. And again, that is because we want to be sure your application is received on time, and we can accept it.

So, after you click submit, you then have to track your application in grants.gov and eRA Commons. And we do say that you need to do this in Commons, don't rely on email notifications. So grants.gov validates a few federal-wide issues like is your NOFO expired. Commons is going to be validating about 6 to 800 pages worth of NIH-specific issues. So, you would be typically seeing your application image in Commons within half an hour to four hours. And that is the final step of submit, track, and view. You have to look at your application and image Commons and this is the exact application image that we receive. So if text is garbled, if there's an attachment missing, it's not lurking around somewhere in our system, this is the real thing. And again, I think I'm up to my fifth time now mentioning this, there is no error correction window. So if you want to be able to correct that garbled text, it's important that you submit early so you can do so. Otherwise, you'll have this two-day viewing window where you can sit and view your garbled text knowing that if you replace it, you'll be after the due date.

And so, I talked about the validations, but it's important to keep in mind that validations actually only enforce some of our requirements. Now we have two types of validations. One of these are errors, these are an electric bar to submission. It means that your application was not accepted. There is not an application in the system that I can go into and look at. The other type of validations are warnings from Commons, and we talk about how you have to resolve warnings and that might be deciding that you don't need to change anything. Now that is because our validations are not AI, all they can do is flag high-risk topics. And so what these warnings do is they let you know that the application got in the system, but there is something high-risk for being wrong about it, and staff like myself rather than systems are going to check it. And this is important because when staff check that application, the decision might be that there is something wrong and the application needs to be withdrawn. And I will be very unhappy and the applicant will be even more unhappy.

And so here are some of those checks that are done only by NIH staff. Any NOFO-specific requirements, those are not validated. And I also want to remind you that those NOFO-specific instructions only apply to that NOFO. The content of the attachments is not validated. We have received completely irrelevant attachments like recommendations for nannies to NIH applications because, again, that content is not validated. And the presence of unallowed extra attachments or extra material on an allowed attachment. That's also something that's not validated. And just something to keep in mind when we talk about reading the application instructions thoroughly, I also say to read the application instructions with your head rather than your heart. So, the application instructions state what is allowed and nothing else is not allowed. And your heart might think it'd be awfully nice if I could put this information about my approach on a different attachment. And what your head will help you realize is that no, that extra material is not allowed.

And so, the next thing that happens after your application is submitted and you resolve the errors and the warnings, and the application passes your two-day viewing window, it then reaches NIH, and it actually gets handled by actual real people who are neither robots nor trolls. And I am one of them. And what first happens before it gets peer reviewed is what we call the receipt and referral process. So here I'm going to talk about application referral and your assignments to either an institute or center, and I'm sorry, I'm a government official. I might use the acronym IC, but I will try to call this institute, and your review group assignments. And I'll also talk about how you can communicate with us on the assignment request form. And so, referral is the process by which applications are assigned to an institute or center and a review group. And this is done by scientists, again. And what we do is we progressively sort an application by topics, and we do this concurrently for the review group assignment and the institute assignment. And at each level the topics are getting progressively more focused. Now the procedures vary, but typically four scientists will look at the application at each of those more focused levels. So, all of these decisions are made by scientists. You see some of the tools available that I'll be talking about later that are based on data scientists like myself have created, but all of the assignments are done by actual scientists.

And the way that we do this is the CSR review groups, and the ICs have created lists of topics for the applications that they each handle. The way that we communicate all of this is on eRA Commons and the information is updated throughout the pre-review period. If you're like me, you're probably checking Commons three times a day because that's my personality. But there's really a few times where you should be more focusing your attention in Commons. So, assignments are usually visible within two weeks, and you'll get this information progressively, but at the end of the full period, you will see the IC assignment, a full grant number, a review group, and then two names of a Scientific Review Officer and a Program Officer. Now what you will also see are official communications linked in Commons. You will typically receive an email, but we strongly encourage you not to rely on that email because it will be potentially unreliable. And instead, you should regularly check Commons to see if there have been any notifications or any actions that you need to take. What you will also see later on in the process is the meeting date and the list of reviewers. Then I'll say this a couple of times, do not contact the reviewers, only contact NIH staff.

And so, of your two assignments, one of them is the institute and center assignments. So, this is the person, the group who will be writing the check and funding your application. Many people are proposing research that it is potentially relevant to multiple institutes. For example, who supports lung cancer? Is it the Heart, Lung and Blood Institute or is it the Cancer Institute? And the institutes get together and they decide those topics and they delineate the how those topics are going to be assigned and shared interests. And I encourage you strongly to talk to Program Officials about your research to be sure that it can be assigned to an institute or center that participates in the NOFO. And the RePORTER Matchmaker is a great opportunity to find those individuals. And this is critical because if your application cannot be assigned to an institute or center on the NOFO or an OC but I'm not talking much about those, your application will be withdrawn. And again, I will be unhappy, and you will probably be even more unhappy. So, this is why making sure your application can be assigned is so critical. And here is how you can tell this on your NOFO, in the first screen that you see in the NOFO, in the section that says Components of Participating Organizations, make sure your intended institute or center is listed there. And again, reach out to Program Officers there. It is literally part of their job to have these discussions with you. Do not be shy about reaching out to them.

Now, the second assignment that you will receive is the review group assignments. Many PDs, PIs share review group assignments, and I assume that your colleagues will tell you it is extraordinarily important to share suggestions. But I want to reassure you is an application would never be withdrawn because there is not an ideal CSR review group assignment. We also have a tool, the assisted referral tool that can help you identify CSR review groups. And again, I want to reiterate that you should contact the NIH Scientific Review Officers rather than reviewers. Now, some notices of funding opportunities have special review arrangements. Then this also includes reviews convened by the institutes and centers themselves. And these NOFOs will list a peer review contact at the end of the NOFO in the agency contact's section. And here is how you can tell us what your suggestions are. Do not use the cover letter, that hasn't been the process for at least eight years now. Instead, we have an optional form called the Assignment Request Form. And you use this to enter your suggestions. You can suggest assignments and provide rationales. And particularly, if you have had a discussion with a Program Officer, that's an important thing to note in your rationale. You can also list areas of expertise that are needed to evaluate the application. And these again, are your suggestions because DRR will make assignments based on those topics that are delineated by the institutes and by the review groups.

MEGAN COLUMBUS: Okay, so with that, we're turning it over to Dr. Stephanie Constance to talk about peer review.

STEPHANIE CONSTANT: Thank you. And thank you, Michelle. I am Stephanie Constant, I'm the NIHs Policy Review Officer, and I am part of the Office of Extramural Research. And so, I'm going to be covering the peer review process. Essentially, we have to assume your application has made it through the Division of Receipt and Referral, and it is compliant and it's ready for review. So, what I want to go over with you is the first level of review, the second level of review that the application will go through. Who to ask for questions at each of these stages and some tips throughout the slides. So, you might have heard right at the beginning, Dr. Lauer mention that we receive a lot of grant applications and actually typically we receive more than 80,000 a year. In fact, in FY fiscal year 2024, we received close to 85,000 applications. And so, the big challenge at the NIH is to determine which of these applications should be funded. In other words, which ideas should be funded. And this is the purpose of peer review, is to be able to evaluate the applications and determine which of these are the scientifically most meritorious.

So, I mentioned there were two levels of peer review, and this is actually a requirement. We have a Public Health Service Act that requires for a grant to be awarded by the NIH applications must go through two levels of peer review. The first of these is a written description of the work, which is the application must be reviewed by a Scientific Review Group or SRG. And the second level is that the outcome of the SRG review must then be provided to the funding institute or centers advisory Council for a second level of review. So, I'm going to go into more detail about each of the levels. So, level one, the Scientific Review Group or SRG. So, the purpose of level one is to evaluate the scientific and technical merit of the work proposed in the application. And again, we have legal requirements for the makeup of SRG panels. They must be experts in the relevant scientific or technical field, they must have broad to diverse scientific views, and there must be a balanced representation within the panel. Now, in terms of what types of expertise are included in panels, it's going to be dependent on what kinds of applications are going to be reviewed. So, in the case of research projects such as RO1s, we would typically have mostly basic or translational research scientists. If they're clinical type of applications, we would of course include clinician scientists as well.

For small business applications, we would invite biotech entrepreneur-type researchers to serve as reviewers. And then of course, if we have training grants, we would want to have research mentors, we would also bring in evaluators, modelers, economists, whatever the type of expertise is needed for the applications that are being reviewed. So, my first tip is that SRG rosters, Scientific Review Group rosters are publicly posted, and you can check out their membership, and I've put the link here. And this is a good way for you to get a sense of what kinds of reviewers, what types of expertise on that review group are going to be evaluating your application, and whether it's an appropriate panel to be reviewing your type of research. So, what type of criteria do reviewers use to evaluate the applications? So, it's very important, and again, we have a legal requirement for this, that standard review criteria must be used for certain types of applications. So that means all the applications within that type will get to using the same standard review criteria for their evaluation. So, in the case of research grants, again, these are RO1s, R21s, et cetera, we have what are called the five regulatory criteria that are regulated. These include significance of the goals, the investigators, whether they're qualified and experienced, is the project innovative, original, are the approaches and methodology being proposed adequate? And is the scientific environment and the resources available for the research appropriate?

For certain types of applications, there may also be a need to evaluate protections of human subjects and animals, the adequacy of inclusion plans for gender minority in children, of course, this is very important for clinical trial applications, and then the reasonableness of the proposed budget. Are you asking for too much money relative to the work being proposed? And all of these criteria are pulled together in order for the Scientific Review Group to provide an overall impact that the project could have on the research field. Another tip for you is that section five of the notices of funding opportunity, and you will have heard this already. Section five is where the review criteria are located. So, look at the review criteria in the NOFO to which you are applying so that you can see what kinds of criteria the reviewers will be using to review your application. Then you can make sure that you are addressing these review criteria. So, review criteria actually are divided up into different flavors and they're used in different ways. And we have three categories of review criteria. The first of these are the scored review criteria, and again, these include the regulatory criteria, significance investigators, innovation, research, approach, and environment. And these will individually be scored, they will each get a separate numerical score, and they will impact the final overall score for your application.

The second category are the additional review criteria, and that will include items such as human subjects and animal protections. They do not get an individual numerical score instead they will be rated as acceptable or unacceptable, but they do impact your final overall score. And especially if there are concerns with this section, this can negatively impact your final score. And then we have the additional review considerations, this is a category that will include items such as the budget. No criteria scores are given for these, they will not impact your final score. They're mostly administrative type items which can be addressed after review. Now, when we talk about scores, the NIH has a scoring scale that goes from one to nine, with one being the best score and nine being the worst.

So, coming soon, you will have heard Dr. Lauer, if you were there right at the beginning of the webinar. He mentioned something called the Simplified Review Framework. And we're very excited about this, it's going to apply for most types of research grants. So again, RO1s, R21s, et cetera. It's going to be rolled out for application due dates on or after January 25th, 2025. And what is included in this is that the five regulatory criteria, again, that I mentioned earlier, significance, investigators, innovation, approach, and environment are being reorganized into factors. And so, reviewers will be using three factors to evaluate applications with factor one, addressing the importance of the research, factor two, the rigor and feasibility of the research, and factor three, the expertise and resources. And the first two factors will still be scored using the one to nine scale. And factor three will receive a binary rating of sufficient or gaps identified in the expertise or resources. And the rationale for using this new approach is as Dr. Lauer mentioned, it's a way of refocusing review on evaluating the scientific and technical merit of an application and removing some of the more administrative types of criteria that reviewers were sort of getting caught up in.

Also, we're trying to address some concerns of reputational bias that have been observed in peer review by deemphasizing expertise and resources, removing some of that halo effect of individuals who are very well known in the field or institutions that are very elite and really pulling it back and saying, is the expertise and the resources that's being proposed sufficient and will work for the project being proposed? So, another tip for you, we have a really excellent website that tells you all about the simplifying framework and we hope that you'll be excited about it just as much as we are. So then how are the applications actually evaluated? So, you've heard that during the whole peer review process, it's the Scientific Review Officer that is your point of contact. So, the individual that's going to manage the review of your application, that is the NIH person for you to contact. So, there are two steps, two major steps during the peer review process. Step one is that each application will be assigned at least three reviewers, a minimum of three reviewers. These assigned reviewers will look at your application really carefully, they will score, the scored review criteria using the one to nine scale. They will provide written critiques of strengths and weaknesses that they perceive in your application.

And then the second step is that all of these reviewers will come together as a Scientific Review Group, SRG, and they meet to discuss typically the top 50% scoring application. So, the top 50% that the assigned reviewers felt were the best of the applications. So, the assigned reviewers will then present the strengths and weaknesses of the applications that they reviewed, after discussion of each application, the assigned reviewers provide their final scores, and then everybody in the Scientific Review Group provides a final score. And that's how your final score for your application is determined. After the scoring, any non-scoreable issue such as the budget, for example, will then get discussed. So another tip, if you have not had the opportunity to serve on a peer review panel, we actually have a recorded NIH mock study section, and this is a great way for you to sort of get a sense of what it is that reviewers discussed when they are on a review panel and what are some of the concerns that get brought up. And it could be a way for you maybe to mitigate some of these concerns ahead of time.

And so, I've talked about final scores, what does that really mean? So, the final impact scores reflect the Scientific Review Group's assessment of the overall impact that your project could have on the research field. And they calculated by taking the average of all the reviewers scores, so everybody who scored on the SRG, the average of that score and multiplied by 10. So, if your average turned out to be 2.5 of all the scores submitted by the reviewers, it gets multiplied by 10 so your final overall impact score would be 25. So, the range of final scores will be from 10 through 90, with 10 having the highest impact, 90 the lowest impact. And for some activity codes in particular RO1s, the scores may be further, may be percentiled as well, so when you hear the outcome of your review, you'll get your final impact score, but also a percentile. And that's to give you an idea of where in the range of discussed applications your application landed, was it in the top 10% of the scores or maybe the top 20%, et cetera.

So then how are the level one review outcomes communicated? You've heard the term summary statement; summary statements are documents that summarize the level one review outcomes. And so summary statements include your final overall impact score, they will include the scores for each score review criteria from the assigned reviewers, they will include the reviewer's comments, and if your application was one of those discussed, meaning it was in the top 50% you will get a summary of the Scientific Review Groups discussion. And this is written by the Scientific Review Officer. Summary statements are shared with applicants, but also with the institute center's advisory Councils. And so, another tip for you is tomorrow on day two of this event, we have an SRO that will go do a walkthrough, a step-by-step walkthrough of a summary statement to help you understand what it is, what are the different things that are included there, and help you interpret the different sections.

So, I've talked a lot about level one. We do have level two, and these are the advisory Councils, NIH National Advisory Councils. And the role of level two review is to make funding recommendations to institute center directors based on the level one Scientific Review Group reviews. So, the makeup of advisory Councils are, again, broad, diverse membership is required, they often include public members, they can be lawyers, they can be advocates, and their role is to recommend applications for funding. It's just recommendations. And as I mentioned, we have legal requirement that an NIH award cannot be made without Council approval. It must go through two levels of review. Advisory Councils also advise institute directors about areas of research priority that they feel might need to be addressed, any policy issues, and funding priorities. And so, the big question is then how do all of these review outcomes, these two levels of review translate to funding? You've heard this already; it is the institute or center director that makes the final funding decisions. And these will be based on the outcomes of the initial peer review, so this is the score, the percentile that came out of the Scientific Review Group review, recommendations of the advisory Council, the mission, what is the mission of the specific institute or center, program Priorities, sometimes there are congressional mandates to fund certain areas of research, and, of course, really importantly, availability of funds.

And so, this is my final slide. What should you do next? You are an applicant, you have received your summary statements, you know what your score is, you've seen the Commons, what do you do next? Your point of contact now is back to the program official that was assigned to your application. Now, if you get a good score and funding is a possibility, they may ask you to submit some additional information. We call this Just in Time information. This is typically a lot of administrative type stuff. You may need to resolve some human subjects or vertebrate animal concerns, but they are there to guide you on this. Now on the flip side, if the funding is unlikely, you didn't get a particularly meritorious score, they will help you consider your next steps. What are your options? It could be to submit a new application, or it could be to revise and resubmit your application. The Commons, there was a lot of strengths maybe from the reviewers, you may want to kind of go back in and strengthen some of the sections of your application or provide some additional new data. Now there is always an option, if you feel your application was unfairly reviewed for whatever reason, we do have an appeals process, it must meet certain criteria, but again, your program official can help advise you on whether this is really the next best step for you as an applicant. And so with that, I will turn it over to my colleagues, Crystal and Sean to talk about awards.

CRYSTAL WOLFREY: Thank you, Stephanie. Hi everyone, my name is Crystal Wolfrey, I am the Chief Grants Management Officer at the National Cancer Institute. Sean Hine is with me; he's the Deputy Chief Grants Management Officer. So, you've spent a lot of time going through the several months it takes to go forward with applying for a grant to the National Institutes of Health, you're at the final stage, which is what we're going to talk about, which is the award stage. So as Stephanie mentioned, there are a couple of things that we're going to cover. We're going to cover something known as just in time, also, you may hear that called JIT or because the federal government loves to make words out of acronyms, you might actually hear it called JIT. We're also going to talk about the notice of award, also called the NoA or the NoA. And we're going to talk a little bit about terms and conditions of the award.

So first, Just in Time. So Just in Time and how we request Just in Time has changed a little bit this year. So previously, prior to this year, what NIH would do was as soon as a score was released and it met a certain threshold, NIH would send out an automated message for Just in Time to all applicants who met that score threshold. That request would go out way in advance, and it sometimes was misleading because not every institute or center was able to pay at that score. So, starting this year, the process has changed and each of the individual at NIH Institutes and Centers will send out requests directly for just in time. So whatever center or institute that your grant was assigned to, we'll send out the request for just in time. So, you received a just in time request, it's time to celebrate, right? Woo-hoo! Not to be a Debbie Downer, but this is good news. The NIH IC is considering your application further and it started the administrative review process. So, the just in time information is needed to continue the review and to start potential negotiations. But just remember a just in time or a JIT request is not a notification of a forthcoming notice of award. It is just a request for additional administrative information.

So, are you wondering what's asked for in the just in time request? So Sean, we are saying JIT is critical for administrative review process. What exactly is needed in that submission?

SEAN HINE: Well, Crystal, it's a great question. For those that are new to NIH, you'll become very comfortable with this answer, and for those that have been with NIH for quite a while, you'll know this answer very well. And the answer is, it depends.

CRYSTAL WOLFREY: Oh, so true. The classic NIH answer. There have to be some items that are always needed, right?

SEAN HINE: Most definitely. So, you're going to need to provide updated other support regardless which will provide details on what support beyond the grant that you are applying for, are you receiving and have pending. So those will be the main items that you're looking for from another support perspective, but there's, of course, layers because it's NIH. This will add in the review in the number of things, so identification of overlap or concerns with over-commitment potentially and effort, as well as other things such as contracts with foreign organizations that NIH may need to consider further. So other support is a must have.

CRYSTAL WOLFREY: Okay. So, I'm guessing this is when it gets to the it depends items, right?

SEAN HINE: You've got it. So, for example, if there are human subjects research planned and it's not exempt from the policies, the JIT needs to include a date for institutional review board or IRB approval. For animals research for instance, there would've to be the IACUC approval date as well. What's really important for our small business program applicants out there, the JIT must include a foreign disclosure form. So that's another must have in addition to other support for just those small business applicants.

CRYSTAL WOLFREY: Okay, lots of stuff. So, how's all of this submitted?

SEAN HINE: So, it's a commonly asked question, so it's definitely recommended, NIH across the board highly recommends that this is all submitted through the eRA Commons, even revisions can be done through the Commons. So back to our small business applicants, you must submit your JIT foreign disclosure form and other support through the Commons, nothing else can be considered here. There's areas of where emails can be considered, we'll talk about that in just a few minutes.

CRYSTAL WOLFREY: Okay. So, lots to consider. So why don't we actually show you what we just talked about.

SEAN HINE: Right. So, to summarize some of the items that we just covered. So again, that must have is other support, so complete other support for all key personnel. So that is a must across the board, so make sure that you're submitting that other support documentation. Another area is, this is in the it depends space, so it's more as applicable. So, it really depends on the nature of the research, for example, if human subjects research is involved, we talked about this a moment ago, IRB approval date and human subject research studies education documentation has to be included. If animals research is included, then you're going to be looking at the IACUC approval date. Human embryonic stem cells, there's information that needs to be provided on there. If your research, for instance, has genomic data sharing, that will also be a piece of this. So that's another as applicable space. And again, for those small business, just because we really like to make a point. So, for those small business applicants you must include that foreign disclosure form and also as an extra add too, is the SBIR or STTR funding agreement certifications. So those must be included as well with this JIT request.

So, we touched up on it about a little bit during our back and forth. So, the when and how? So technically the JIT link, this is actually a question that comes up often, which is, when can I submit? Should I submit right away? Technically the link is available right after the application score is published, so it'll be available to you. But the one piece which Crystal touched upon at the very beginning is, it's a different process now. So, the ICs, the individual institutes and centers of NIH are going to submit a request for JIT. So, we highly recommend that you wait until you get that request, so that way, quite frankly, you're not wasting your resources. And then the submission, as we already mentioned, submission is done through the eRA Commons. At times, the NIH may request this to be done through an email submission, make sure you have that understanding with each of the individual ICs. But across the board is that first submission should almost always come through the eRA Commons. And again, just to really, again, hammer on the point, for those small business applicants out there you must submit your JIT through the Commons with the foreign disclosure form, other support in that agreement. So, you want to hear about a few more JIT issues, Crystal and I have something planned for you all. So here we go.

CRYSTAL WOLFREY: Hello, this is Crystal at Happy Land University. How can I help you?

SEAN HINE: Hey Crystal, this is Sean from NIH. I'm the Grants Management Specialist on the grant that we've been emailing on. Dr. Juniper is the PI.

CRYSTAL WOLFREY: Oh, right. So weird to get a phone call these days. Is your email broken?

SEAN HINE: [LAUGHTER] Not today, luckily. I figured it would be better if we just discussed this one. So, I got your revised JIT so thanks for sending that. It looks like Dr. Juniper's other support was updated after I mentioned that it looked like they were overcommitted.

CRYSTAL WOLFREY: Yes, I got that one turned around in record time. I am pretty proud of myself.

SEAN HINE: Well, you should be. And yes, I definitely agree. You got it back to us very quickly and I really appreciate that. And it even included that required signature, so the digital signature has to be included on the form. So that was great. One snag, well, Dr. Juniper is still showing as overcommitted. When I total up that other support, the current other support that we're looking at, along with a couple of those pending grants that appear to be lined up for funding. I'm still getting over 12 calendar months.

CRYSTAL WOLFREY: Really? I thought for sure we were at 11.99 calendar months.

SEAN HINE: Well, you were, except for if I add in this grant, so the competing grant that we're negotiating right now, we push over that 12.

CRYSTAL WOLFREY: Oh, okay. All right. I will get with Dr. Juniper on that point. Hopefully, third time is the charm.

SEAN HINE: Great. I look forward to receiving that update. So those Common JIT pitfalls that we talked about. So other support going over 12 calendar months comes up all the time. So that's really going to be helpful if you can make sure that those other support is calculated to where it's not over to 12 calendar months. All the active support and pending support. Other support not being signed correctly, so we have a lot of other support that just show up and no signatures. Please, check those resources that comes with NIH's other support documentation that helps support that a little bit. Not other support related, is IRB or IACUC approvals dates just simply being too old. They're definitely out of date. So those still get submitted in. And then again, for the small business applicants out there, forgetting to include that foreign disclosure document, those are some of the snags that we see. Help us help you, please. All right, so JIT is in, NIH is completed its review, now it's that time to celebrate, right Crystal?

CRYSTAL WOLFREY: Absolutely, pop that bottle of champagne because the next stage in this process is that you will receive a notice of award so that you can get your research project started. So, we want to talk a little bit about what is included in that notice of award. The first page you'll see from the notice award is a standard cover page that applies to all HHS funding-- all HH agencies that issue grant awards. That cover page is, sorry, excuse me. The notice award is really important to realize it's a legally binding document. What it basically does is to let you know that we've issued an award and that you can start drawing down funds from the HHS payment management system. It does identify some things that are super important. It will give you the grant number, it will tell you some information about the recipient including the employer identification number, it will give you the name of the PD/PI, it also is going to give you some federal agency information and some federal award information. That cover page is going to communicate the transmission of dollars, the directs and the indirect costs and the anticipated period of support. It's also really important and this has come up multiple times today, it's going to give you the contact information for your assigned NIH Grants Management Specialist and the program official.

The rest of the notice of award is all sort of NIH driven. It has a lot of additional payment information; it will give you the budget that's been approved by the NIH Awarding Institute or Center for this year. It's going to give you the anticipated future year commitments, if there are any. It's going to also provide for you the indirect cost rate that was used for the purposes of calculating the award. It's also going to include some terms and conditions. A couple of important things, the notice of award is sent to the email address of the individual identified in the eRA Commons, in the NoA email field. Really important to know that that is maintained by the recipient, not NIH. We do get calls from people who did not receive their notice of awards, so it's important that that email address is correct. It's also available for viewing in the eRA Commons. So, as I mentioned earlier, it does provide terms and conditions. So, let's talk a little bit more about what those are. So, the notice of award sets forth terms and conditions, there are two sections. Section three are standard terms and conditions that go on all NIH awards. The things that are included is a reminder that the award is based on the application that you submitted and was approved by NIH. It does incorporate statutory requirements, regulations, policies, public access policy, federal rights laws, things like that. It will tell you whether or not the project that we're funding allows for you to carry money over from one budget period to the next, which is the unobligated balance carry over. And it also states whether or not the award falls under the streamlined non-competing procedures. So, Sean, that's what the NIH standard is. How do the ICs transmit terms and conditions?

SEAN HINE: Yes, so there's definitely the options for the ICs to include-- the institutes and centers to include additional information. So again, this is going to be a little bit specific depending on the nature of the research, which is human subjects and animals, for instance, maybe designation of key personnel. So that can be incorporated within the notice of award as a special term to condition. Additional funding information, whatever that may be. For instance, funding on a continuing resolution. A big point to make here is restriction of funds for a specific purpose. So that's really important for those recipients to acknowledge and keep track of. And the last few things which can come up is special grant or program specific things, such additional reporting milestones minimum effort. So, all those could potentially come up as well. So, lots of stuff to go through. We'll talk more about that also on day two.

So, accepting those terms and conditions, it's pretty straightforward. You start drawing money you've accepted. So, make sure you keep that in mind. Here's the resource as well for that particular piece. So, we're going to jump right in real fast to monitoring and reporting. I know it's going to be fast because we're coming close on time. And so additional monitoring and reporting that we're going to cover post award requirements, just an overview. Managing changes to the awards and data management and data reporting requirements. So just a few things, again, it's after that award. So now we're kind of in that post award space, which we probably could take up an entire day on that alone. So now that you've got the award, what's next? Lots of monitoring and reporting, so responsibility on you all as recipients, responsibility on us as the awarding components. And so, what's going to be covered here is the day-to-day responsibility is all on you as a recipient. NIH is going to monitor it through an annual reporting perspective, for instance. A few things to really consider is progress reporting through the RPPR. So, this way it's really clear as far as eRA Commons and at least what comes in annually. The invention reporting, make sure you're keeping track of all those inventions. Public access policy, this is a big trip up because if you don't have a compliance with public access, you will not get your next awards. So just keep that in mind. And then human subject clinical trial reporting is all based off of obviously, if that's applicable and some closeout reporting is filed.

This is prior approval; I'm going to just gently touch upon this. There's a lot of it in the grants policy statement. That is our go-to. So, a few links just to keep track of, if you need prior approval, send it through the module but one of the most important things when it comes to prior approval, make sure that you have a response from the grants management officer, program staff out there, we love you, we love working with you. However, you can't speak for them, so you got to make sure it comes through us.

CRYSTAL WOLFREY: So, wait, before we go, I know we're overtime, but really quick, we need to talk a little bit about data management and sharing. So, for most applications that are submitted to NIH now, it is required that you include a data management and sharing policies. Please, make sure you check the policies to see if the DMS policies apply to your application. Under this policy, there's a couple of things NIH expects investigators and institutes to do. One, plan and budget for managing and sharing data, submit a data management and sharing plan for review and applying for funding, comply with the approved data management sharing plan and make sure your RPPRs you're reporting on the data sharing that you are doing during your year. So, we touched the tip of the iceberg, there's a lot more to it. If you have more questions, please reach out to your NIH grants management specialist or program official. We are here to help. Now we're going to turn this over to Sheri Cummins, who's going to wrap it up with resources. There you go, Sheri.

SHERI CUMMINS: All right, thanks, Crystal. Okay, I'm exhausted. That overload thing was really hitting home for me. And we're really just talking about what it takes to put together an application, not even actually doing the work itself. So, it takes time, and we really mean it. All right, so let's talk about some of these resources. You know I started today talking about the NIH Guide, sorry, the NIH Grants and Funding website. And that everything you need to apply is there. And oh goodness. I'll be back. Okay. Here is that website. All right, grants.nih.gov. I talked about the utility link for the glossary in the upper right-hand corner. I also want to alert you to FAQs; we have hundreds and hundreds of FAQs out there on just about every topic you can think of. It's a wealth of information, so please check that out. We also have our help page as a utility link on every one of our pages throughout the site. I started off talking about these key concepts to know about NIH that is all found in our new to NIH section of the site. I want to highlight the registration information there, again, if you are not yet registered to work with us, please get started on that. It can take six weeks or more. And just to step back, we went through all of the different steps in this grants process today, and it is a huge amount of information. Slide sets are point in time, the website evolved, so we really structured this event to follow the website so that you can return to the website rather than the slides to get the latest and greatest information. So, spend some time on that site.

All right, in the funding area, this is where you're going to find the NIH Guide for grants and contracts. Remember, that's where we post all of our funding opportunities and all of our updates and policies changes and all of those things. In this section we also have the learn about funding category. So, if you want to learn more about some of the things we talked about or some of the things we didn't like, loan repayment, we just said it's out there. You can go and investigate, do a little digging into more information on all of those funding categories. You'll also find the find a fit page. Remember that's where we had all of the institutes and centers with their links to their missions and their priorities and their funding strategies and some tips for how to use Matchmaker to find that IC. We also have this explore who and what NIH funds, and really that's just a acknowledgement of the fact that we have that wonderful suite of report tools out there and gives you links to go take a peek at those as well. And we'll have a session on that tomorrow.

All right, dig in a little bit deeper into some of these. The NIH Guide for grants and contracts, we do have a quick video tour on our page that talks about all of the new features that we have for the NIH Guide. It will walk you through things like sharing your results and how to save results, to get notified if a change is happening to a funding opportunity and things like that. We do have a session tomorrow about finding the right opportunity, so I encourage you to tune into that. This is that section for explore who and what NIH funds, and tomorrow we will have a RePORT, RePORTER, and NIH data book session. But you can get links to those tools through this part of our site. And the grants process, and this is really that whole process we just walked through to today from plan, write, submit, review, award, and post-award monitoring and reporting. Within the right section of the grants process is where you find our how to apply application guide. All right? And I just want to touch on that a little bit because I saw some questions in the chat that some folks are confused. The general instruction guide is a document that you can use for any one of the opportunities that any of our applications, it has all the basic instructions and then it has call outs for the different program specific instructions. So, I have an example here for a field in one of our forms, facilities and other resources. There's some basic instructions on top, and then there's different call out boxes. There's a little green one that says, additional instructions for career development, and a blue one for additional instructions for training and an orange one for additional instructions for fellowship. All right. So, if I'm using that general guide, I'm going to follow those basic instructions. And if I'm doing a fellowship application, I'm also going to follow those additional instructions called out for fellowship. All right? But it's all within those general instructions.

The other ones that we have listed on our page are just filtered views of that full set of instructions. So, for example, let me pull out the career development instruction set. So, this is the filtered view. It's going to have all the same information that was in general, but if the only call outs it's going to show is for career development, so it gets rid of all the other noise, you're not going to see the call outs that were there before for fellowship and for training for others. Okay? So, you don't have to use both the general and the filtered views. The filtered views, just a subset of the general. So often I'll find that administrators use those general instructions because they want to see the differences between the programs and they're working with lots of different principal investigators. Whereas if you're the principal investigator, you may just want to hone right into that type of application that you're preparing. Okay? So that's how those instruction sets work. We do have a new application set coming out, forms I for due dates on and after January 25, we just posted an advanced copy of the instructions, okay? And it's just that general PDF, but again, that means you've got it all, right? We just don't have the specific filtered versions available for you yet. They will be there later this month, but you have everything you need right now, okay?

In policy and compliance, we've got the page for changes coming in January 2025. The grants policy statement, policy notices, and other topics there. We have pulled together all of the different changes that are happening for January 2025 due dates and beyond into this single area on our website to kind of help you walk through those all and kind of get a handle on it. So, I really encourage you to check out that portion of our website. And again, that's under policy and compliance. And then our news and events. And I've mentioned this is really a great place to go out and find all of the access to our social media, our podcast, the open mic blog, the Extramural Nexus newsletter, all of those wonderful resources that we have out there for you. Okay. That utility link, that help link at the top, our help page is a critical resource for you. But I really want to pull out that red box right there that says, see something, say something. You can use that link there report a concern to report anything that you're concerned about with scams and fraud and research misconduct, and harassment, foreign interference, peer review integrity violations. If you are experiencing or know of something that is inappropriate going on, you need to speak up. And this is a resource that will show you how to do that. It's important for all of us to work together to make sure we have a safe and respectful work environment to do the work. All right?

Now back to the actual science, we've been talking a lot about reaching out to NIH staff and we absolutely want you to do that, but that doesn't mean every time you have a question, you're going to go and pick up the phone or key off an email, right? We do expect you to do your homework, check out the resources that are on our website, check out the funding opportunity if you've identified one, our FAQs, talk to the folks within your institution, your office of sponsored research. You've got great people within your organizations that may be able to help you. If you've exhausted those resources and you still need help, then let's reach out to your IC contacts, our understand staff roles page talks about your POS, and your SROs, and your grants management folks, and when to reach out to them, and how to reach out to them, and how to find the contacts that you needed at different stages of your application. And if you have general questions that can't be answered through those other mechanisms, we also do have within the Office of Extramural Research in the OD here, we have Offices for Human Subjects and policies and so forth. And we do have those central NIH contacts there as well. All right. Now we're going to go ahead and do our final Q&A session and then wrap it up and then we'll be done for today. So, Megan.

MEGAN COLUMBUS: All right. Yes. Thank you. So, if I could get my panelists back on screen here. Here we go, we've got Dr. Constant. Let's see. All right, we have Dr. Timmerman. All right, Michelle, let's go ahead and start with you since you're here [LAUGHTER]. We have a few questions about receipt and referral, when should people be checking their application in the Commons after it's submitted?

MICHELLE TIMMERMAN: So, view your application image in about half an hour to four hours after you submit. And be sure to submit early so that you can make changes if you don't like what you see.

MEGAN COLUMBUS: Good advice. All right. And I did have somebody in the Q&A who was saying, hey, I submitted in October, and I haven't seen my application there. Yes. Call the eRA service desk, right? Like you really want to make sure that you get help and don't wait because if there's a problem with one of our systems, we have policies that help with that. Michelle, sticking with you. What does an applicant do if the institute that the individual thinks would be most interested in the proposed research is not listed on the notice of funding opportunity?

MICHELLE TIMMERMAN: Sure. So first of all, they should pat themselves on the back for recognizing that this is an issue they need to resolve and not just submitting their application anyways. There are a few things that they can do. One is to look for another NOFO using our new wonderful guide search, and to find a NOFO that you're interested institute does participate in. Another opportunity is to contact a program officer at your desired institute to discuss the available funding opportunities. And a third option is if your application seems related, you should consider contacting one of the scientific research contacts on that NOFO and discussing your full range of research interests. I'm often surprised to hear from investigators about how their research interests are much broader than any individual application and often can align with a specific institute.

MEGAN COLUMBUS: All right, thank you so much for that. I have a couple of more questions just for you. And I think we went over this, but is an individual allowed to submit the same application to two different funding opportunities at the same time?

MICHELLE TIMMERMAN: No. Saying a few more words, the applications do not need to be identical. Merely being overlapping, substantially overlapping is enough to earn the no. This also applies to different Council rounds, different activity codes, and it starts at the date you click submit and it ends on the date you receive your summary statement. And we had some great questions in the chat. It also applies to any public health service agency like AHRQ, FDA, CDC.

MEGAN COLUMBUS: Very good, very good. But the same application going to a non-HHS agency would be okay as long as you don't accept both, right?

MICHELLE TIMMERMAN: Correct. Your grants management will need to have a chat with you, but in terms of overlap during peer review, that would be acceptable.

MEGAN COLUMBUS: Right. Does NIH have any kind of grace period after that due date?

MICHELLE TIMMERMAN: So, we don't have a grace period the way you might have for your mortgage of its due on the first and not a big deal if you don't pay it until the 15th. We require that that final error-free submission that you click submit for the last time by the due date and the due time. Now we do have a late policy, and again, it's NOT-OD-15-039. It's in my slides. It applies to a few humanitarian reasons, like sudden acute illness. It applies not to every NOFO, there are some RFAs that prohibit this, and it applies to the applicant institution and the PD/PI. So, it's important, especially for smaller institutions to have a backup AOR.

MEGAN COLUMBUS: Great. Hey, thank you so much. All right, you're off the hook for a little while here. So, Stephanie, putting you in the hot seat. What's the relationship between the review committee and the institute offering funding?

STEPHANIE CONSTANT: All right, so I think Michelle did mention this. When an application is submitted to the NIH, it'll be assigned to whichever of the 24 funding ICs is the best fit for the science being proposed. So, the idea being that once your application is reviewed and it's actually time for funding, it's in the right institute in terms of its assignment. But in most cases, the place where the application is reviewed has nothing to do with the funding Institute. In most cases actually, review happens at the Center for Scientific Review. More than 75% of applications are reviewed by the Center for Scientific Review. In other cases, the review may be conducted within the funding institute, but it's conducted by a scientific review branch within that funding institute. And regardless of where the review takes place, whether the Center for Scientific Review or within a scientific review branch, within an institute the outcome of the review will be shared with the funding institute's advisory Council. And this is where the final funding recommendations will take place.

MEGAN COLUMBUS: So then following that up, how does an individual know if the application scored well enough to get funded? Right? How are they notified?

STEPHANIE CONSTANT: So, this is where your program official is going to be very important as a resource. So, they will help you to interpret the scores that you get, the written comments in your summary statement and will help you understand what this means with regards to your likelihood of being funded. Also, institutes have pay lines so it may give you a hint. Certain institutes do publish where their cutoff pay line is. So obviously if you get a really, really great score, that's well within that pay line. That's a good start. However, the final funding decisions are not made until after the advisory council has met for the second level of review. So, you're not going to know one way or the other what the final outcome is of your score. And formal notification of funding as was shared by Crystal and Sean is provided through a notice of award the NoA.

MEGAN COLUMBUS: Great. Okay. Thank you so much.

STEPHANIE CONSTANT: Mm-hmm.

MEGAN COLUMBUS: We actually have a link to a resource that actually Sheri helped develop, which was a link that'll get you to the ICs, where they publish all their pay lines and things really quickly. And so, when I have a moment and I'm not talking, I'll try and put that in the chat. Unless you want to try and do that, Sheri. Stephanie, I know you touched on this during your presentation, but can you just reinforce the right steps to take when a grant application's not discussed?

STEPHANIE CONSTANT: Okay. So again, the program official is your friend here, they will help you interpret the concerns that were raised by the review panel. So, using the summary statement, which is a summary of the Commons, the strengths, and the weaknesses that were raised by the reviewers. And even if your application is not discussed by the Scientific Review Group, the Commons from the assigned reviewers, the original three assigned reviewers will be there for you to see. And so, the program official can help you interpret those Commons, and depending on the Commons, your program official may advise you to completely revise the application. There was just not a lot of enthusiasm for the research or the way it was proposed that it was going to be done. And they may say, revise this application. Try again, use the Commons as a guide for improvement. Alternatively, they may say, you know what, the Commons are not too bad. So rather than doing a brand-new application, you can resubmit that application, address the reviewer's Commons, you can make it stronger. Another alternative is they may advise you to apply to a different type of funding opportunity. Maybe this is not the right opportunity, they can help you find something that's maybe more appropriate for the type of research that you want to propose.

MEGAN COLUMBUS: Right. Good advice. Okay. So, we have a bunch of grants management questions. So, turning to you, Crystal and Sean when's the grant considered pending to include on the current pending support document?

CRYSTAL WOLFREY: So, it would be considered pending from the time the application is submitted and accepted by NIH up until the time that that application is either funded and an award notice has been received, or you've received some indication that it will not be funded. So as Stephanie mentioned, if the results of the review were not discussed, then you would not list that application as pending but if it was discussed and you received a score, it would be pending until it was awarded or until for sure that it won't be funded.

MEGAN COLUMBUS: Thank you so much. And Sean, could you explain when an application should be expected to be notified about the just in time material? And I saw a bunch of questions here today in our Q&A about how that notification happens and can they go see if that notification has happened anywhere or what?

SEAN HINE: Yes, so it's a great question. So, each of the individual ICs as mentioned, are taking over that responsibility for submitting requests for the JIT submission. And so that you should anticipate from the ICs, like for instance here at NCI, we will send out an email notification to the business official to PI and say, it's now time to submit. So, I think there's going to be different walks based off the individual institute and center. A lot of it is going to go through email notifications to the signing official and the PI, so keep an eye out for your emails. The timing of when that would be, again, very IC dependent. We were talking a little bit about funding decisions and those sort of things. I think probably a good ballpark would be about 60 to 90 days give or take before that anticipated start date. That's just a general rule of thumb. If you're not sure, reach out to your specialist that's shown up in the Commons or your program official, we'd be happy to help.

MEGAN COLUMBUS: And we use just in time to reduce administrative burden, so everybody submitting an application doesn't have to submit all this information. And I know you mentioned this in your presentation, but just to reinforce the fact, just because we ask for just in time material, does that mean that people will necessarily get awarded?

SEAN HINE: That's as simple as Dr. Timmerman addressed. No.

MICHELLE TIMMERMAN: Mm-hmm.

SEAN HINE: So, this is a straightforward no on that one. So again, that's collecting documentation, it's looking pretty positive, so administratively, it may be heading in the right direction but there's definitely going to be areas where we may need to reach out for information for potential awards. But definitely no until you get that notice of award.

MEGAN COLUMBUS: Great. Yes. So Crystal, after an application's been reviewed, when should an applicant speak with a grants manager versus a program official?

CRYSTAL WOLFREY: That's a really good question. So, I'm going to do this as in general question, but then as Sean and I mentioned a lot is it depends, but generally speaking until you have some indication that your institute or center has decided that the application's going to be funded, selected it for funding. So really kind of up until that point of a just in time request, your program official really is your primary point of contact. Generally speaking, grants management gets involved at the time of funding selection because that's when our big piece of the puzzle comes in. Having said that, I would strongly recommend that if you have a relationship with a Grants Management Specialist or a Grants Management Officer, if you have administrative questions, always feel free to reach out, we're happy to help. But for a specific application, use your program official until it's time to actually start working on negotiating an award.

MEGAN COLUMBUS: Great. Sheri, we have a final question. And we talked about this in the previous Q&A segment, but just is it worth repeating, how can potential applicants and recipients keep up with latest changes?

SHERI CUMMINS: And again, I would go back to subscribing to the NIH Guide for Grants and Contracts.

MEGAN COLUMBUS: Okay.

SHERI CUMMINS: But I did want to follow up on something that I just heard from Sean and Crystal, and it's that it depends. A lot of our policies and practices are NIH-wide but there are variances between the ICs. So, you have to kind of get comfortable with the it depends, and sometimes and generally, and typically, and I know it can be frustrating but you're going to see those words quite a lot when you're working with NIH. So just take a deep breath and find out what it depends on and go from there.

MEGAN COLUMBUS: Great. And I do see that that Kim Biondi put in the chats a link that doesn't have any context around it, but it's for find a fit for your research and that gets to each individual institutes and centers information about their mission, their priorities, their funding strategies. It's a really great useful link. Okay. With that, I wonder could we open up the chat so that we can hear a little bit from our attendees because I would love to hear, given the afternoon, since we had such great response this morning, I would love to hear from this afternoon what your key takeaways are, what you want to share.

SHERI CUMMINS: I love the I need a bigger village.

MEGAN COLUMBUS: Yes. It depends. Thank you for the great session. It depends, it depends, it depends. Know the NIH website. I better start writing, just in times important. Great. Reading is fundamental. It really is, those instructions, that funding opportunity announcement, notices that are really important. All right, so can someone throw the slide set back on for me? Because I think I have a few closeout slides. All right, so congratulations, you've taken the first steps to success, right? You're here, you've understanding NIH, you've got the basics of the grants process, we've given you some resources. So, what are we going to do tomorrow? We're going to do a little bit of testing to see what you learned. We're going to do a little bit of deeper dive into some systems and to letting you try some things out. And we're going to be hopefully, a little bit more engaging with you in terms of knowledge, checks, and touching on things like understanding the notice of funding opportunity and application writing tips and all those kinds of things. So, I very much hope that we see you all tomorrow and come ready to interact and play. And I hope you all have a wonderful afternoon.